NATIONAL INSTITUTES OF HEALTH

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008
Volume II

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

TABLE OF CONTENTS

VOLUME II

Fogarty International Center

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

FOGARTY **I**NTERNATIONAL **C**ENTER

MISSION/VISION STATEMENT

The mission of the Fogarty International Center (FIC) is to reduce global health disparities by supporting and promoting research and to prepare the current and future generation of international and U.S. scientists to meet global health needs. To achieve these broad objectives, FIC supports a range of international collaborative research projects, research training efforts and scientist-to-scientist exchanges, and works through intergovernmental and diplomatic channels to identify and strengthen collaborative efforts. FIC partners with academic groups from around the world as well as with bilateral and multilateral agencies, private groups, and other federal agencies.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Broadly, all FIC international research and research training programs play a unique role in addressing health disparities that exist within and among population groups in the United States and in developing countries. Certain populations abroad share similarities with U.S. groups by virtue of their genetic makeup, health practices, lifestyles, or other features and, for this reason, advances made through international research studies stand to benefit both U.S. and developing country populations. Such research could lead to effective and culturally relevant education or counseling strategies; foster development of novel diagnostics, drugs, or other intervention technologies; or contribute to identification of new avenues of research that ultimately would lead to health care interventions. FIC's programs to support collaborative research and capacity building in low- and middle-income nations are critical to advancing global health research priorities. FIC programs also support the development of the next generation of U.S. scientists and health professionals, including those from minority groups, to address health disparities that exist within the U.S. and within the global community.

Response to Public Comments

None of the public comments received directly relate to the FIC mission in global health. However, several comments indicate the need to support more individuals from underserved/underrepresented groups to pursue careers in health research. Therefore, FIC incorporated specific minority trainee recruitment and support in all its international research career development programs.

1.0 AREAS OF EMPHASIS IN RESEARCH—N/A

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: International Research Training

FOGARTY **I**NTERNATIONAL **C**ENTER

In the United States, minorities and other underserved populations are underrepresented in the biomedical research enterprise, comprising only a fraction of graduate students, postdoctoral students, and faculty in the health sciences at schools of medicine and public health. FIC will strengthen its efforts to support the research training of undergraduate, graduate, and medical students and postdoctoral fellows from underserved/underrepresented populations.

Priority: Highest priority area of emphasis

2.1.1 Objective One: International Research Training for Minority Students

FIC and the National Center for Minority Health and Health Disparities (NCMHD) support what were originally referred to as Minority International Research Training (MIRT) programs but were renamed in 2004 to Minority Health and Health Disparity International Research Training Programs (MHIRT) to reflect broadened eligibility criteria that include health disparity populations more generally. These programs are conducted at universities across the United States including Historically Black Colleges and Universities (HBCUs) and Hispanic Serving Institutions (HSIs). MHIRT programs provide opportunities for approximately 300 U.S. minority undergraduate, graduate and medical students to gain 10-12 weeks of research experience abroad each year. Initial data on the program indicate that 70 percent of undergraduate MHIRT trainees go on to graduate or health professional school.

Priority: High

Response to Public Comments: None of the public comments received directly relate to the FIC mission in global health. However, several comments indicate the need to support more individuals from underserved/underrepresented groups to pursue careers in health research. Therefore, FIC will continue to support the MHIRT program after management of the program moves to NCMHD.

2.1.1.1 Action Plan

The MHIRT program is being transferred from FIC to NCMHD. In FY2005, NCMHD will reissue the Request for Applications for MHIRT programs in collaboration with FIC. FIC will provide co-funding and program staff support for the international aspects of the supported programs for the length of the new awards.

2.1.1.2 Performance Measures

FIC will measure the performance of its contribution to the MHIRT programs managed by NCMHD by monitoring the levels of co-funding provided and international programmatic activities supported.

2.1.1.3 Outcome Measures

FIC will provide NCMHD with the web-based trainee tracking system developed for the previous MHIRT directors to record trainee career progress. FIC will collaborate with NCMHD to evaluate the outcomes of the MHIRT training using the data collected in this tracking system.

2.1.2 Objective Two: International Clinical and Public Health Research Training

FIC and the Ellison Medical Foundation support 1-year clinical research training experiences for graduate-level U.S. students in the health professions, including minority students, with additional support from FIC/NCMHD. Ellison trainees receive mentored clinical and public health research training at National Institutes of Health (NIH)-funded research centers in developing countries in Africa, Asia, and the Americas.

Priority: High

Response to Public Comments: None of the public comments received directly relate to the FIC mission in global health. However, several comments indicate the need to support more individuals from underrepresented groups to pursue careers in health research. Therefore, FIC incorporated more recruitment and support to individuals from these groups in the FIC-Ellison Clinical Research Training program.

2.1.2.1 Action Plan

FIC will make specific efforts to recruit individuals from minority and other underserved/underrepresented groups and support qualified candidates to participate in the program for the length of the program.

2.1.2.2 Performance Measures

FIC will measure its performance by monitoring its specific recruitment efforts, applicant success rate, and training and career outcomes for health professionals from minority and other underserved/underrepresented populations.

2.1.2.3 Outcome Measures

FIC will measure immediate training outcomes such as presentations of research at scientific conferences and publication authorship as well as long-term career impact including involvement in clinical or public health research.

2.1.3 Objective Three: International Graduate Research

At the time the Fogarty International Center submitted its Health Disparities Plan, the activities described in Objective 3 (supporting research training experiences for minority graduate students through supplements to existing FIC international research training programs) were part of the trans-NIH Program Announcement "Research Supplements for Underrepresented Minorities," including the description of eligibility criteria. FIC subsequently incorporated the broadened eligibility criteria included in the trans-NIH Program Announcement "Research Supplements to Promote Diversity in Health-Related Research" reissued in 2005 into all its training opportunities to support the development of a diverse scientific workforce.

Priority: High

Response to Public Comments: None of the public comments received directly relate to the FIC mission in global health. However, several comments indicate the need to support more individuals from underrepresented groups to pursue careers in health research. Therefore, FIC will ask its current international research training program directors to recruit trainees from minority and other underserved/underrepresented populations and provide support for the inclusion of qualified candidates in research at collaborative developing country sites.

2.1.3.1 Action Plan

FIC will support qualified candidates proposed by FIC-supported research training program directors to participate in the program for the length of the program.

2.1.3.2 Performance Measures

FIC will measure its performance by monitoring training and career outcomes.

2.1.3.3 Outcome Measures

FIC will measure immediate training outcomes such as presentations of research at scientific conferences and publication authorship as well as long-term career impact including involvement in international health research.

2.1.4 Objective Four: International Postdoctoral Research

The International Research Scientist Development awards (IRSDA) provide junior U.S. scientists with an opportunity to embark on or enhance their careers in research related to global health, and prepare them for independent research careers. The IRSDA is similar to other NIH career development awards (K01s) but requires research in developing countries and two mentors—one in the United States and the other in the developing country where research is being conducted. The award supports salary, research expenses, and international travel, initially for up to 4 years, and is renewable for up to 3 additional years.

Priority: High

Response to Public Comments: None of the public comments received directly relate to the FIC mission in global health. However, several comments indicate the need to support more individuals from underserved/underrepresented populations to pursue careers in health research. Therefore, FIC incorporated specific minority postdoctoral recruitment and support for qualified candidates in the IRSDA program.

2.1.4.1 Action Plan

FIC will make specific efforts to recruit junior scientists from underserved/underrepresented populations and support qualified candidates to participate in the program for the length of the program.

2.1.4.2 Performance Measures

FIC will measure its performance by monitoring its specific recruitment efforts, applicant success rate, and training and career outcomes for health professionals from minority and other underserved/underrepresented populations.

2.1.4.3 Outcome Measures

FIC will measure immediate training outcomes such as presentations of research at scientific conferences and publication authorship as well as long-term career impact including involvement in developing country research.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION—N/A

The National Cancer Institute

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL CANCER INSTITUTE

MISSION/VISION STATEMENT

The National Cancer Institute (NCI) conducts and supports research, training, health information dissemination, and other programs to address the causes, diagnosis, prevention, and treatment of cancer; rehabilitation from cancer; and the continuing care of cancer patients. The overarching goals of the NCI to overcome health disparities are to understand the causes of cancer health disparities, provide scientifically based evidence, support the development and implementation of effective and sustainable intervention strategies to eliminate these disparities, participate in improving the delivery of what we already know and all new cancer advances to all people, and inform policy- and decision-makers of evidence-based policy strategies with potential to eliminate cancer health disparities.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

In the recently published *"Annual Report to the Nation on the Status of Cancer, 1975-2001,"* a collaborative effort among the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the North American Association of Central Cancer Registries (NAACCR) to provide up-to-date information on cancer rates and trends in the United States, it was reported that overall observed cancer incidence rates dropped 0.5 percent per year from 1991 to 2001. Death rates from all cancers combined dropped 1.1 percent per year from 1993 to 2001. According to the report's authors, the new data reflect progress in prevention, early detection, and treatment.

However, the report also highlights very disturbing data related to minority populations—namely, that there are wide variations in survival associated with race and ethnicity. Black men were at higher risk of dying of 12 cancers compared to White men, with the increased risk ranging from 9 percent (lung cancer) to a high of 67 percent (cancer of the oral cavity). Black women experienced higher risks of death from 12 cancers, with the increase ranging from 7 percent (lung cancer) to 82 percent (cancer of the corpus uterus and melanoma). Additionally, non-Hispanic White and Asian/Pacific Islander (API) patients tended to have higher survival rates than other racial and ethnic groups (except for patients with brain cancer and leukemia).

Those populations at higher risk of death from cancer are significantly more likely than the overall U.S. population to:

- Be diagnosed with and die from preventable cancers.
- Be diagnosed with late-stage disease for cancers detectable at an early stage by screening.
- Receive either no treatment or treatment that does not meet currently accepted standards of care.
- Die of cancers that are generally curable.
- Suffer from terminal cancers in the absence of adequate pain control and other palliative care.

Many NCI-supported cancer research advances have improved survival and quality of life for many people. However, not all people have benefited equally from these research advances. Without doubt, if all populations were to have timely access to currently available medical approaches and information for prevention, early detection, and treatment of cancer, we would see a nearly immediate reduction in cancer incidence and mortality. Access to screening, early detection, and follow-up treatment for all populations for certain cancers, such as cervical and colorectal cancers, could immediately improve cancer outcomes. Survival rates for some cancers, such as breast cancer, could be increased if all populations had access to regular screening to detect early, more treatable tumors.

The 2015 Challenge Goal to Eliminate Suffering and Death Due to Cancer

Many of our greatest opportunities for reaching NCI's goal to eliminate suffering and death due to cancer by the year 2015 can be found in efforts to overcome cancer health disparities. NCI has highlighted overcoming cancer health disparities as one of the seven major strategic initiatives leading to improvements in survival and quality of life for all people.

Cancer research advances, particularly over the past decade, have increased our understanding of the cancer disease process and its various stages of development, even at the earliest stages of susceptibility when environmental exposures such as tobacco and other carcinogens or aging increase our susceptibility to developing cancer and other life-threatening diseases. From the period of susceptibility, we know that this process continues to a point where we actually develop cancer—a malignant transformation—and this malignancy continues to evolve, grow, and develop to the point where it is large enough to be detected and diagnosed as clinical cancer. The malignancy process then continues to the point where clinical cancer progresses, spreads, and metastasizes, ultimately taking the individual's life.

Pre-empting this disease process is critical to an individual's survival. NCI is examining all the steps that are associated with the process in the development of cancer and examining ways to intervene in that process in multiple places and in multiple ways to preempt its development. Currently, we can pre-empt cancer by preventing it from occurring in the first place or by detecting it earlier, where we already have weapons available to eliminate it. By continuing to discover and develop innovative mechanistic interventions that will enable us to detect the disease, and to be able to predict, to treat, to eliminate, or to modulate the disease, we can have a significant impact on the ultimate outcome of what we see as the incredible burden of cancer today, where one patient every minute is dying as a result of the disease, many from minority populations.

Discovery and development of such research efforts are vital to eliminating suffering and death due to cancer. However, what the latest surveillance data highlight—a disproportionate burden of cancer in minority and underserved populations —underscores the immediate need to address the "gaps in delivery" of our current cancer research advances to these populations. We must urgently address the "gaps in delivery" to remove access barriers to timely and effective cancer care and education for everyone who is in need.

NATIONAL **C**ANCER **I**NSTITUTE

NCI is committed to substantial investments and initiatives across the entire spectrum of research, from discovery through development to delivery. However, NCI embraces the most immediate and critical need to deliver all that we currently know across the cancer continuum to all people in this Nation—from cancer prevention, diagnosis, and treatment through survival and improvements in quality of life. Without this deliberate focus, needless suffering and death from cancer, particularly in minority, poor, and other underserved communities, will continue to be exacerbated. This "gap" in our delivery enterprise is a key determinant of cancer health disparities and constitutes a moral and ethical dilemma for this Nation.

NCI is limited in what it can accomplish with respect to the delivery of cancer care services. However, the Institute recognizes that it must play a central role in developing a broad range of partnerships and collaborations, both public and private, to aid in closing the delivery gap. Of particular note is the central role NCI played in the development of the *Report of the Trans-HHS Cancer Health Disparities Progress Review Group,* published in January 2004. This Report consists of 14 priority recommendations that constitute a Call to Action for the Department of Health and Human Services (HHS) to lead the Nation in eliminating cancer health disparities. NCI is committed to participating fully in this Call to Action.

RESEARCH

NCI will continue to conduct and support research to examine the inequalities in cancer and the social, cultural, environmental, biological, and behavioral determinants of cancer; the interactions among them; and the mechanisms by which they contribute to disparities in early detection, cancer care, prevention, and quality of care. Further, NCI will continue to support initiatives to develop sustainable interventions, and identify priority areas for future policy development to ameliorate cancer health disparities. To direct the implementation and coordination of these activities, support NCI health disparities research opportunities, conduct activities to better understand the causes of disparities, and conduct health policy research to recommend alternatives to integrate research advances into health services aimed at reducing or eliminating disparities, NCI established the Center to Reduce Cancer Health Disparities (CRCHD) in 2001.

NCI will continue to strengthen and expand many ongoing activities and establish new initiatives aimed at reducing and ultimately eliminating cancer health disparities. Some initiatives may overlap or interface with more than one of the categories listed below. For example, an initiative may provide infrastructure for conducting clinical trials aimed at developing new or improved approaches to research in treating cancer. Moreover, improving participation in these trials by ethnic and racial minorities may require communication/outreach activities and additional research to understand how best to engage in effective communication, education, and outreach.

Recognizing that such overlaps may exist, this Plan outlines objectives within the following categories: expanding research, building research capacity and infrastructure, and expanding community outreach, information dissemination, and public health education to impact on the elimination of cancer health disparities. Collaborations and partnerships with federal, state, and local decision makers can facilitate the development and adoption of policies to eliminate barriers to health care access, and improve access to quality health education and to prevention strategies that lower the risk of cancer. Information needs to be provided in culturally competent formats. Communities, caregivers, and researchers must form strong collaborations in developing these formats and exploring creative solutions to address the problem of disparities in their communities. This cross-fertilization of ideas will provide a greater opportunity to develop programs that can achieve effective results in overcoming cancer health disparities.

NCI has developed and will pursue a research framework that builds upon the growing evidence that socioeconomic, cultural, health care provider, institutional, and environmental factors contribute substantially to cancer-related health disparities. The elements that influence health disparities are complex, and their interactions are largely unknown. Although health disparities have been framed historically in the context of racial and ethnic disease differences, and racial and ethnic classifications always have been socially and politically determined and have no legitimate place in biological science, there is mounting evidence that race and ethnicity should be used as a measure of social injustice. There is broad agreement among experts that racism, born of racial and ethnic classifications, is rooted in the erroneous concept of biological superiority and is a part of the cultural framework of societal, institutional, and civilizational values that continues to shape scientific thought. The power of scientific discovery must be used to elucidate the meaning and effect of the human circumstances in which differential disease burdens occur.

RESEARCH CAPACITY AND INFRASTRUCTURE

Training and career development for the next generation of scientists remains one of our most important challenges. Our success will depend upon our ability to move beyond traditional educational and research cultures, overcome health financing constraints, and address socioeconomic inequities that have proven to be barriers to progress in the past. The theme for the future is to train scientists to work on problems as integrated, multidisciplinary teams.

To meet these challenges, we must continue to promote diversity in cancer research, and to implement outreach, training, and career development strategies to address a number of crucial issues related to cancer health disparities across the cancer research continuum. In keeping with National Institutes of Health (NIH) policy, NCI expects that these efforts will lead to:

- the recruitment of the most talented researchers from all groups;
- an improvement in the quality of the outreach, training, and educational environment;
- a balanced perspective in the determination of research priorities;
- an improved capacity to recruit subjects from diverse backgrounds into clinical research protocols; and
- an improved capacity to address and eliminate cancer health disparities.

In addition to developing targeted approaches to reach these goals, NCI is providing training for new scientists focused on health disparities through the Cancer Prevention Fellowship Program, the Community Networks to Reduce Cancer Disparities, and the Minority Institution/Cancer Center Partnership Program. A variety of individual and institutional training and career development awards are being employed to meet the needs of new and established investigators and NCI's anticipated research priorities. Special programs have focused increased resources on career tracks for physicians in cancer research, behavioral and population scientists, minority scientists, and scientists in highly technical fields important to the future of cancer research. Education programs for health practitioners and the public are being more effectively integrated and made accessible through improved national networking and exploitation of informatics technologies.

COMMUNITY OUTREACH, INFORMATION DISSEMINATION, PUBLIC HEALTH EDUCATION

To maximize the effectiveness of all our communications efforts to eliminate barriers to quality education and information resources, and to support communications research, planning, implementation, and evaluation, NCI continues to take steps to collect, more effectively analyze, and disseminate critical information about the communication needs of various audience groups.

To build on our progress in refining health communication theories and interventions, we must close major gaps in our understanding of how people access and use health information. We must:

- Provide accurate and balanced information about all areas of cancer prevention, diagnosis, treatment, and care, including complementary and alternative therapies to all.
- Learn how to help all people distinguish important health risks from insignificant ones and make informed choices despite exposure to contradictory or inaccurate health messages.
- Inform physicians, nurses, and other health care providers from all segments of the population of emerging best practices, help them become more effective communicators, and integrate cancer communications into all aspects of cancer care.
- Find and implement the best ways to disseminate research results to the cancer research community, medical practitioners, patients, at-risk persons, and the public in all segments of the population.
- Increase patient access to and participation in high-quality clinical trials to speed the pace of discovery.
- Expand the cadre of health communications scientists and practitioners from all segments of the population who conduct research and apply results.

Through these efforts, NCI will remove the access barriers to effective, quality, and culturally appropriate cancer health information services. NCI is committed to reducing and ultimately eliminating cancer-related health disparities, and we are convinced that health communications research and health communications activities are critical to meeting this goal.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One

Improve cancer-related health outcomes, especially in high-risk populations, by accelerating research in prevention, cancer control, and surveillance.

1.1.1 Objective One

Support the Centers for Population Health and Health Disparities (CPHHD) to conduct transdisciplinary multi-level, integrated research to elucidate the complex interactions of the social and physical environment, mediating behavioral factors, and biologic pathways that determine health and disease in populations, leading to an understanding and reduction of health disparities.

1.1.1.1 Action Plan

Stimulate trans-disciplinary population-based research to understand the causes of health disparities in cancer outcomes, access, and care to develop knowledge to reduce and eliminate health disparities in cancer. Resulting from collaboration among the NCI, the National Institute of Environmental Health Sciences (NIEHS), the National Institute on Aging (NIA), and the Office of Behavioral and Social Sciences Research (OBSSR), this program supports a network of eight centers working to understand the complexity of health disparities rather than single-factor relationships. Employing a community-based participatory research approach, these Centers engage and include community stakeholders in the planning and implementation of health research. This initiative employs NIH's most advanced and innovative population science to address the problem of health disparities.

1.1.1.2 Performance Measures

- Advance understanding of the development and progression of disease.
- Develop new or improved approaches for preventing, detecting, diagnosing, or delaying the onset or progression of disease and disability.
- Develop new or improved approaches to treating disease and disability.
- Advance the understanding of the social and environmental determinants of cancer and the psychosocial, behavioral, and biologic factors that mediate them.
- Develop, apply, and evaluate interventions to improve cancer outcomes and reduce outcome disparities.
- Expand existing epidemiological studies and conduct new studies to evaluate factors influencing participation by specific populations in cancer epidemiological studies.
- Disseminate health promotion and disease prevention interventions to the research and provider communities.

1.1.1.3 Outcome Measures

- Development of a population-based research approach to health disparities that links multiple levels of analysis (ranging from social to biological).
- Development of a network of trans-disciplinary collaborators to research health disparities in cancer.
- Inclusion of community stakeholders in research on health disparities in cancer by employing a community-based participatory approach.
- Number of publications, presentations, and awards for projects that examine determinants of cancer health disparities.
- Number of new grants, contracts, and intramural projects for fundamental cancer control and population research directed toward minority and underserved populations.

1.1.2 Objective Two

Establish the Community Networks to Reduce Cancer Disparities program to raise awareness activities in vulnerable populations to a new level of effectiveness in reducing cancer disparities by conducting community-based education, training, and research among racial minorities—African Americans, Hispanics, Asians, Pacific Islanders, and Native Americans/Alaska Natives—as well as Appalachian, rural, and other underserved populations. The goals of this program are to build on community-based awareness activities by significantly improving access to and utilization of beneficial cancer interventions in target communities, thereby closing the delivery gap and reducing cancer disparities among vulnerable populations.

1.1.2.1 Action Plan

Three phases:

Phase I. **Develop and increase capacity building to support community education, research, and training to reduce cancer disparities (Years 1-5). (1.1) Develop a core organizational infrastructure** in the first year, including establishing and training Community Networks staff. **(1.2) Create partnerships with communities experiencing cancer disparities and organizations that can aid in reducing cancer disparities**. (For example, create partnerships with communities experiencing cancer disparities, with primary and secondary prevention centers and cancer diagnosis and treatment facilities that serve the community, and with government and non-government organizations that can assist in reducing cancer disparities.) **(1.3) Form at least four collaborations with NCI Centers/Divisions/Offices to support other NCI efforts to reduce cancer disparities**. (That is, collaborate on at least four projects with NCI Centers/Divisions/Offices on their efforts to reduce cancer disparities, such as recruiting to clinical studies and clinical trials and working with the Cancer Information Service.) **(1.4) Increase utilization of beneficial interventions to reduce disparities in the community.** (Develop and implement community-based activities to reduce cancer disparities; activities should focus on cancer education and on increasing participation in primary and secondary prevention programs, such as smoking cessation, screening and early detection, and associated activities that reduce disparities.) **(1.5) Leverage Community Networks activity by obtaining non-CRCHD funding for community-based education and training activities directed at reducing cancer disparities.** (Active pursuit of non-CRCHD funding should also begin as a source of sustainability of the Community Networks program.)

Phase II. Develop community-based research and training programs to reduce cancer disparities (Years 2–5). Within Phase II, objectives are to: **(2.1) Develop cancer disparities research that focuses on the spectrum of research issues necessary to reduce cancer disparities**, with emphasis on developing interventions that can be used in and by the community. (Research may include, but is not limited to, identification of cancer disparities among subpopulation racial minorities and underserved groups; determination of factors that prevent/inhibit access to and utilization of primary and secondary prevention centers and cancer diagnosis and treatment facilities; development of effective interventions to overcome access and/or utilization barriers; and assessment of effectiveness of policy issues that may influence reducing cancer disparities.) **(2.2) Train researchers, particularly those from racial/ethnic minority and underserved populations, in community-based intervention research to reduce cancer disparities**. (These researchers should design and implement pilot research projects addressing community-based cancer disparities issues and knowledge and research gaps.) **(2.3) Develop pilot projects in community-based research**. (Create 1-year pilot projects to address research issues in cancer disparities research.)

Phase III. Establish credibility and sustainability of the Community Networks program (Years 4–5). Within Phase III, objectives are to: **(3.1) Reduce cancer disparities at the local level**. (In the short term, this involves increasing participation in primary and secondary prevention activities; in the longer term, this may reflect changes in stage distribution of cancers. Also, Community Networks should provide information on efficacious interventions so that these interventions can be implemented and used by other communities with disparities. Efforts should be made to transport successful programs to other communities with cancer disparities.) **(3.2) Obtain funding for research proposals** (such as R01, R03, and K awards) that address issues directly related to reducing cancer disparities that have been identified from pilot projects and other community-based research activities**. (3.3) Provide evidence-based information for reducing disparities to decision- and policymakers at the local, state, and federal levels**. (The Community Networks will inform decision- and policymakers about community-based disparities research that can reduce disparities in their communities. For example, they can provide local leaders with information on efficacious community interventions that increase participation in early detection procedures. This evidence-based information should be published and presented in a variety of media formats to inform local, state and federal officials.)

1.1.2.2 Performance Measures

- Develop an infrastructure for community-based education, research, and training directed toward reducing cancer disparities.

- Develop effective partnerships with communities experiencing disparities, primary and secondary prevention facilities, and groups that can aid in reducing disparities.
- Develop strong collaborations with other NCI Centers/Divisions/Offices.
- Conduct community-based research that develops interventions to reduce cancer disparities.
- Develop effective information dissemination networks to inform decision- and policymakers about successful ways to reduce cancer disparities.
- Identify and examine relevant factors related to reducing disparities, as collaboratively defined by grantees.

1.1.2.3 Outcome Measures

- Measurable increases in community participation in primary and secondary prevention activities.
- Number of quality pilot projects submitted and funded to conduct community-based research on cancer disparities or assess health policies and their impact on reducing cancer disparities.
- Number of new research investigators trained in health disparities research, with an emphasis on training researchers from minority/underserved communities.
- Number of peer-reviewed publications that deal with cancer disparities research developed from the Community Networks Program.
- Amount of non-CRCHD program funding leveraged for community-based activities to reduce disparities.
- Evidence of raised awareness activities in vulnerable populations to reduce cancer disparities among racial minorities—African Americans, Hispanics, Asians, Pacific Islanders, and Native Americans/Alaska Natives—as well as Appalachian, rural, and other underserved populations.
- Measurable impact of program activities on achieving reductions in cancer disparities in the target communities (specific reduction metrics to be defined in collaboration with grantees).

1.1.3 Objective Three

Enhance surveillance activities to create up-to-date statistical and analytical measures and improve the ways we apply the data.

1.1.3.1 Action Plan

Strengthen the NCI Surveillance Research Program, support activities within the NCI Applied Research Program, and support the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) to better define subpopulations and to analyze disparities in the delivery of quality cancer care.

Through the Cancer Surveillance, Epidemiology, and End Results (SEER) program, track ethnic and racial minorities and rural and low socioeconomic status (SES) populations by registering every cancer diagnosed and collect data on patient demographics, site/type, first course of treatment, stage, and follow-up, as well as cancer survival.

Provide population-based data for studying quality of care of cancer patients and for ecologic studies of emerging trends in cancer rates and status.

1.1.3.2 Performance Measures

- Strengthen a national consortium of competitively selected research teams focusing on colorectal and lung cancers to collaborate on large observational cohort studies of newly diagnosed cancer patients.
- Examine factors, such as the clinical and non-clinical characteristics of patients; provider knowledge, attitudes, and practices; and health system factors that also may be related to quality of cancer care.
- Continue to strengthen the collection and dissemination of information on changing U.S. cancer trends.
- Continue support for new population-based registries in areas populated by minorities and medically underserved groups through the system of cancer registries collecting and reporting data in the multiple states and geographic areas.
- Continue support for the Alaska Native Tumor Registry and collection of data on American Indians.
- Continue to extend coverage for population groups experiencing the greatest disparities.

1.1.3.3 Outcome Measures

- Measurable increases in patient and provider knowledge and modifications of attitudes and practices.
- Evidence of appropriate linkages to Medicare data for studies of treatment and outcome and the National Longitudinal Mortality Study for studies of long-term trends by socioeconomic levels.
- Standards set for data collection and reporting, publication of poolable data from such registries, and development of training workshops as part of the process of disseminating technical assistance to registries outside of SEER.
- Number of new grants, contracts, and intramural projects to examine issues related to epidemiological studies with specific populations.

1.1.4 Objective Four

Support cancer research efforts in the Pacific Rim and U.S. territories

1.1.4.1 Action Plan

- Create a community-based team that can articulate the cancer health needs of indigenous people living in these jurisdictions.
- Move to strengthen and sustain community capacity.

- Include community members in the programs and services of the NCI and NIH that address those needs.

1.1.4.2 Performance Measures

- Improve the quality of life of these populations, which may be underserved.
    - Institutionalize a mechanism to address issues.
    - Improve data collection and analysis.
    - Ensure access.
    - Protect civil rights and equal opportunity.
    - Strengthen and sustain community capacity.
    - Recognize and include communities in programs and services
- Establish a viable organizational unit that is capable of successfully competing for funding to address the cancer research and health needs of the community as well as other health conditions and diseases.
- Work to establish representation on NCI Advisory committees (e.g., the National Cancer Advisory Board, the Board of Scientific Advisors).
- Develop programs that are based on region-specific cancer health issues and the daily circumstances faced by people in these jurisdictions.
- Translate data and other information to help the community set the agenda for strategic action to begin addressing the cancer needs of these populations.
- Implement a network of individuals and partnering organizations to provide sustained support and a continuum of effective interventions over an indefinite number of years.
- Demonstrate the abilities of indigenous/native researchers to plan, develop, and conduct research projects within their own communities.

1.1.4.3 Outcome Measures

- Number of patients referred for screening and follow-up.
- Number of organizations working collaboratively to support programs to address the issues of indigenous peoples.
- Number of publications highlighting cancer surveillance and control issues in these jurisdictions.
- Number of community representatives on boards and committees related to health conditions and cancer.
- Measurable improvements in community capacity and infrastructure to address cancer problems of indigenous peoples.

1.1.5 Objective Five

Develop human papillomavirus (HPV) testing to improve cervical cancer screening in underserved populations.

1.1.5.1 Action Plan

The paradigm shift from cytology to HPV testing is well underway based on market forces in wealthy settings, because of the greater sensitivity of HPV testing. Nonetheless, currently marketed HPV DNA tests require a clinician-obtained cervical specimen, repeated clinic visits, and substantial cost. At NCI, we feel that the promise of HPV testing is still untapped; we need to make sure that the tools we helped develop actually help the underserved women we are targeting (rather than adding more costs for already well-screened women). The NCI has played a major intellectual and financial role (including investments of many tens of millions of dollars) in the validation of HPV testing. We are strongly committed to making HPV-test methods available to the public sector to promote maximal use of accurate cervical screening. We believe that two new strategies can realistically address problems of access: (1) Improved self-sampling at home; and (2) inexpensive, rapid testing permitting same-day management in the clinic. The technical feasibilities of both approaches are already evident. We wish to study the success of field implementation.

1.1.5.2 Performance Measures

- Development of self-sampling “kits” with postage-paid, pre-addressed packaging that could be distributed to women age 30 and older through the mail, at the pharmacy, or at common gathering locations such as churches or town meeting places.
- Development of rapid, low-cost HPV and cervical cancer biomarker tests. Rapid low-cost tests would permit same-day clinical management and reduce loss to follow-up. These tests would be useful for mobile clinics and providers serving transient populations.

1.1.5.3 Outcome Measures

- Validation of the ability of self-sampling “kits” to be sensitive as clinical tests.
- Development of rapid, low-cost HPV cervical cancer biomarker tests.

1.2 Area of Emphasis Two

Establish an integrated clinical trials system to accelerate intervention development and ensure that interventions are efficiently and seamlessly incorporated into the standard of care for all populations.

1.2.1 Objective One: Increase Minority Accrual to Cancer-Related Clinical Trials

1.2.1.1 Action Plan

Increase minority accrual to its clinical trials by partnering with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and their Community Health Center facility in the Shaw/Cardozo area of the District of Columbia to develop an NCI community-based site for patient screening, evaluation and enrollment into the Center for Cancer Research (CCR) protocols.

Develop partnerships in minority communities to find innovative and effective ways to remove barriers to clinical trials. These barriers include:

- **Long-standing fear, apprehension, and skepticism** among some minority populations about medical research because of abuses that have happened in the past (e.g., the legacy of the Tuskegee syphilis study). Among these populations, there is often widespread fear and distrust of the medical care system as a result of discrimination, indifference, and disrespect. Many feel that they do not want to give up rights or lose power to be "experimented on." Others may be skeptical about the quality of care that would be provided in a clinical trial. Some may find that trial recruitment strategies are not sensitive to their needs.
- **Doctors may not mention clinical trials as an option** for cancer care. As noted above, many physicians do not refer people to clinical trials. However, some physicians may avoid suggesting a clinical trial to people who belong to racial or ethnic minorities out of concern that they would seem insensitive. Moreover, some physicians may inadvertently discriminate against older people or those from certain ethnic or cultural backgrounds.
- **People from various cultural or ethnic backgrounds may hold values and beliefs that may be different than those of Western medicine.** Many people have a cultural belief that Western medicine cannot address their health concerns. Different ethnic and cultural views of health and disease (e.g., fatalism; family decisions about treatment; use of "traditional healers," prayer, or herbal medicines; or use of complementary/alternative health practices) may make clinical trials a less attractive treatment option. For prevention trials, many may feel that the risk of a potential disease and its consequences may be less important than meeting daily needs.
- **Language or literacy barriers** may make it difficult for some people to understand and consider participating in clinical trials. The complexity of forms, including informed consent documents, also may be a barrier to those considering participation in a clinical trial. Translation can also be difficult if the person translating information has not had specialized training.
- **Cost barriers and additional access problems confront many people.** Depending on where they live or their access to transportation, people may have difficulty getting back and forth from a clinical trial site. Those with low incomes may find it difficult to take time off work or find appropriate childcare. Other barriers, such as a lack of health insurance or a source of health care, clearly present difficulties in accessing trials.

1.2.1.2 Performance Measures

- Partner with the local community in providing access to state-of-the-art clinical care and research to underserved populations in the Washington, DC, area and educate providers and fellows in minority cancer care. Increase the participation of racial and ethnic minorities in clinical trials at the NCI Center for Cancer Research.
- Continue to expand access to NCI clinical trials to more oncologists around the country to allow cancer patients anywhere in the United States to participate more easily in advanced (Phase III) treatment trials.

- Develop community partnerships to address community concerns regarding clinical trials and develop effective ways to eliminate these barriers.

1.2.1.3 Outcome Measures

- Increased participation of minorities in Center for Cancer Research clinical trials.
- Improvements in our ability to diagnose and treat breast and prostate cancers in the minority population.
- Measurable improvements in survival rates from cancer among minority populations.

1.2.2 Objective Two: Support the Cancer Disparities Research Partnership Program

1.2.2.1 Action Plan

Continue support for the Cooperative Planning Grant for Cancer Disparities Research Partnership Program, a cooperative initiative that supports institutions that provide radiation oncology care to a disproportionate number of populations experiencing cancer-related health disparities but traditionally have never been significant participants in the NCI/NIH clinical research trials enterprise.

1.2.2.2 Performance Measures

- Support the planning, development and conduct of radiation oncology clinical research trials in medically underserved, low-income, ethnic, and minority populations and support the planning, development, and implementation of partnerships.
- Increase early access to the health care system for patients diagnosed in the advanced stages of disease.

1.2.2.3 Outcome Measures

- Measurable improvements in survival and reduction in mortality among populations experiencing excess mortality from cancer.
- Removal of barriers to timely and adequate cancer care for all cancer patients.

1.2.3 Objective Three: Support the Minority-Based Community Clinical Oncology Program (MBCCOP)

1.2.3.1 Action Plan

Continue support for the Minority-Based Community Clinical Oncology Program (MBCCOP) concept, which seeks to strengthen the MBCCOP by: (1) linking community cancer specialists, primary care physicians, and other health care professionals to NCI's Cooperative Groups and Cancer

Centers to conduct NCI-approved cancer treatment and cancer prevention and control clinical trials; (2) expanding and strengthening the cancer prevention and control research effort; (3) utilizing the MBCCOP network for conducting NCI-assisted cancer prevention and control research; and (4) evaluating on a continuing basis MBCCOP performance and its impact in the community.

1.2.3.2 Performance Measures

- Bring the advantages of state-of-the-art cancer treatment and prevention and control research to minority individuals in their own communities.
- Involve communities in cancer prevention and control research and investigate the impact of cancer therapy and control advances in community medical practices.
- Increase the involvement of primary care providers and other specialists in cancer treatment and prevention research.
- Facilitate wider community participation among racial/ethnic minorities, women, and other underserved populations. Provide an operational base for extending cancer control in minority populations.
- Evaluate CCOP impact in the community.
- Bring the advantages of state-of-the-art cancer treatment, prevention, and control research to minority individuals in their own communities.
- Increase the involvement of primary health care providers and specialists with the Minority CCOP investigators, providing an opportunity for education and exchange of information.
- Enter participants into NCI-approved cancer treatment and prevention and control clinical trials.

1.2.3.3 Outcome Measures

- Measurable increases in survival among minority populations through improved treatment for lung and colorectal cancers.
- Measurable improvements in survival and reduction in mortality among populations experiencing excess mortality from cancer.

1.3 Area of Emphasis Three

Examine the effect that factors such as social position, economic status, cultural beliefs and practices, and environmental exposures have on cancer risk, and develop and evaluate interventions to counter the effects of the numerous and complex variables that cause and contribute to cancer health disparities in U.S. populations.

1.3.1 Objective One: Develop and Evaluate the Patient Navigator Research Program (PNRP)

The purpose of the *Patient Navigation Research Program* (PNRP) is to develop an intervention to reduce the time to delivery of standard cancer care services—non-cancer resolution or cancer diagnosis and treatment—after identifying a suspicious finding for cancer.

1.3.1.1 Action Plan

The patient navigator program will assist patients and their families through the cancer care continuum. Examples of navigation services may including: arranging various forms of financial support, arranging for transportation to and childcare during scheduled diagnosis and treatment appointments, identifying and scheduling appointments with culturally sensitive caregivers, coordinating care among providers, arranging for translation/interpretation services, ensuring coordination of services among medical personnel, ensuring that medical records are available at each scheduled appointment, and other services to overcome access barriers encountered during the cancer care process. The patient navigator will link patients and families with appropriate follow-up services.

1.3.1.2 Performance Measures

- Improve NCI's knowledge and understanding of how to best support racial/ethnic minorities, people of lower SES, residents of rural areas, and other underserved populations with cancer-related abnormal screening findings in accessing and navigating the cancer care system.
- Assess the impact of patient navigators on the timely provision of quality standard care and patients' adherence to standards of care.
- Elucidate characteristics of institutional and patient-related barriers to quality standard cancer care.
- Encourage research collaborations and partnerships across cancer care delivery systems and organizations (e.g., primary care facilities, community health centers, hospitals, and academic centers).

1.3.1.3 Outcome Measures

- Improve access to and navigation of the cancer care system through timely provision of quality standard care and patients' adherence to standards of care.
- Elucidate characteristics of institutional and patient-related barriers to quality standard cancer care.
- Obtain measurable improvements in survival and reduction in mortality among populations experiencing excess mortality from cancer.

1.3.2 Objective Two

Examine the effect that factors such as social position, economic status, cultural beliefs and practices, and environmental exposures have on cancer risk by increasing fundamental research into the social causes of health disparities, the psychosocial factors that mediate them, and the biologic pathways that can explain their impact.

1.3.2.1 Action Plan

Examine gaps in knowledge and address questions emerging from Center-supported "think tanks." These "think tanks" will be composed of professionals who can provide the expertise, insights, and guidance the Center needs to shed light on the complex set of issues related to cancer health disparities. These groups conduct an in-depth analysis of a specific issue related to health disparities, identify gaps in current knowledge, and recommend areas where further research is needed.

1.3.2.2 Performance Measures

- Develop a cadre of experts across multiple disciplines to examine specific issues that have been implicated in a variety of research studies as possible causes, as key determinants, or as having some linkage to the causes of cancer health disparities.
- Conduct workshops, think tank meetings, and open forums and lectures to examine and analyze the breadth, complexity, and interplay of the issue(s) causing disparities, and recommend a course of action to minimize, or where possible, eliminate the effects of these issues (e.g., poverty, culture, social injustice) on populations experiencing cancer health disparities**.**

1.3.2.3 Outcome Measures

- Number of publications and reports emerging from these meetings.
- Number of recommendations that emerge from meetings that are designed to reduce cancer health disparities.
- Number of publications from multiple disciplines addressing the complex issues causing cancer health disparities.
- Number of funded programs developed to minimize the effects of causes/determinants of cancer health disparities.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One

Expand quality programs to build a diverse cadre of competitive researchers in biomedical research professions, and to address the need to develop a stronger cancer program in research and in health disparities.

2.1.1 Objective One: Support Network for Cancer Control Research Among American Indian/Alaska Native (AI/AN) Populations

2.1.1.1 Action Plan

The Network for Cancer Control Research among AI/AN populations is designed to build capacity of AI/AN cancer researchers who work with native populations. This program trains young investigators to carry out well-designed cancer prevention and control studies and establishes a network of mentors.

2.1.1.2 Performance Measures

- Improve community links to the NCI, the Cancer Information Service, and the ACS.
- Increase the number of AI/AN researchers, scientists, and medical students involved in cancer control activities in AI/AN communities.
- Develop, implement, and assess cancer education among AI/AN community workers and their health care providers.
- Strengthen collaborations of AI/AN communities with NCI.
- Increase the number of AI/AN patients in clinical trials (prevention, screening, treatment, and supportive care)
- Maintain the Native Researchers' Cancer Control Training Program, a supplement to support pre- and postdoctoral research work for Cancer Control Research.
- Maintain the Native CIRCLE (Cancer Information Resource Center and Learning Exchange) for individuals involved in the education, care, and treatment of AI/AN groups under experienced mentors.
- Continue to establish mentor/student relationships.
- Continue to develop, test, and disseminate culturally appropriate materials.
- Continue to support biennial national conferences on "Cancer in Indian Country."
- Continue to develop evidence-based information and materials for individuals involved in the education, care, and treatment of AI/AN populations.

2.1.1.3 Outcome Measures

- Number of educational programs and campaigns.
- Number of community members and amount of minority representation on advisory boards.
- Number of new research and community collaborations.
- Number of new resources distributed to the community.
- Number of minority patients seeking access to clinical trials.
- Number of successfully trained physicians and scientists from health disparity populations in clinical and academic medicine.

- Number of newly developed and funded research studies.
- Number of new successful cancer control training techniques.

2.2.2 Objective Two

Create a pipeline to a competitive career in cancer research by continuing support for Continuing Umbrella of Research Experience (CURE) and the Science Enrichment Program (SEP) designed to attract young high school students into science and public health careers.

2.2.2.1 Action Plan

The CURE philosophy of research training and career development builds on the success of the Research Supplements to Promote Diversity in Health-Related Research (PA 05-015) (formerly the Research Supplement for Underrepresented Minorities) and strategically addresses each level of the biomedical research and educational pipeline to: (A) increase the pool of underrepresented populations including minority candidates; (B) emphasize scientific areas of greatest need; and (C) expand and extend the period of training and career development. CURE has become a multi-year, multi-institutional educational and research continuum from high school to the first professional appointment.

2.2.2.2 Performance Measures

- Recruit, train, and sustain underserved individuals in cancer research and provide partnership opportunities for training and career development.

2.2.2.3 Outcome Measures

- Increases in the pool of underrepresented candidates, such as individuals from racial or ethnic groups and other underserved groups that have been determined by the grantee institution to be underrepresented in cancer-related biomedical, behavioral, clinical, or social sciences research (often based on regional profiles).
- Increased emphasis on scientific areas of greatest need
- Measurable expansion and extension of training and career development for minority individuals.
- Number of students entering biomedical, health care, or public health careers.

2.2.3 Objective Three

Support Minority Institutions/Cancer Center Partnerships (MI/CCP) The goal of these grants is to initiate and develop collaborations between researchers from minority-serving institutions (MSI) and Cancer Centers.

2.2.3.1 Action Plan

Continue to implement the MI/CCP program initiated in April 2000 as a collaboration between NCI and the National Center for Minority Health and Health Disparities (NCMHD) focused on developing comprehensive partnerships between NCI-designated Cancer Centers and institutions at which students from groups that are underrepresented in biomedical sciences comprise a significant proportion of the enrollment, as indicated by designation by the U.S. Department of Education as MSIs. MSIs are defined as institutions in which students of racial and ethnic minority groups that are underrepresented in the biomedical sciences comprise a significant proportion of the enrollment, and have a track record of commitment to racial and ethnic minority faculty, students, and investigators. These partnerships between MSIs and NCI-designated Cancer Centers are designed to increase cancer research capabilities at the MSIs, and to build and stabilize collaborative and independent research in cancer and cancer health disparities as well as develop and sustain other related activities focused on the disproportionate incidence, mortality, and morbidity of cancer among populations that are experiencing an excess burden from cancer and that reside in the region of the Cancer Center and are served by the MSI.

The aims of these partnerships are: (1) to provide cancer research training and education to qualified underrepresented students and investigators to strengthen diversity in the cancer research professions and to encourage recruitment of the most talented researchers to pursue careers in research in cancer and cancer health disparities; (2) to improve the quality of the outreach, training, and educational environment for cancer research at the partnering institutions; (3) to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and (4) to strengthen the National Cancer Program by broadening the perspective of the cancer research community in setting cancer research priorities and improving the Nation's capacity to address and eliminate health disparities.

2.2.3.2 Performance Measures

- Increase formal arrangements between the partnering institutions.
- Build and stabilize independent and collaborative, competitive research and research training projects and programs in institutions that serve populations experiencing disparities in cancer.
- Create stable and long-term collaborative relationships between MSIs and NCI-designated Cancer Centers or groups of Centers in the areas of outreach, research training and career development, education, and cancer research that increase emphasis on problems and issues relevant to cancer research and research to develop an understanding of the causes of cancer health disparities and potential solutions to eliminate these disparities.

2.2.3.3 Outcome Measures

- Increase research capacity in cancer across diverse institutions including Historically Black Colleges and Universities (HBCUs) and other MSIs.
- Increase cancer outreach and education programs.

- Increase collaborative projects on the cancer continuum directed to communities experiencing cancer health disparities.
- Increase the number of trained scientists from underrepresented populations.
- Increase the number of activities that penetrate and have greater effectiveness to benefit communities experiencing cancer health disparities.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One

Increase access to and use of cancer communications by all populations, especially underserved populations.

3.1.1 Objective One: Continue Support for the Cancer Information Service (CIS)

The CIS will continue to routinely disseminate the latest NCI cancer information and initiate cancer education projects that focus on diet and nutrition, cancer screening for cancers prevalent in minority populations, and clinical trials. The CIS is a national information and education network that operates a toll-free telephone service (1-800-4-CANCER) to provide to callers the most recent scientific information in understandable language in both English and Spanish.

Two-thirds of CIS partners focus on reaching minority audiences, including African Americans, Hispanics, American Indians, Asian Americans, Native Hawaiians, and Alaska Natives. More than three-quarters of CIS partners strive to reach medically underserved audiences—(including older Americans and individuals living in communities lacking adequate health services or experiencing language, educational, financial, or transportation barriers). Strengthened by its regional structure, the CIS focuses on the distinct needs in each community to provide a service tailored to culturally diverse populations throughout the Nation.

The CIS shares resources on cancer programs and services in communities across the country and helps bring cancer information to people who do not traditionally seek health information or who may have difficulties doing so because of educational, financial, cultural, or language barriers; provides expertise to organizations to help strengthen their ability to inform people they serve about cancer; and links organizations with similar goals and helps them plan and evaluate programs, develop coalitions, conduct training on cancer-related topics, and use NCI resources.

3.1.1.1 Action Plan

Work with the Community Networks program and other NCI community programs at minority institutions to develop effective communications techniques and materials to reach populations experiencing cancer health disparities.

3.1.1.2 Performance Measures

- Develop partnerships with MSIs to develop and disseminate the latest NCI cancer information to minority communities.
- Initiate cancer education projects that focus on diet and nutrition, cancer screening for cancers prevalent in minority populations, and information to access clinical trials and address the barriers to clinical trials.
- Strengthen awareness of populations on cancer-related issues of high importance.

3.1.1.3 Outcome Measures

- Number of partnerships developed with MSIs.
- Number and type of NCI publications and materials disseminated to MSIs and populations.
- Number and types of collaborative projects that address diet and nutrition; prevention; screening for breast, cervical, prostate, colorectal, and lung cancers; and clinical trials.

3.1.2 Objective Two: Support the Cancer Tobacco and Health Disparities Research Network (THDRN)

3.1.2.1 Action Plan

The THDRN aims to: (1) Advance the science in understanding the etiology, prevention, and treatment of tobacco use and nicotine addiction among underserved populations in the United States; and (2) translate knowledge into practice and inform public policy. The THDRN will stimulate new studies, challenge existing paradigms, and address significant gaps in research on understudied and underserved populations.

Develop a model for examining tobacco and health disparities. Establish a multi-disciplinary network including: methodology, treatment, cessation, prevention, policy, community, and translation of research into practice.

3.1.2.2 Performance Measures

- Encourage collaboration and serve as a forum for focusing on tobacco-related health disparities.
- Communicate and interact with community advocacy groups.
- Train junior investigators.
- Promote senior researchers' participation in health disparities research.

3.1.2.3 Outcome Measures

- Number of collaborations developed focusing on tobacco-related disparities.

- Number of investigators trained to participate in tobacco-related research.
- Increased number of senior researchers incorporating cancer health disparities into their research portfolio.

3.1.3 Objective Three: Support the Energy Balance Research and Promotion Initiative

3.1.3.1 Action Plan

Synthesize and integrate relevant and promising prevention and weight loss interventions to include physical activity promotion and caloric reduction.

3.1.3.2 Performance Measures

- Develop a comprehensive national action plan, including research, education, marketing, and policy/advocacy components, to promote energy balance among priority audiences for the control and prevention of cancer and other chronic diseases.
- Develop a research portfolio to understand the mechanisms of energy balance in cancer prevention.
- Identify messages appropriate to educate target audiences.
- Recruit partners from the public, private, and non-profit sectors to participate in the development of the national action plan.

3.1.3.3 Outcome Measures

- Publication of a national action plan to promote energy balance.
- Number of grants to understand the mechanisms of energy balance in cancer prevention.
- Number of publications and other materials distributed to target audiences.
- Number of public, private, and non-profit partnerships developed to achieve the recommendations in the national action plan.

3.1.4 Objective Four

Conduct biobehavioral, psychological, and social research on the interrelationships among biological processes, cognition, emotion, and physical health among ethno-culturally diverse survivors of breast, prostate, and AIDS-related cervical cancers.

3.1.4.1 Action Plan

Continue support for several survivorship programs sponsored by the NCI, including Centers for Psycho-Oncology Research Specialized Center, minority and underserved cancer survivor supplement, Overcoming Barriers to Treatment Adherence in Minorities and Persons Living in Poverty, and Long-term Cancer Survivors' research initiative.

3.1.4.2 Performance Measures

- Develop and test Spanish translations of interventions for breast and prostate cancer patients.
- Understand survivorship issues among minority and underserved patients and their families who have returned to their communities after completion of cancer treatment.
- Develop collaborations between cancer centers and community organizations to address survivorships issues in communities.

3.1.4.3 Outcome Measures

- Number of materials translated for Spanish-speaking cancer patients.
- Number of collaborations and partnerships with communities.
- Number of cancer survivors using community services designed for cancer survivors.

3.1.5 Objective Five: Continue Support for the Cancer Control Planet Web Site

3.1.5.1 Action Plan

Cancer control planners, program staff, and researchers have the same goals: to reduce cancer risk, the number of new cancer cases, and the number of deaths from cancer, as well as enhance the quality of life for cancer survivors. Although many share the same goals, all do not have easy access to resources that can facilitate the transfer of evidence-based research findings into practice. This PLANET portal provides access to data and resources that can help planners, program staff, and researchers design, implement, and evaluate evidence-based cancer control programs.

3.1.5.2 Performance Measures

Provide access to Web-based resources that can assist in:

- Assessing the cancer and/or risk factor burden within a given state.
- Identifying potential partner organizations that already may be working with high-risk populations.
- Understanding current research findings and recommendations.
- Accessing and downloading evidence-based programs and products.
- Finding guidelines for planning and evaluation.

3.1.5.3 Outcome Measures

- Number of persons who access the web site
- Number of links to information and resources related to cancer health disparities issues.
- Number of evidence-based programs highlighted on the web site.

The National Center for Complementary and Alternative Medicine

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL **C**ENTER FOR **C**OMPLEMENTARY AND **A**LTERNATIVE **M**EDICINE

MISSION/VISION STATEMENT

The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training complementary and alternative medicine (CAM) researchers, and disseminating authoritative information to the public and health professionals. NCCAM seeks to advance CAM research to yield insights and tools to benefit the health and well-being of the public, while enabling an informed public to reject ineffective or unsafe practices.

The vision of the NCCAM *Health Disparities Strategic Plan* is a health system in which no health disparities exist between the majority population and racial/ethnic minority populations; a system in which appropriate CAM practices are integrated with conventional practices in promoting health and treating disease. NCCAM will contribute to the elimination of health disparities by conducting research to identify CAM practices that are effective, disseminating research findings on those practices to all groups of Americans, and enriching the diversity of the CAM research community itself.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

CAM practices can be described as those not presently considered an integral part of conventional medicine. Although recent national surveys document a substantial and growing use of CAM by Americans as a whole (with most people using CAM in addition to conventional care), little is known about CAM use in minority and other health disparity populations, either by lay members or their care providers. Such research can shed light on the relationships between beliefs and health behaviors and their influence on conventional health care and methods of health promotion and disease prevention. In this way NCCAM can gather key information, opening the door to information exchange and improving the understanding, cultural sensitivity, and competence of health care providers working within the conventional medical care system. These activities, as well as the integration of CAM therapies found to be safe and effective into conventional health care, will help us realize the vision of the NCCAM health disparities plan.

NCCAM regards America’s diverse racial/ethnic groups as a valuable resource for learning about systems of healing and health practices outside the mainstream. For example, the rich heritage of traditional Native American medicine remains to be investigated more thoroughly, as do the many CAM practices that originated in or are traditional to cultures and countries outside America and which were brought here by immigrating racial/ethnic minority populations. NCCAM’s research programs can serve a dual purpose, establishing which CAM interventions can benefit the health and well-being of *all* Americans but may be particularly useful and accepted in selected populations, and facilitating the integration of CAM practices into conventional health care in the United States. NCCAM is well-positioned to support research on the health beliefs and practices of various health disparity populations, particularly on uses of CAM instead of, or in association with, conventional medical care.

NCCAM continually evaluates its programs, including programs that seek to diversify the scientific workforce and to diversify the range of institutions and individuals from which it receives applications. To this end, NCCAM regularly revises and updates its programs.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One

Advance understanding of the role of CAM in the development and progression of diseases and disabilities that contribute to health disparities.

In general, CAM systems and practices are aimed not only at treating disease, but also at promoting general health and wellness. Defining "wellness" for the purposes of research is challenging in itself; it is even more challenging to investigate the safety and efficacy of the many highly complex and diverse therapies that constitute CAM modalities. Adding to the difficulties of conducting rigorous CAM research is the fact that CAM interventions frequently are customized for the individual patient and thus may not be as replicable as conventional medical regimens for the purposes of establishing safety and efficacy. The research methods used to investigate CAM need to be sensitive to cultural variants within the many types of CAM systems to be studied. With the ultimate goal of identifying safe and efficacious CAM systems and practices in mind, it may be necessary initially to conduct descriptive or qualitative research to understand health behaviors and the meaning of a given approach in a given culture prior to conducting quantitative research.

NCCAM research in pursuit of this objective will entail general studies on uses of CAM by various health disparity populations. By continuing secondary analyses of data collected from previous surveys on CAM use as well as undertaking new initiatives, NCCAM will expand knowledge of CAM use by minority and other health disparity populations and provide a more comprehensive view of CAM use by the entire U.S. population.

Public comments will inform implementation of the action plan for this Area of Emphasis. This Area of Emphasis is the first priority for NCCAM's research regarding health disparities.

1.1.1 Objective One

Fund research on CAM and its role relative to health disparities, including use, costs, and outcomes.

This objective will increase the understanding of CAM's role relative to health disparities in general through investigator-initiated research projects.

1.1.1.1.1 Action Plan

In collaboration with the National Center for Health Statistics of the Centers for Disease Control and Prevention, NCCAM developed a supplemental module on CAM use that was incorporated into the National Health Interview Survey (NHIS) in 2002. Because NHIS oversamples African Americans and Hispanic Americans, the survey collected much-needed information on CAM use in these groups. Data from this CAM supplement to the 2002 NHIS are an important component of an ongoing initiative, *Secondary Analysis of Data on CAM Use in Minority Populations*. NCCAM will provide continuation funding for previously awarded grants and new grant funding through this initiative. The two additional receipt dates (August 2004 and August 2005) for this Program Announcement will provide opportunities to fund additional grants.

Data from the CAM module of the NHIS and additional in-depth projects also could be used for studies of clinical outcomes. Information on the extent and types of CAM use by minority populations, especially for treatment of conditions targeted by the National Institutes of Health (NIH) and the Department of Health and Human Services in their plans for eliminating health disparities, could be compared to data on outcomes of patients receiving conventional health care. Through such comparisons, NCCAM research may identify potential roles for CAM modalities in contributing to the elimination of health disparities.

In addition to the “Secondary Analysis” Program Announcement, the Center plans to issue a new solicitation that will support exploratory/developmental (R21) research projects that focus on CAM and its role in health disparities. The new solicitation will fund investigator-initiated research projects in 2006 on a range of topics including the impact of CAM on: use and costs of conventional health care services; disease outcomes; quality of care, and quality of life. This initiative will provide opportunities for those investigators experienced in examining health disparities issues to focus their research efforts on CAM. NCCAM also will explore potential opportunities for collaborating with other NIH Institutes and Centers (ICs) in funding research regarding CAM and health disparities and providing technical assistance to encourage additional research on health disparities and CAM.

Overall, these projects will permit NCCAM to collect information on CAM use by minority and health disparity populations as well as targeted information on use by specific populations.

1.1.1.2 Performance Measures

- Number of grants funded on CAM and health disparities issues
- Release of a Program Announcement (PA) on CAM and health disparities
- Number of grant applications received and funded in response to the PA
- Amount of funding awarded
- Number of contacts and collaborations with NIH ICs

1.1.1.3 Outcome Measures

New research findings on CAM and health disparities

1.2 Area of Emphasis Two

Explore CAM approaches for treating diseases and disabilities that contribute to health disparities.

Although CAM use is widespread, information on the effectiveness of CAM for treating specific conditions is limited. Research is needed to investigate specific disease conditions for which CAM interventions are believed to be effective. Research to detail these practices will provide important insights into how particular CAM interventions are utilized and their impact on the health of U.S. health disparity populations. This Area of Emphasis, addressing the use of CAM for specific conditions, is second in priority to Research Area of Emphasis One which is designed to promote a general understanding of the uses and impact of CAM. Public comments will inform implementation of the action plans for this Area of Emphasis.

1.2.1 Objective One

Provide continuation and new funding for research exploring roles for CAM in treating specific diseases.

NCCAM funds, independently and in collaboration with other NIH ICs, support ongoing research investigating the use of CAM for specific diseases. For those diseases identified as priority health disparities conditions (e.g., HIV/AIDS, cancer, diabetes, etc.), this research may have an important impact. Studies are needed to determine whether there are roles for CAM modalities in treating specific diagnoses, either singly or in combination with other approaches, and for what indications – to treat the disease, lessen side effects of conventional treatment, or improve quality of life.

1.2.1.1 Action Plan

NCCAM will continue funding grants addressing issues relating to CAM and health disparities conditions. This includes such collaborative grant funding as the NCI SELECT Trial to determine whether there are roles for selenium and vitamin E in the treatment of prostate cancer. NCCAM also will explore possibilities for funding new projects investigating specific conditions, such as the role of milk thistle in treating end-stage liver disease, and fund, as appropriate, other investigator-initiated grants on CAM and health disparities for specific disease conditions.

The prospect of utilizing CAM to contribute to the elimination of health disparities will require identification of those conditions for which CAM systems and modalities are safe and effective. Through existing research projects, NCCAM will study the use of CAM to treat various health conditions known to affect disproportionately minority and health disparity populations.

1.2.1.2 Performance Measures

- Number of grants funded
- Amount of grant funding

1.2.1.3 Outcome Measures

- New research findings on CAM and health disparities
- Number of health disparities investigators newly engaging in CAM research

1.2.2 Objective Two

Stimulate collaborative research projects to explore CAM and health disparities.

NCCAM will explore development of an initiative to facilitate collaborative interactions between investigators at institutions that train individuals predominately from HBCUs and other institutions with student populations underrepresented in research and institutions experienced in CAM research. The provision of planning grants will enable researchers at institutions that train individuals predominately from HBCUs and other institutions with student populations underrepresented in research to establish productive collaborations that will help them compete successfully for peer-reviewed research support. The goals of this program are to stimulate research on CAM and health disparities, to establish productive research collaborations, and to diversify the CAM research community.

1.2.2.1 Action Plan

Fund planning grants to develop research collaborations between institutions that train individuals predominately from HBCUs and other institutions with student populations underrepresented in research and research-experienced institutions. It is expected that these planning grants will lead to the submission of R21 and R01 research project grants targeting CAM and health disparities research issues.

1.2.2.2 Performance Measures

- Number of collaborations developed
- Number of planning grant applications submitted and funded
- Amount of funding for planning grants

1.2.2.3 Outcome Measures

- New research findings on CAM and health disparities
- Number of R21 and R01 applications submitted and funded as a result of the planning grants

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One

Expand opportunities in research training and career development for, and provide research supplements to, research investigators from racial and ethnic minority populations and other health disparity populations.

Studies document the under-representation of investigators from historically socio-economically disadvantaged backgrounds in biomedical research and the lack of research funding at institutions whose primary mission is to train such individuals. The goal of building a diverse CAM research community may require not only supporting programs to increase the number of health-disparity researchers in general, but also investing in those institutions that continue to train a large share of health-disparity investigators at HBCUs and other institutions with student populations underrepresented in research. A variety of NIH programs provide research training opportunities to increase the diversity of students at various educational levels. In addition, there are programs to enhance the research capability of faculty at health professions associated with HBCUs and other institutions with student populations underrepresented in research. In view of the ever-broadening cultural diversity of the American population and the wealth of CAM traditions, NCCAM's ongoing and planned initiatives are aimed at broadening the range of backgrounds of investigators who apply for NCCAM grant funding and enhancing research capacity at institutions that train such individuals. Both Areas of Emphasis regarding research capacity have equal priority. Public comments will inform implementation of the action plans for this Area of Emphasis.

2.1.1 Objective One: Fund Training and Career Development Opportunities

Increasing the diversity of students preparing for careers in CAM research is critical to any plan to eliminate health disparities. Toward that end, NCCAM will help to build diversity in the CAM research community by providing extramural and intramural research opportunities. This initiative will help develop a cohort of scientists from health disparity populations investigating CAM and enhance the ability of HBCUs and other institutions with student populations underrepresented in research to support CAM research.

2.1.1.1 Action Plan

NCCAM has funded two T32 National Research Service Award (NRSA) institutional training grants at HBCUs and other institutions with student populations underrepresented in research. Continuation funding in 2004 and 2005 will provide ongoing opportunities for training in CAM research. When the funding period for these training grants has ended, NCCAM will encourage these two institutions to submit competitive renewal applications to the omnibus NIH T32 announcement. This will help diversify the spectrum of institution types at which NCCAM supports NRSA institutional training grants. NCCAM staff will encourage and support all of NCCAM's T32 grantees in increasing the diversity of backgrounds of trainees, as well as an increased use of the range of training and career development mechanisms, including F and K awards.

NCCAM participated in the NIH program, Research Supplements for Underrepresented Minorities. NCCAM currently participates in this program's successor, Research Supplements to Promote Diversity in Health-Related Research (PA 05-015). Ongoing collaboration with other NIH ICs also will enhance NCCAM's participation in NIH-wide activities to help NCCAM investigators identify eligible minority and health disparity trainees.

2.1.1.2 Performance Measures

- Amount of funding supporting health disparity investigators and trainees and investigators and trainees from Historically Black Colleges and Universities (HBCUs) and other institutions with student populations underrepresented in research
- Number of trainees from populations underrepresented in research participating in institutional grants
- Number of grants to health disparity research investigators, individuals from historically socioeconomically disadvantaged backgrounds, and the institutions that train such individuals
- Number of Diversity Supplement applications received for Research Supplements to Promote Diversity in Health-Related Research, and amount of funding for supplement awards

2.1.1.3 Outcome Measures

- Number of subsequent applications submitted by trainees and investigators
- Number of trainees who pursue research careers
- Number of grants funded
- New research findings on CAM and health disparities

2.1.2 Objective Two: Outreach to Students and Trainees Interested in Health Disparities and Other Research Careers

The National Science Foundation (NSF) has documented racial and ethnic disparities in the composition of the Nation's research workforce. The National Research Council has also documented a range of disparities, rooted in differences between racial and ethnic populations in the United States, in the Nation's health care system. Reports such as *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* and *Eliminating Health Disparities: Measurement and Data Needs* make recommendations to the Nation in general and the NIH specifically to address these disparities.

NCCAM will engage in a range of outreach activities targeted to high school and college students from racial and ethnic minority populations. The goals of these outreach activities are to inform students of research career opportunities in CAM, to diversify the population of applicants to NCCAM for grant support, and to diversify the Nation's pool of CAM investigators.

2.1.2.1 Action Plan

Reach out and inform diverse populations of high school, undergraduate, and graduate students of career options in research through high school youth initiatives and other outreach activities.

2.1.2.2 Performance Measures

- Amount of funding for youth initiatives and outreach to students and trainees
- Number of students supported in youth initiatives

2.1.2.3 Outcome Measures

- Number of students pursuing research careers

2.2 Area of Emphasis Two

Promote the development of inter-institutional partnerships between research-intensive institutions and institutions that historically have trained student populations underrepresented in research and that are seeking to build research capabilities.

Building a diverse CAM research community requires support of programs to increase the number of individuals from diverse socioeconomically disadvantaged backgrounds and health disparity researchers in general and measures to enhance the research capabilities at those institutions that train a large share of such researchers. Both Areas of Emphasis regarding research capacity have equal priority. Public comments will inform implementation of the action plan for this Area of Emphasis.

2.2.1 Objective One: Enhance Research Capacity at HBCUs and Other Institutions With Student Populations Underrepresented in Research

This initiative will fund planning grants to facilitate collaborative interactions between investigators at institutions that train individuals predominately from HBCUs and other institutions with student populations underrepresented in research and institutions experienced in CAM research. This will enable researchers at HBCUs and other institutions with student populations underrepresented in research to establish productive collaborations that will help them compete successfully for future peer-reviewed research support. The program also will target research on issues that affect health disparities populations. The goals of this initiative are to increase research on CAM and health disparities, to foster productive research collaborations, and to diversify the CAM research community and the institutions from which NCCAM receives applications.

2.2.1.1 Action Plan

Fund planning grants (R03) to foster academic partnerships and support research collaborations between HBCUs and other institutions with student populations underrepresented in research and research-experienced institutions. These planning grants will target health disparities issues and are expected to lead to the submission of R21 and R01 research project grants.

2.2.1.2 Performance Measures

- Number of collaborations developed
- Number of applications submitted
- Number of planning grants funded
- Amount of funds for planning grants

2.2.1.3 Outcome Measures

- New research findings on CAM and health disparities
- Number of R21 and R01 grant applications submitted/funded as a result of the
- planning grants

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One

Provide the latest research-based information to health care providers to enhance the care provided to individuals within racial and ethnic minority populations and other health disparity populations.

NCCAM will expand its participation in, and linkages with, minority health professions organizations to educate conventional health professionals about the widespread use of CAM. NCCAM will encourage providers to interact with patients in an open, non-judgmental manner and to facilitate communication between the conventional medical community and the CAM community. This Area of Emphasis is the second priority under outreach, dissemination, and education. Public comments will inform implementation of the action plans for this Area of Emphasis.

3.1.1 Objective One: Increase Awareness by Health Care Providers Regarding Risks and Potential Benefits of CAM

The development of integrative systems of health care delivery can lead to improved health outcomes for patients as well as foster collaborative opportunities for CAM research. At the same time, providers need to know about CAM to be able to discuss with patients the potential risks of certain CAM therapies alone or in combination with conventional interventions.

3.1.1.1 Action Plan

Explore partnerships with professional societies to disseminate research results and raise awareness about CAM. Attend meetings of health professions associations, such as physician organizations (National Medical Association, National Hispanic Medical Association, Association of American Indian Physicians, etc.), nursing organizations (National Association of Hispanic Nurses, Black Nurses Association, etc.) and others. Post findings from the NHIS and other relevant CAM studies on NCCAM's web site and disseminate findings in the NCCAM newsletter.

3.1.1.2 Performance Measures

- Number of organizations engaged
- Number of activities undertaken
- Number of web site postings
- Mailings to health professions organizations

3.1.1.3 Outcome Measures

- Increased CAM awareness reported among organizations
- Increased participation in CAM-related activities

3.1.2 Objective Two: Support Development of Datasets and Tools

Utilize computer databases and Internet resources to disseminate current information about scientific research and discoveries and other activities regarding health disparities.

3.1.2.1 Action Plan

NCCAM will disseminate findings from the NHIS Advance Data Report and will continue to work with the National Center for Health Statistics (NCHS) to conduct CAM-use surveys. NCCAM will continue to use its web site and electronic listserv to disseminate research results. NCCAM will seek to increase its Internet presence by exploring partnerships and linkages with related organizations.

3.1.2.2 Performance Measures

- Number of organizations engaged
- Number of activities
- Number of datasets initiated

3.1.2.3 Outcome Measures

- Number of datasets completed

3.1.6 Area of Emphasis Two

Maintain ongoing communication linkages and partnerships with community-based and faith-based organizations, health care associations, foundations, and academic institutions, and foster dialogue with racial and ethnic minority populations and other health disparity populations, including the underserved.

Various types of organizations may be helpful in disseminating information regarding the risks and demonstrated or perceived benefits of CAM. Outreach to, and interactions with, a broad array of organizations is important to communicate effectively with constituent populations. This Area of Emphasis is the first priority under outreach, dissemination, and education. Public comments will inform implementation of the action plan for this Area of Emphasis.

3.2.1 Objective One: Engage Organizations to Increase Awareness of Issues Unique to CAM Among Constituents

Many CAM practices are widely used even though they have not been shown in clinical studies to be effective. NCCAM supports research on a range of CAM practices and is building the knowledge base regarding those CAM practices that are effective, those that remain unproven or are shown to be ineffective, and potentially dangerous CAM practices. This scientific information needs to be disseminated broadly to minority communities in culturally appropriate ways. NCCAM will work with community organizations and institutions to encourage the appropriate use of CAM and the integration of CAM with the conventional health care delivery system.

3.2.1.1 Action Plan

- Develop an outreach plan for information dissemination, including community exhibits, culturally-sensitive materials, and other communications products in selected languages
- Sponsor “listening circles” with indigenous healers from Native American communities
- Attend meetings of constituent groups
- Hold meetings with organizational leadership to identify partnership opportunities
- Develop partnerships with other NIH ICs to coordinate outreach activities

- Engage minority-focused media in CAM information dissemination
- Develop a listserv for organizations
- Deliver presentations to minority institutions, investigators, and students about opportunities for research and training
- Develop a tutorial on CAM decision-making

3.2.1.2 Performance Measures

- Number of organizations engaged
- Number of activities developed
- Number of contacts and presentations made

3.2.1.3 Outcome Measures

Increased awareness among and participation of organizations in CAM information dissemination

3.1.6.1 Area of Emphasis Three

Facilitate the incorporation of science-based information regarding CAM into the curricula of medical and allied health professions schools and public health schools, and into continuing education activities of health professionals. This Area of Emphasis is the third priority under outreach, dissemination, and education. Public comments will inform implementation of the action plan for this Area of Emphasis.

3.3.1 Objective One: Support the Incorporation of CAM Information Into Curricula of Health Professions Education and Training

Education of current and future providers on CAM issues is important to increasing the knowledge of all populations about the risks and perceived or demonstrated benefits of CAM.

3.3.1.1 Action Plan

Continue funding educational grants to incorporate CAM information into health professions curricula.

3.3.1.2 Performance Measures

- Number of grants for curriculum development
- Amount of funding for curriculum development grants

3.3.1.3 Outcome Measures

- Number of educational programs sustaining curriculum changes regarding CAM
- Number of participants in CAM educational programs

The National Center for Research Resources

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL **C**ENTER FOR **R**ESEARCH **R**ESOURCES

MISSION/VISION STATEMENT

The National Center for Research Resources (NCRR) serves as a catalyst for discovery for National Institutes of Health (NIH)-supported investigations throughout the Nation by creating, developing, and providing access to a comprehensive range of human, animal, and technology-related resources and other research tools to facilitate biomedical research. NCRR promotes collaborations within and across scientific disciplines and provides quick, flexible approaches to address new and evolving research queries.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

NCRR intends to mobilize its research resources and other infrastructure components to continue to facilitate initiatives of other NIH Institutes and Centers (ICs) to study Health Disparities (HDs), with the ultimate goal of eliminating the disparities frequently observed among ethnic and minority populations. NCRR provides funds to support institutional and faculty development as well as research on diseases that disproportionately impact minority and other special populations.

The following are NCRR's objectives for increasing the research capacity needed to conduct health disparities research:

1. Increase research competitiveness through institutional development.
2. Create a translational research network.
3. Upgrade research laboratories.
4. Support research training and career development.
5. Expand collaborations to involve minorities in clinical research and recruitment of minority patients.

The above objectives address the public comments received in response to the initial NIH Health Disparities Plan. Specifically, NCRR will continue to support the infrastructure needed at institutions to conduct health disparities research.

1.0 AREAS OF EMPHASIS IN RESEARCH—N/A

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One

Provide increased funding at institutions across the country for resources, new equipment, and shared instrumentation programs for use in health disparities research.

NATIONAL **C**ENTER FOR **R**ESEARCH **R**ESOURCES

Institutional development strengthens an organization's infrastructure and increases its capacity to conduct cutting-edge biomedical and behavioral research. A strong institutional infrastructure includes modern research resources, laboratories, and equipment that help to develop the research skills of talented investigators at the institution and attract established investigators to the institution.

2.1.1 Objective One: Increase Research Competitiveness Through Institutional Development

To enhance the distribution of biomedical and behavioral research geographically, NCRR, on behalf of NIH, developed the Institutional Development Award (IDeA) Program to foster research within states that traditionally have not received significant levels of competitive funding from the NIH. These 23 states, plus Puerto Rico, provide a special opportunity to study special populations.

The purpose of the IDeA Program is to foster capacity building for health-related research through support for faculty development and enhancement of the research infrastructure of institutions located in states with historically low aggregate success rates for grant awards from NIH. Two recently developed programs provide competitive support to attain the goals of the IDeA Program. The first, Centers of Biomedical Research Excellence (COBRE), provides 5 years of support for a multidisciplinary team, led by an NIH-funded investigator, to develop faculty biomedical research expertise and competitiveness within a thematic research focus. Funds are provided to build the research infrastructure to enhance the institution's research capacity and competitiveness for NIH grant funds. The second IDeA program, IDeA Networks of Biomedical Research Excellence (INBRE), provides up to 5 years of support to augment and strengthen the state's biomedical research capacity via support to expand and develop biomedical faculty research capability and enhance research infrastructure through support of a multi-disciplinary, thematic scientific focus network to allow them to more fully compete for research support from the NIH. In addition, INBRE is intended to enhance the caliber of science faculty at undergraduate schools; this, in turn, will attract more promising students to those institutions.

Special populations within the IDeA states include Native Americans, Aleuts, Native Alaskans, African Americans, Hispanics, and Hawaiians/Pacific Islanders, with diseases that affect them disproportionately. Both INBRE and COBRE provide research support for studies on those populations as well as the impact of health disparities on those populations.

2.1.1.1 Action Plan

<u>Support Institutional Development Award (IDeA) Program (NCRR SP pg 19)</u>
NCRR will provide competitive support through COBRE and INBRE to IDeA state investigators for health disparity studies of the special populations within the 23 IDeA states and Puerto Rico.

2.1.1.2 Performance Measures

Each grant must contain an evaluation component to assess whether the effectiveness of the approach taken will meet the goals or benchmarks for building an effective institutional research network. The NCRR will routinely monitor and assess the implementation of proposed activities.

2.1.1.3 Outcome Measures

NCRR will routinely monitor the implementation of proposed activities through the increase in research grant awards to IDeA state institutions that participate in INBRE and COBRE; increased number of peer reviewed research papers focusing on health disparities; and better-quality graduate students attending graduate schools in the state.

As part of the Government Performance and Results Act, NCRR will be conducting a formal evaluation of the IDeA Program. The first phase of the evaluation will be to develop an evaluation methodology, which will include the identification of specific performance and outcome measures.

2.1.2 Objective Two: Increase Shared Instrumentation

The NCRR Shared Instrumentation Grant (SIG) Program allows three or more NIH-supported investigators to purchase sophisticated commercial instruments that cost at least $100,000. The maximum award amount is $500,000. In recognition of the need for and advantages of continuing investment in new instrumentation for the advancement of biomedical research, NCRR began a new program in FY2002 for the support of high-end research instrumentation.

2.1.2.1 Action Plan

<u>Ensure the Availability of Shared Instrumentation (NCRR SP pg 17)</u>
Through the SIG Program, NCRR will ensure the availability of shared state-of-the-art instrumentation to meet the needs of the biomedical research community. The instrumentation will facilitate investigators’ studies, including research on why health disparities exist and to test approaches to eliminate them.

2.1.2.2 Performance Measures

NCRR will use the specialized expertise of workgroups and the National Advisory Research Resources Council (NARRC) to routinely monitor and assess the implementation of proposed activities to ensure programs are designed to meet the needs of stakeholders. This includes monitoring Program Announcements (PAs), Requests for Applications (RFAs), and grantee activity and progress.

2.1.2.3 Outcome Measures

NCRR plans to measure impact and outcomes by tracking new awards made and analyses/findings disseminated by grantees and staff.

2.2 Area of Emphasis Two

Improve research data collection systems, enhance data quality regarding health disparities, and develop uniform data systems that facilitate strategies for the elimination of health disparities.

Connecting institutions through electronic networks will increase the capacity of each institution to conduct health disparities research. These electronic networks will allow data sharing and will facilitate collaborations between investigators.

2.2.1 Objective One: Create a Translational Research Network

Although NIH provides institutional support to a wide variety of institutions, some specialized programs have been developed at institutions known to have students predominantly from minority and other underrepresented populations. Such support benefits all students/faculty/others associated with the grant institutions, not just minority students. The Research Centers in Minority Institutions (RCMI) Program began in 1985 in response to Congressional report language (House Report 98-911, on the Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill for FY1985 (July 26, 1984, pages 78-79)) directing funds to “establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health.” RCMI support includes funds to recruit established and promising researchers, acquire advanced instrumentation, modify laboratories for competitive research, and fund core research facilities and other research support. Because many investigators at RCMI institutions study diseases that disproportionately affect minorities, NCRR support serves the dual purpose of bringing more minority scientists into mainstream research and enhancing studies of minority health. The next step in increasing the research capacity of the RCMIs is to link each of them together.

An RCMI Translational Research Network (RCMInet) will be a cooperative research network that will facilitate clinical research in health disparity areas. This Network will consist of a consortium of clinical investigators from the RCMI, RCMI Clinical Research Infrastructure Initiative (RCRII), and Clinical Research Education and Career Development (CRECD) programs; other NIH-supported Clinical Research Centers; relevant organizations, including community health centers, with an interest in health disparity areas; and a Data and Technology Coordinating Center (DTCC).

To enhance translational research capabilities, the RCMInet will require Internet2 or other broad band-width connectivity for participating sites, for access to computational tools and other instrumentation, and to share large data sets; enhanced videoconferencing capabilities; access to training in the use of tools for the next generation of clinical investigators; and a DTCC.

2.2.1.1 Action Plan

Develop an Internet-based Network to Facilitate Collaborative Research Among Investigators at the RCMIs (NCRR SP pg 11)

The RCMInet will foster research collaborations within the RCMI institutions, as well as with others outside this network. The RCMInet will provide remote access to virtual laboratories, scalable computing, and national databases. The network must be compatible with other NCRR networks to optimize research opportunities. The RCMInet will create a test bed for distributed clinical data management that incorporates novel approaches and technologies for data management, data mining, and data sharing, across specific health disparity areas, data types, and platforms.

2.2.1.2 Performance Measures

NCRR will use the specialized expertise of workgroups and the NARRC to routinely monitor and assess the implementation of proposed activities to ensure programs are designed to meet the needs of stakeholders. This includes monitoring PAs, RFAs, and grantee activity and progress.

2.2.1.3 Outcome Measures

NCRR plans to measure impact and outcomes by tracking new awards made and analyses/findings disseminated by grantees and staff.

2.3 Area of Emphasis Three

Support for construction and renovation of research facilities across the nation enhances the capacity of these institutions to conduct health disparities research.

The objective of the extramural Research Facilities Improvement Program (RFIP) is to facilitate and enhance the conduct of Public Health Service (PHS)-supported biomedical and behavioral research by supporting the costs of designing and constructing non-federal basic and clinical research facilities to meet the biomedical or behavioral research, research training, or research support needs of an institution or a research area at an institution.

2.3.1 Objective One: Upgrade or Build Research Laboratories

NCRR will provide support to upgrade or build research laboratories to accommodate modern research and to increase health disparities research. Special emphasis will be given to smaller, developing institutions.

2.3.1.1 Action Plan

Construct or Renovate Biomedical Research Facilities for Health Disparities Research (NCRR SP pg 18)

NCRR will assist institutions in developing the research infrastructure necessary to provide stable, well-maintained, state-of-the-art research environments that will enable them to conduct HD-related research.

2.3.1.2 Performance Measures

NCRR will use the specialized expertise of workgroups and NARRC to routinely monitor and assess the implementation of proposed activities to ensure programs are designed to meet the needs of stakeholders. This includes monitoring PAs, RFAs, and grantee activity and progress.

2.3.1.3 Outcome Measures

NCRR plans to measure impact and outcomes by tracking new awards made and analyses/findings disseminated by grantees and staff.

2.4 Area of Emphasis Four

Expand opportunities in research training and career development for, and provide research supplements to, research investigators from minority and other underrepresented populations experiencing health disparities.

2.4.1 Objective One: Support Research Training and Career Development

NCRR will support research training and career development programs to ensure that investigators are positioned to focus their research on those diseases that disproportionately affect minority and other underrepresented populations.

2.4.1.1 Action Plans

Mentored Medical Student Program (NCRR SP pg 20)

NCRR plans to support mentored clinical research development programs to pique the interest of medical students, as well as provide career development programs for postdoctoral fellows and junior faculty to acquire the research tools for state-of-the-art clinical investigation through the Mentored Medical Student Program. NCRR will promote and support these model programs to the seven RCMI institutions with affiliated medical schools.

Support Science Education Partnership Awards (NCRR SP pg 21)

NCRR plans to support Science Education Partnership Awards (SEPA) that will expose the public and K-12 students, including inner city, minority, rural, and other underserved students, to science to increase their understanding of biomedical research and its implications to their health. This includes expanding their awareness of HD prevention and treatment strategies so that these groups will make healthier lifestyle choices. The SEPA Program will build partnerships among biomedical and behavioral researchers, educators, community groups, and other interested organizations to develop HD-related science museums and other comparable exhibits. Researchers who study human disease and illness can make major contributions to science education programs by passing on their knowledge and also demonstrating the excitement of carrying out health-related research.

2.4.1.2 Performance Measures

NCRR will use the specialized expertise of workgroups and NARRC to routinely monitor and assess the implementation of proposed activities to ensure programs are designed to meet the needs of stakeholders. This includes monitoring PAs, RFAs, and grantee activity and progress.

2.4.1.3 Outcome Measures

NCRR plans to measure impact and outcomes by tracking new awards made and analyses/findings disseminated by grantees and staff.

2.5 Area of Emphasis Five

Increase the number of participants in clinical trials from minority and ethnic populations and other special populations experiencing health disparities.

Through collaboration, NCRR will enable increased participation of physicians from diverse backgrounds in clinical research that includes high proportions of ethnic minority patients or volunteers. NCRR-supported resources provide a unique mechanism to leverage research participation. Research partnerships can be developed between these resources and NIH-supported investigators. One such example is the RCMI Clinical Research Centers that are geographically located close to major academic health centers. Utilizing this geographical relationship, research partnerships can be developed between RCMI Clinical Research Centers with many young, aspiring clinical investigators from diverse backgrounds and General Clinical Research Centers (GCRC)-based clinical investigators who may serve as mentors to these promising physicians and dentists.

Although the NIH requires the inclusion of minorities in clinical research and clinical trials, it has, at times, proven difficult for investigators to recruit adequate numbers of representative minority patients for research studies, either because of their geographic location or due to a lack of trust of non-minority health providers within the community. Through facilitating the career development of minority and other underrepresented clinical investigators, the participation of minority and other underrepresented populations in clinical trials most likely will increase.

2.5.1 Objective One: Expand Collaborations to Involve Minorities in Clinical Trials and Recruitment of Minority Patients

The collaboration between GCRCs and RCMI Clinical Research Centers will provide RCMI investigators ready access to the more robust clinical research infrastructure available through the GCRCs. In addition, NCRR will encourage formation of consortia between RCMI Clinical Research Centers and new Clinical and Translational Science Awards to create a critical mass of collaborating investigators who will be positioned to more effectively address HD research.

2.5.1.1 Action Plans

<u>Provide Research Tools and Networking Across the General and Minority Clinical Research Centers (NCRR SP pg 9)</u>

NCRR will provide tools and networking across the GCRCs and RCMI Clinical Research Centers (CRCs) to facilitate efficient recruitment of individuals so that there is adequate representation of underserved ethnic minorities in all appropriate clinical research studies.

<u>Increase Capacity to Study the Causes of Health Disparities (NCRR SP pg 10)</u>

NCRR will increase the capacity of clinical research centers associated with RCMIs to study the causes of health disparities in racial and ethnic minority populations. Prevention and intervention research programs targeted to minority populations will be developed, and collaborations between RCMI institutions and institutions with more extensive research programs will be promoted.

2.5.1.2 Performance Measures

NCRR will use the specialized expertise of workgroups and NARRC to routinely monitor and assess the implementation of proposed activities to ensure programs are designed to meet the needs of stakeholders. This includes monitoring PAs, RFAs, and grantee activity and progress.

2.5.1.3 Outcome Measures

NCRR plans to measure impact and outcomes by assessing changes in participation level of individuals and institutions engaged in NCRR-sponsored research related to minority populations. In addition, research development programs will be monitored to determine degree of participation in research.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION—N/A

The National Center on Minority Health and Health Disparities

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL CENTER ON MINORITY HEALTH AND HEALTH DISPARITIES

MISSION

The mission of the National Center on Minority Health and Health Disparities (NCMHD) is to promote minority health and to lead, coordinate, support, and assess the National Institutes of Health (NIH) effort to reduce and ultimately eliminate health disparities. In this effort the NCMHD will conduct and support basic, clinical, social, and behavioral research; promote research infrastructure and training; foster emerging programs; disseminate information; and reach out to minority and other health disparity communities.

VISION

The NCMHD envisions an America in which all populations will have an equal opportunity to live long, healthy, and productive lives.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Despite improvements in the overall health of the American people, ethnic and racial minorities and other underserved populations suffer from significant disparities in the burden of illness and premature death. These health disparities are not limited to one or two disease categories. They apply to a broad spectrum of disease types that include infectious diseases, vascular diseases, endocrine diseases, arthritic diseases, connective tissue diseases, malignancies, and mental illnesses. Health disparities thoroughly transcend many diverse areas of biomedical science and public health and involve all of the NIH Institutes and Centers (ICs). Some of the diseases/conditions disproportionately affecting racial and ethnic minorities and the underserved are listed in Figure 1: Examples of Disparities in Health.

Figure 1: Examples of Disparities in Health

Infant Mortality – Over the last decade, the infant mortality rate has remained twice as high among African Americans as compared to Whites, even when controlling for socioeconomic factors. Native American and Alaska Native infants also have a death rate almost double that of Whites.

Heart Disease and Stroke – Cardiovascular disease takes a heavy toll on certain populations. Heart disease rates have been consistently higher in the African American population than in Whites. Data on stroke risk factors are sparse for most racial and ethnic populations, except for African Americans whose stroke deaths, when adjusted for age, are almost 80 percent higher than in Whites. Stroke death rates for people aged over 35 years from 1991 to 1998 show that African American men (182 per 100,000 population) and women (153 per 100,000 population) have higher stroke death rates than any other race or ethnic group.

Cancer – Cancer deaths vary by gender, race, and ethnicity. Certain racial and ethnic groups have lower survival rates than Whites for most cancers. Colorectal cancer rates among Alaska Natives are higher than the national average, and Asian Americans suffer disproportionately from stomach and liver cancers. African American men have the highest rates of colon, rectum, prostate, and lung cancers. Specifically, colorectal cancer incidence and death rates are higher among men than among women and are higher among African American men and women than among White men and women. Five-year trends in death rates in all states were stable or declined for both men and women, with the exception of African American men in Louisiana and Oklahoma.

Mental Health – The disease burden associated with mental disorders falls disproportionately on ethnic minority populations. Native Americans and Alaska Natives not only suffer disproportionately from depression, but this population also experiences a higher rate of suicide.

Type 2 Diabetes – The prevalence of diabetes in African Americans is nearly 70 percent higher than in Whites. Native Americans, Hispanics, African Americans, and some Asian Americans and Pacific Islanders, including Japanese Americans, Samoans, and Native Hawaiians, are at particularly high risk for development of type 2 diabetes.

HIV and AIDS – The disproportionate impact of HIV/AIDS on certain populations underscores the importance of sustained research and prevention efforts. In 2002, the AIDS diagnosis rate among African Americans was almost 11 times the rate among Whites. African American women had a 23 times greater diagnosis rate than White women. African American men had almost a nine times greater rate of AIDS diagnosis than White men. In addition, the AIDS incidence per 100,000 population among Hispanics in 2000 was 22.5, more than 3 times the rate for Whites.

Although research is critical to understanding the causes of disparities and identifying ways to reduce and ultimately eliminate disparities among populations, research alone will not solve the health disparity problem. To fully address this problem, the combined efforts of both the NIH and the NCMHD will be utilized to reach out to health disparity populations and groups to bring the fruits of research to those communities. Furthermore, the NCMHD will continue efforts to strengthen the infrastructure supporting minority and health disparity research and increase the involvement of individuals from health disparity populations and groups in research, both as researchers and as participants in clinical trials.

Transition From ORMH to NCMHD

In its role within the NIH Office of the Director (OD), the former Office of Research on Minority Health (ORMH) worked with stakeholders across the Nation and within the government to develop the Minority Health Initiative, which subsequently guided the NIH minority research efforts. Over a 10-year period, the ORMH was able, through collaborations with the NIH ICs, to identify many projects and initiatives to improve the health of minorities and to provide additional funding to supplement IC funding in addressing minority health issues.

Furthermore, during the past decade generous funding of biomedical and behavioral research by the U.S. Congress has contributed to scientific advances to improve health and quality of life. However, at the same time the U.S. Congress and the American people have become increasingly aware that minorities and other populations have not equally benefited from our Nation’s progress in scientific discovery.

To meet this challenge, the U.S. Congress enacted Public Law (P.L.) 106-525, the Minority Health and Health Disparities Research and Education Act of 2000, creating the NCMHD. The NCMHD represents a significant evolution of the ORMH. The NCMHD is an equal partner with the other NIH ICs. Furthermore, with its generous funding and new authorities, the NCMHD will be able to build upon the collaborative research endeavors initially undertaken by the ORMH and the NIH ICs.

P.L. 106-525 identifies a number of responsibilities that the NCMHD must carry out in its role to coordinate the NIH efforts of addressing minority health and other health disparities. To support this broad coordination requirement, the NCMHD will focus its efforts across three primary initiatives:

- Establish and regularly update a comprehensive strategic plan and budget encompassing all NIH minority health and other health disparity research activities.
- Provide mandated reports evaluating progress made by the NIH in addressing minority health and other health disparities.
- Coordinate NIH minority health and other health disparity research, infrastructure, and outreach activities.

Through these efforts, the NCMHD will continue to ensure the coordination of NIH activities in addressing minority and other health disparity populations and disseminate information to these populations and other stakeholders with the intent of reducing the health disparity gap in the United States.

Establish and Regularly Update a Comprehensive Strategic Plan and Budget Encompassing all NIH Minority Health and Other Health Disparity Research Activities

According to P.L. 106-525, the Director of the NCMHD, in collaboration with the NIH Director and IC Directors, is responsible for the oversight and development of a comprehensive NIH-wide plan and budget highlighting the collective efforts of all the NIH ICs in addressing minority health and other health disparities. With input from each IC, the plan must: (1) establish priorities among health disparity research activities conducted throughout the NIH; (2) give priority to the expenditure of funds to conduct and support minority health disparity research; and (3) describe the means for achieving stated objectives, the dates objectives are expected to be achieved, and the anticipated funding required to accomplish the objectives.

The NIH Strategic Plan facilitates close cooperation and coordination with each of the NIH ICs. The plan and budget serve as a broad binding statement of policies regarding minority health and other health disparities research activities of the NIH. The NCMHD will continue to update the NIH Strategic Plan in collaboration with the NIH OD, the other NIH IC Directors, the National Advisory Council on Minority Health and Health Disparities, and stakeholders across the nation.

The Crucial Role of Public Comment

Prior to the establishment of the NCMHD, the NIH and the ORMH recognized the need to engage the public in developing strategies to reduce health disparities across America. Consequently, the ORMH sponsored a conference in April 2000 to identify ways to improve biomedical research and training opportunities for minority populations. More than 1,000 participants from minority communities, the general public, and the NIH ICs attended the conference and provided a series of recommendations. From October 2000 to February 2001, the NCMHD posted the first draft of the Trans-NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities on its web site for public comments. The NCMHD considered the public comments and recommendations from both the April 2000 conference and the responses to the web posting of the draft plan in developing the *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006*.

From late October 2003 to early January 2004, to receive public comment, the NCMHD posted on its web site the *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006*. Several major themes emerged from the public comments:

- Increase the number of health disparity populations studied by the NIH; in other words, add additional populations, such as: lesbian, gay, bisexual, and transgender communities; Haitians; individuals suffering from orphan diseases; underrepresented Asian subpopulations; the mentally ill; men; prisoners; and the disabled.
- Use racially and culturally sensitive and appropriate communication and ensure that all communications with health disparity populations and groups and their sub-groups address their needs and perspectives.
- Expand the scope of scientific inquiry to include cultural, psychological, behavioral, social, racial, and gender-based influences on health and study access to health care. Produce accurate "health disparities" definitions and data.
- Improve research infrastructure at minority academic institutions.
- Strengthen the capacity of minority communities by broadening partnerships and leveraging resources available from professional associations, health care organizations, academic institutions, and other community entities that serve minority communities.
- Distribute NIH resources equitably across all population groups by increasing research regarding men, Native Americans, Hispanics, and groups from Southeast Asia.

Based upon the public comments received, the NCMHD expanded the objectives within the three overarching NIH goals for the Strategic Plan, as delineated in the Executive Summary within Volume I. The public comments also were provided by the NCMHD to each of the NIH ICs and involved offices of the NIH OD for their consideration in developing their updated submissions contained within Volume II of the *NIH Health Disparities Strategic Plan, Fiscal Years 2004-2008*. Each IC and OD Office was specifically asked to address how they applied the public comments in developing their revised submission. The NCMHD will ensure that thorough consideration of public comments will continue to be a fundamental component of the development of each future iteration of the *NIH Health Disparities Strategic Plan*.

As indicated above, the NCMHD received a number of public comments recommending that additional groups be designated as health disparity populations. The NCMHD is sensitive to these comments and will follow the process described in Volume I of this Strategic Plan, and reiterated below, to determine whether additional groups should be so designated.

The findings section of P.L. 106-525, the Minority Health and Health Disparities Research and Education Act of 2000, notes the impact of health disparities upon minorities and upon the medically underserved across the nation:

1. Despite notable progress in the overall health of the Nation, there are continuing disparities in the burden of illness and death experienced by African Americans, Hispanics, Native Americans, Alaska Natives, and Asians/Pacific Islanders, compared to the United States population as a whole.

Minority Health Disparities
Diseases, disorders, and conditions that disproportionately afflict individuals who are members of racial and ethnic minority groups

Other Health Disparity Populations
Population groups who suffer from health disparities when compared to the general population

2. The largest number of the medically underserved are White individuals, and many of them have the same health care access problems as do members of minority groups.

Section 485(d)(2) of the law states that the Director, NCMHD, "shall give priority consideration to determining whether minority groups qualify as health disparity populations…."

The law defines the term "minority group" by reference to Section 1707 of the Public Health Service (PHS) Act, which states at paragraph (g):

1. The term "racial and ethnic minority group" means American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics.
2. The term "Hispanic" means individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or any other Spanish-speaking country.

Public Law 106-525 required the NCMHD to report to the Congress by December 2003 recommendations for the methodology the NIH will use to determine the amount of NIH resources dedicated to the conduct and support of health disparities research.

In October 2003 the NIH Director and the Director, NCMHD, established an NIH Committee on Minority Health and Health Disparities Research Definitions and Application Methodology, which developed new definitions and a revised application methodology that were used by the NIH in developing this updated version of the NIH Strategic Plan. In January 2004, the Committee provided uniform NIH Guidelines that:

- Provide NIH operational definitions, based on Public Law 106-525, for minority health and health disparities research;
- Provide a consistent methodology for applying the definitions;
- Contain the criteria necessary to identify both minority health and health disparities population groups and diseases; and
- Serve as the foundation for identifying, coding, tracking, and reporting on NIH activities and resources.

The health disparity populations included in the NIH Guidelines and covered by the *NIH Health Disparities Strategic Plan, Fiscal Years 2004-2008* are the minority groups delineated within Section 1707(g), PHS Act, above, as well as low socioeconomic status (low-SES) populations and rural populations.

The Congress recognized, however, that the *NIH Health Disparities Strategic Plan* should be an evolving document. In this way, the Congress also foresaw that additional health disparity populations may be identified and provided in Section 485(d)(1) of the law a vehicle for the designation of additional health disparity populations as follows:

NATIONAL **C**ENTER ON **M**INORITY **H**EALTH AND **H**EALTH **D**ISPARITIES

"A population is a health disparity population if, as determined by the Director of the Center after consultation with the Director of the Agency for Healthcare Research and Quality (AHRQ), there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population."

In the future, as the *NIH Health Disparities Strategic Plan* is revised and updated over the years, and based upon the Institute of Medicine (IOM) Report described below, the NCMHD will work with the AHRQ to determine whether other populations meet this definition and should be designated as health disparity populations. Thus, future iterations of the plan will reflect the evolution of the development of health disparity populations.

In addition, the Center will continue to provide support to the other ICs to assist them in convening workshops that will include outside experts to assess their health disparities agendas, progress, and outcomes in health disparities research. This process will enable further refinement of the IC submissions to the NIH Strategic Plan in future years.

The diversity of the American population is one of the greatest assets of the nation. One of the greatest challenges facing the nation is reducing and eliminating the profound disparity in health status that exists for many of its populations. Without decisive action now, the health challenges of the 21st century will grow as the number of racial and ethnic minorities, inhabitants of rural areas, and low-SES populations increases.

The NCMHD will continue to combat health disparities through its flagship programs, conducting research in a wide array of disease areas and reaching out to diverse health disparity populations. The Center will seek new opportunities to support academic development for health disparity researchers of tomorrow. The NCMHD will explore opportunities such as a Health Disparities Biomedical Scholars Program. The goal of this effort would be to support the advancement of the biomedical research workforce and infrastructure. The Scholars Program would bring together senior scientists, policy experts, and educators to share their expertise in biomedical science and health disparities and would encourage promising scientists to pursue opportunities in health disparities research.

The NCMHD also will seek to create innovative programs to serve as a bridge between NCMHD capacity building programs and an investigator's first research effort. The Center will explore creating a Health Disparities Young Investigator Program. Such a program would serve as an excellent bridge between other NCMHD capacity-building programs like the Loan Repayment Programs and an investigator's first independent research effort. In this way, the Young Investigator Program would serve as a vehicle for retaining health disparities researchers in the area of health disparities research by providing funding to support independent research efforts both at the NIH and at the researcher's home institution.

Cognizant of the value of engaging communities in the elimination of health disparities, the Center will lead efforts to conduct effective community-based participatory research and outreach among health disparity populations. The Center is launching and establishing its Office of Community-Based Participatory Research and Outreach, which will:

- Develop and implement partnering initiatives to promote cooperation among federal agencies; state, local, tribal, and regional public health agencies; and private entities in minority health research and research on other health disparities;
- Develop and implement a community-based research program for the NIH with a focus on disease prevention, implementation of health messages in relevant racial and ethnic minority and disadvantaged communities, and elucidation of barriers to effective health care; and
- Coordinate with appropriate Department of Health and Human Services (HHS) organizations and other federal entities on programs of relevance to the mission of the NCMHD.

In addition, the NCMHD has asked the National Academy of Sciences/IOM to conduct a study that will review the NIH Strategic Research Plan. This review will assess the adequacy of the plan in achieving the NIH's goals and objectives regarding research, research infrastructure, and public information and community outreach. The study also will assess the adequacy of coordination across NIH ICs in helping to develop and carry out the elements of the strategic plan.

The primary product of this study will be a technical report, reviewed in accordance with National Research Council procedures. The report will be widely disseminated to stakeholders, including the NCMHD, NIH ICs, scientific leaders, health policymakers (including the Congress and relevant federal agencies), advocacy groups, major health care provider professional organizations, foundations, and relevant individuals and organizations. Copies of the report summary will be produced for broader distribution and made available on the Internet through the National Academy Press (www.nap.edu).

The Center will continue its legacy of creating and nurturing partnerships to further increase the reach of its activities to eliminate health disparities, and it will encourage its fellow NIH ICs to join the core health disparities programs of the NCMHD. The Center's vision of the future is a collective one that is embodied in the NIH Health Disparities Strategic Plan. With leadership, commitment, and strong scientific partnerships, the NIH can advance scientific discovery to ensure the health of all Americans, so that all citizens have an equal opportunity to live long, healthy, and productive lives.

Provide Mandated Reports Evaluating Progress Made by the NIH in Addressing Minority Health and Other Health Disparities

In addition to developing an NIH-wide strategic plan and budget for addressing minority health and other health disparities, the Public Law also tasks the Director of the NCMHD with developing and supporting several additional reports. As the lead coordinator of minority health and other health disparities research throughout the NIH, the Director of the NCMHD will monitor and report on the progress of research efforts, evaluate coordination efforts throughout the NIH, determine the resources needed, and describe a means to measure the needs, current activities, and private sector activities as they relate to minority health and other health disparities. The activities include:

- Develop annual reports describing and evaluating the progress made and funds expended in health disparities research conducted or supported by the national research institutes [P.L. 106-525, Title I, Section 101].
- Assist the Secretary of Health and Human Services and the Director of the NIH in developing a report to determine the effectiveness of NCMHD coordination in addressing health disparities; evaluating the extent to which the NCMHD efforts have helped reduce the duplication of administrative resources among ICs; and providing recommendations concerning future legislative modifications with respect to minority health disparities research [P.L. 106-525, Title I, Section 104].
- Develop a report providing recommendations for the methodology that should be used to determine the extent of NIH resources that are dedicated to minority health and other health disparities research [P.L. 106-525, Title I, Section 105].

Coordinate NIH Minority Health and Health Disparity Research, Infrastructure, and Outreach Activities

P.L. 106-525 also requires the Director of the NCMHD to act as the primary federal official with responsibility for coordinating all minority health disparities research and other health disparities research conducted or supported by the NIH. In this role, the Director will represent the health disparities research programs of the NIH at all relevant executive branch taskforces and committees. Additionally, the Director will maintain communications with all relevant PHS agencies and ensure the timely transmission of minority health and other health disparity information among various agencies.

NCMHD Areas of Emphasis and Objectives

In accordance with NIH's established strategic direction to reduce and ultimately eliminate health disparities, the NCMHD has categorized its areas of emphasis, or priority areas, across the three NIH Strategic Plan goal areas: Research; Research Infrastructure; and Community Outreach, Information Dissemination, and Public Health Education. As indicated in the Center's original Strategic Plan Submission, the NCMHD has focused its efforts and funding initially on the development of its mandated infrastructure programs and the continuation and start-up of collaborative research projects with the NIH Institutes and Centers and other HHS agencies. The Center also delineated, however, a number of additional, ambitious objectives in the Center's first Strategic Plan submission, the accomplishment of which would be based upon anticipated growth in future NCMHD staff levels. The Center's overall staff allocation, however, has not increased significantly during the initial phase of its operation, necessitating some modifications in the implementation of several planned activities.

NATIONAL **C**ENTER ON **M**INORITY **H**EALTH AND **H**EALTH **D**ISPARITIES

To guide the Center in establishing its priorities, growing its core programs, and implementing statutory mandates, the NCMHD has established subcommittees of the National Advisory Council on Minority Health and Health Disparities, which have direct linkages with NCMHD staff. These subcommittees comprised of Advisory Council members include: the Research Endowment Subcommittee, the Centers of Excellence (COE) Program Subcommittee, the Loan Repayment Subcommittee, and the Strategic Plan Subcommittee. In collaboration with the Center's National Advisory Council and its subcommittees, the NCMHD has accomplished much since its creation.

Racial and ethnic minorities and other health disparity populations experience a disproportionate burden of illness, disability, and premature death due to cancer, cardiovascular disease and stroke, diabetes, Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS), infectious diseases, infant mortality, and other diseases. HHS, through its Closing the Gap Initiative, designates these areas as major research priorities. NCMHD programs focus on these priorities as well as rural health and many others.

Today, the NCMHD has 71 Health Disparities COEs spread across the nation. These COEs, now located in 26 states, the District of Columbia, Puerto Rico, and the Virgin Islands, support health disparities research, research training, and community involvement to identify factors that contribute to health disparities and to develop and implement new diagnostic, treatment, and prevention strategies.

The NCMHD addresses the national need to develop a diverse and culturally competent scientific workforce by eliminating barriers that prevent racial and ethnic minority students and students from disadvantaged backgrounds from pursuing research careers. Currently, the NCMHD supports about 450 researchers from 40 of the 50 states and the District of Columbia through its two Loan Repayment Programs, which help to level the playing field and make it possible for underrepresented individuals to enter the scientific, public health, and engineering workforce. These Health Disparities Ambassadors are key to creating the culturally competent scientific and clinical research workforce of the future.

The NCMHD also has created a one-of-a-kind Research Endowment Program. Unique at the NIH, this program addresses the national need to build research and training capacity in institutions that make significant investments in the education and training of minority and disadvantaged individuals. This program is making it possible for 14 institutions located in 11 states, the District of Columbia, and Puerto Rico to establish health disparities endowed chairs and programs; enhance student recruitment efforts; provide merit-based scholarships; recruit and retain faculty; develop innovative instruction delivery systems in minority and health disparities research areas; and access emerging technologies.

The NCMHD Research Infrastructure in Minority Institutions (RIMI) Program, born out of a partnership between the NIH National Center for Research Resources and the former NIH Office of Research on Minority Health (the predecessor to the NCMHD), is making it possible for institutions to target research efforts on health disparities that exist in the Southwest Border States; in rural communities, such as the Appalachia Region, the Mississippi Delta, and the Frontier States; and in urban centers of the nation. Since assuming responsibility for the RIMI Program, the NCMHD has tripled the number of participating institutions.

In addition to using its core programs, the NCMHD strategy to eliminate health disparities also includes leveraging NIH dollars and expertise by creating partnerships with the NIH ICs and other agencies within HHS to fund health disparities research, training, and outreach programs. The NCMHD has forged many new partnerships, supporting more than 400 collaborative research projects to combat health disparities in our nation. Examples include:

- The NCMHD and the National Cancer Institute (NCI) have worked together to increase the number and to broaden the geographic distribution of NCI-designated Cancer Centers and to create partnerships between minority institutions and medical schools. As a result, the following partnerships have been created: (1) Howard University Cancer Center and Johns Hopkins University; (2) University of Puerto Rico and MD Anderson Cancer Center; (3) Meharry Medical College and Vanderbilt-Ingram Cancer Center; and (4) Morehouse School of Medicine and University of Alabama at Birmingham.

- The NCMHD partners with the National Heart, Lung, and Blood Institute (NHLBI) to support the Jackson Heart Study. This study evaluates the environmental and genetic factors contributing to the disproportionate incidence of cardiovascular disease in African American men and women living in Mississippi. To date, almost 5,000 participants have benefited from the program by visiting the clinic, with an average of 25 participants per week.

- The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), in partnership with the NCMHD, is supporting the development of a public domain research resource. The purpose of this resource is to facilitate the scientific evaluation of biomarkers for osteoarthritis (OA) as potential surrogate endpoints for disease onset and progression. The individual clinical centers will be enrolling subjects and collecting data, and their objectives are to: (1) cooperate with the Data Coordinating Center in implementing the overall Osteoarthritis Initiative; and (2) recruit, enroll, and follow for 4 years individuals from the general population, over the age of 50, at high risk for the development of osteoarthritis (because of obesity, previous knee injury, low-grade knee pain, abnormal gait, etc.). It is intended that minorities and women will be represented in proportions similar to those found in the U.S. population over the age of 50.

- The National Institute of Dental and Craniofacial Research (NIDCR) and the NCMHD have formed a partnership to respond to the report *Oral Health in America: A Report of the Surgeon General* (NIH Pub No. 00-4713). Oral, dental, and craniofacial diseases and disorders are among the most common health problems affecting the people of the United States. Diseases and disorders affecting the mouth and its surrounding tissues go beyond dental caries and periodontal diseases. Oral manifestations of systemic diseases (i.e., Sjogren’s syndrome, diabetes, and HIV infection) and side effects from drugs and/or treatment add to the burden of oral illness. These craniofacial, oral, and dental diseases and disorders have a disproportionately higher burden on particular population subgroups.

- The NCMHD and the Indian Health Service (IHS) have formed a partnership to develop the Tribal Epidemiology Centers Program to further the missions of both agencies and to address and eliminate health disparities experienced by American Indians and Alaska Natives. Collaborative activities include: (1) development of surveillance for disease conditions; (2) epidemiologic analysis, interpretation, and dissemination of surveillance data; (3) investigation of disease outbreaks; (4) development and implementation of epidemiologic studies; (5) development and implementation of disease control and prevention programs; and (6) coordination of activities with other public health authorities in the region. The IHS and the NCMHD will facilitate the development of Epidemiology Centers (EPI Centers) and public health infrastructure for Native American and Alaska Native communities. Recent NCMHD support enabled the creation of a new Northern Plains Tribal Epidemiology Center in Rapid City, South Dakota; continued funding for the other six existing EPI Centers, and the development of a summer training institute for Indian health professionals. The funding will assist the EPI Centers to carry out their training program for local health staff and expand their outreach activities to include a community-based research training program.

- In collaboration with the Centers for Disease Control and Prevention (CDC), the NCMHD co-funds the Racial and Ethnic Approaches to Community Health (REACH 2010) Program, which supports organizations serving racial and ethnic minority populations at increased risk for infant mortality, diabetes, cardiovascular diseases, HIV infection/AIDS, deficits in breast and cervical screening and management, or deficits in child and/or adult immunization rates. The program will develop, implement, and evaluate innovative community-level intervention demonstrations that could be effective in eliminating health disparities by 2010. The racial and ethnic groups targeted by REACH 2010 include: African Americans, Asian Americans, Pacific Islanders, Hispanic Americans, and American Indian and Alaska Native populations. It is anticipated that a better understanding of the relationships between health status and racial and ethnic minority backgrounds can be achieved through working closely with communities, and that culturally sensitive disease prevention strategies can be identified and implemented. REACH 2010 projects are empowering community members to transform their neighborhoods into places that encourage people to adopt and sustain healthy behaviors and to avoid risk behaviors.

- The AHRQ and the NCMHD support several programs aimed at understanding and eliminating health disparities that focus on community outreach, building research capacity, and training. The AHRQ EXCEED Program is a 5-year effort to analyze underlying causes and contributing factors for racial and ethnic disparities in health care and to identify and implement strategies for reducing and eliminating them. The NCMHD has been providing funds for the AHRQ EXCEED program since its inception in 2000. The NCMHD specifically supports two of the nine Centers under this initiative, one at the Medical University of South Carolina, Charleston, and one at

Baylor College of Medicine. The Medical University of South Carolina activity examines strategies to address disparities in health status between African Americans and Whites, including those in rural areas, with specific clinical conditions including HIV disease, cardiovascular disease, and cancer. The Baylor activity assesses the extent to which problems in doctor-patient communication contribute to racial and ethnic disparities in health care use.

- With the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the NCMHD funds the African American Study of Kidney Disease and Hypertension Cohort Study. This study seeks to determine prospectively the progression of kidney function and the risk factors for kidney disease progression in African Americans with kidney disease who receive antihypertensive therapy. Data from this study should enhance understanding of the risk factors and processes that determine the progression of kidney disease and lead hopefully to new strategies for delaying or preventing end-stage renal disease. A secondary objective of the study is to determine the occurrence and risk factors for cardiovascular disease. The study is being conducted at major medical centers throughout the United States: Case Western Reserve University; Howard University; University of Texas Southwestern Medical Center, Dallas; Medical University of South Carolina; University of Alabama at Birmingham; Charles R. Drew University of Medicine and Science; Johns Hopkins University; Vanderbilt University; University of Southern California; University of Michigan at Ann Arbor; Ohio State University; Meharry Medical College; University of Miami; Morehouse School of Medicine; and Rush-Presbyterian-St. Luke’s Medical Center.

- The NIDDK and the NCMHD support the study of Interferon Resistance in Genotype 1 Hepatitis C (Virahep C) (HCV). The objective of this study is to investigate why African Americans have a twofold greater rate of HCV infection than Caucasians and why they are more likely to be infected with Genotype 1 virus, which is inherently resistant to interferon treatment. Recent studies have shown a reduced response rate among African Americans to interferon treatment as compared to that of Caucasians and that sustained virologic response (SVR) is improved in African Americans treated with interferon and ribivarin. Building on these results, this study aims to measure this response rate.

- The National Institute of Nursing Research (NINR) and the NCMHD fund a number of collaborations among schools of nursing at majority universities and diverse minority-serving institutions to expand the cadre of minority nurses and/or the number of research projects aimed at eliminating health disparities. Examples of some of these collaborations include: Johns Hopkins University and North Carolina Agricultural and Technical State University; the University of North Carolina-Chapel Hill and Historically Black Colleges and Universities; the University of Washington and the University of Hawaii Schools of Nursing; the University of Pennsylvania and Hampton University; *Michigan En San Antonio Center for Health Disparities,* a partnership between the University of Michigan and the University of Texas Health Science Center at San Antonio School of Nursing, a Hispanic-serving institution; *Nursing Partnerships Centers on Health Disparities* that link the University of California, San Francisco, and the

University of Puerto Rico in an effort to reduce HIV/AIDS incidence; the *Southwest Partnership Center for Nursing Research on Health Disparities*, sponsored by the University of Texas at Austin and the New Mexico State University, focused on reducing health disparities among the rural, low-income, Mexican American and American Indian populations; and a *Self and Family Management Initiative* sponsored by Yale University and Howard University.

- In collaboration with the National Institute of Mental Health (NIMH), the NCMHD is sponsoring a 3-year study to develop a comprehensive, nationally representative description of rural mental health care, including patterns of access to treatment and outcomes of care. The study will focus on the problems faced by rural African Americans and Mexican Americans, women, and the poor in obtaining mental health treatment.

- The NIMH and the NCMHD also are funding *Culture, Context, and Mexican American Mental Health*, a study conducted by the University of Arizona to: (1) examine interactions between Mexican American children's cultural orientations and cultural contexts (i.e., family, community, school) as predictors of adaptation; (2) identify mediators of the influences of children's cultural orientation on adjustment and examine whether these relationships depend on culture/context interactions; and (3) investigate the role of children's cultural orientations and cultural contexts as moderators of influences of common risk and protective factors (transition to junior high, puberty, family SES, quality of home environment, quality of community) on their adjustment.

A top priority of the NCMHD is improving rural health across the nation. Collaboration with the other NIH ICs has allowed the NCMHD to extend the reach of its scientific expertise to tackle cancer health disparities in rural populations. The NCMHD has supported opportunities with other NIH ICs in addressing the needs of rural communities, participating in 16 rural health partnerships with NCI, NHLBI, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the National Institute of Environmental Health Sciences (NIEHS), NIMH, and NINR. Examples of these projects include the Appalachia Cancer Network; the Deep South Network for Cancer Control, the Rural Caregiver Telehealth Intervention Trial; and studies on the effects of alcohol and violence on rural women; coronary artery disease in Alaska Natives; migrant worker health and the environment; mental health treatment for rural Mexican Americans, African Americans, women, and the poor; cardiovascular health training and outreach in Latino communities; and substance abuse among Ojibwe children and youth.

The Appalachia Cancer Network, cosponsored by the NCI and the NCMHD, addresses cancer in rural and medically underserved Appalachian residents in West Virginia, Kentucky, Tennessee, Virginia, Ohio, Pennsylvania, Maryland, and New York. The goal of this network is to reduce cancer incidence and mortality and to prevent future increases; to increase cancer survival; and to stimulate greater coordination and participation among regional, state, and community cancer control networks throughout Appalachia.

In addition, during fiscal year 2004 and subsequently, the NCMHD plans to partner with other NIH ICs and other federal agencies with respect to research projects that focus on health disparity issues in the Mississippi Delta Region of the United States, which includes relevant counties of Alabama, Arkansas, Louisiana, Mississippi, Illinois, Kentucky, Missouri, and Tennessee.

A Note on Performance and Outcome Measures

The NCMHD developed performance and outcome measures for each major objective in the areas of emphasis. Constructing outcome measures is a critical component for evaluating NCMHD's programs. In an effort to assess performance, the NCMHD will use two quantitative metrics: (1) milestones; and (2) performance measures. Milestones generally track action plans and provide temporal targets for the completion of tasks. Completion of tasks on time and on budget is an important indicator of performance. Additionally, the milestones provide an indication of the prioritization of efforts and when they are expected to be completed. The second category, performance measures, attempts to capture anticipated improvements in performance over time. These may reflect improvements in productivity, efficiency, or other favorable targets and may be expressed as a percentage improvement or an improvement in absolute numbers. The dynamic nature of performance measures makes them subject to ongoing revision and refinement.

- **Performance Measures:** Shorter term objectives that move us toward the longer term primary outcome measure
- **Outcome Measures:** Enables an organization to quantify or measure success in accomplishing its fundamental mission. In this case, it is reducing or eliminating health disparities

The NCMHD has therefore added a qualitative measure of performance and outcomes to complement the quantitative measures described above. The qualitative approach is derived from recommendations made by a joint committee composed of the National Academy of Sciences, the National Academy of Engineering and the IOM.

It is the opinion of that committee that there are meaningful measures of quality, relevance, and world leadership in a scientific field (benchmarking) that are reasonable predictors of the eventual usefulness of basic science research. In judging quality, relevance, and leadership, the committee recommended an expert review process. Although peer review is commonly applied to individual projects, the intent here is to apply it to entire programs. In the case of judgments regarding relevance, potential benefactors of research and other key stakeholders should be included in the deliberations.

It should be emphasized that these qualitative measures are not meant to replace quantitative assessments of research performance and outcomes, but to complement them and to paint a more complete picture of performance.

Therefore, the performance measures we developed for research fall into three categories: (1) *Milestones*, which are target dates for completing steps in the research action plans; (2) *Performance*

Measures, which track growth in surrogate markers for research productivity; and (3) *Expert Review Measures*, which rely on the opinion of expert panels that judge research on the basis of quality, relevance, and leadership. Expert review may be employed to assess performance or outcome measures or both.

1.0 AREAS OF EMPHASIS IN RESEARCH

Over the last century, the average American life span increased by approximately 30 years. This is due, in part, to remarkable advances in biomedical science and research. As a world leader in biomedical research, the NIH has contributed significantly to these advances. However, the bounty of this research, improved health and greater longevity, has not been enjoyed equally by all Americans. Certain racial and ethnic minorities, as well as other underserved populations, suffer from a greater burden of disease and premature death. Over the last decade, the NIH began to address the issue of health disparities through expanded research initiatives. More recently, the commitment to health disparity research has undergone a quantum increase as the NCMHD replaced the ORMH.

One of the more significant differences between the ORMH and the NCMHD is the authority of the NCMHD to independently support and conduct intramural and extramural research. Additionally, the organization's mission was broadened to include other health disparity groups, in particular the underserved. This section describes the principal research objectives for the NCMHD. They are:

- Establish research priorities;
- Conduct and support research focused on identifying solutions to health disparity challenges in the United States;
- Conduct and support research that may have a direct effect on health disparity populations and communities; and
- Develop methodologies to effectively conduct outreach and maximize the impact of NCMHD's research efforts.

The NCMHD research objectives are, to a large extent, sequential in nature. The NCMHD has worked closely with the National Advisory Council on Minority Health and Health Disparities in formulating and acting upon its research priorities. The establishment of an NCMHD intramural program and the full implementation of its extramural research program, which includes funding investigator-initiated research proposals, must await the attainment of the necessary complement of staff in the Center.

The research supported by the NCMHD through its core programs and collaborations is, to a significant extent, trans-NIH in nature, combining basic biomedical research with behavioral and social science research. This trans-NIH approach addresses the multi-factorial nature of health disparities. Furthermore, the research supported by the NCMHD includes both "targeted" studies that enroll only those populations experiencing health disparities, and "inclusion" studies that oversample populations experiencing health disparities. As part of its research program, the Center, in consultation with its National Advisory Council, is funding many continuing and new research collaborations with the other NIH ICs and other HHS agencies. As it moves forward, however, the Center will need to allocate more of its funding to its mandated programs.

1.1 Area of Emphasis One

1.1.1 Objective One: Review Research Priorities

Proper priority-setting ensures that the finite resources devoted to the research endeavor are expended in the most cost-efficient manner among health disparity populations. Setting these priorities requires a thorough understanding of what research has already been done, and where there are significant gaps in health disparity research. Setting these priorities also requires significant input from minority and other health disparity communities, as well as the professional and scientific communities. The NCMHD research priorities also must reflect priorities established by Congress and the broader federal effort to eliminate health disparities. Research priorities must take into account specific diseases, conditions, and issues previously identified by the federal government. Finally, where possible, it is important to identify and prioritize long-term goals for evaluating the reduction of disparities in specific diseases and conditions.

1.1.1.1 Action Plan

Action Plan	Milestones	
	Target	**Achieved**
▪ Review priorities from other IC submissions and ongoing projects funded by the NCMHD and identify future research opportunities.	FY04-FY08	Ongoing
▪ In consultation with the Advisory Council and based upon the IOM report due to be completed in fiscal year 2005, the Center will review and assess its research priorities.	FY05-FY06	
▪ Explore with the Advisory Council, other experts, and stakeholders the establishment of long-term health disparity reduction goals from which interim goals can be developed. (For example, “Our goal is to reduce the disparity gap in the prevalence of type 2 diabetes in African Americans by X percent in 20 years.”)	FY05-FY08	

1.1.1.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Extent to which the NCMHD research portfolio reflects research priorities as measured by the percentage of funding that is directed toward established priorities		Base	35%	45%	65%
▪ Identify and respond to new priorities, unexpected concerns, and gaps as measured by the percentage of the budget reserved for these contingencies		Base	15%	15%	15%

***** Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant “ramp-up” time is expected.

Timeline

- Noted in the Action Plan

1.1.1.3 Outcome Measures

- An annual updated listing of research priorities and emerging concerns, and an assessment of their relevance. (The Advisory Council and Community representatives will assist in making judgments.)
- Determination of the feasibility of defining long-term health disparity reduction goals in key diseases and conditions by FY04.

1.1.2 Objective Two: Conduct and Support Research Focused on Identifying Solutions to Health Disparity Challenges in the United States

Although it is important to set research priorities, it is clear that certain fundamental areas of investigation must be explored to enable minority health and other health disparity research to proceed. This research will assist in identifying population-specific issues and in developing research tools, such as survey instruments for further research.

1.1.2.1 Action Plan

Action Plan	Milestones	
	Target	**Achieved**
▪ Support research using cutting-edge and emerging technologies to identify biological and other risk factors for disease among significant sub-cohorts of health disparity populations	Late FY06-FY08	
▪ Fund research to develop and validate survey instruments for specific minority populations and sub-cohorts that are relevant to the diseases, conditions, and behaviors known to be the most significant (heart disease and risks, diabetes and risks, cancer and risks, HIV and risks, etc.). Small Business Innovation Research (SBIR) mechanisms will be included in this endeavor.	Late FY06	
o Award first grants	Late FY06	
▪ Explore the feasibility of a longitudinal or "Framingham-like" study for racial and ethnic minority populations that focuses on a spectrum of illnesses. This multi-disease approach can provide data for multiple ICs and therefore is a cost-efficient way of exploring the epidemiology and evolution of disease in health disparity populations.		
o Background exploration of feasibility and cost	FY06	
o Ascertain level of interest/commitment of other ICs	FY06	
o Develop candidate populations and sites	FY06	
o Create more specific budget and examine impact on resources	FY06	
o Propose 1–3 pilot sites	FY07	
o Commence enrollment	FY08	

1.1.2.2 Performance Measures

Performance Measures	Targets*				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Scientific publications that report on the progress and results of the research.				Base	5%
▪ Increased support of longitudinal and epidemiological studies as measured by the number of RFAs developed by disease segment.				Base	5%

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in utilization of the tools developed, as measured by the extent to which the original paper in which they were presented is cited in the literature.					Base

***** Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant "ramp-up" time is expected.

Timeline

- Indicated in the Action Plan

1.1.2.3 Outcome Measures

- Final feasibility assessment of Framingham-like study described above.
- Assessment by an external panel of experts and community representatives regarding the attempt to better define the disparity research domain and develop research tools that are population specific as judged by the following criteria:

    - Quality of research
    - Relevance of research
    - Extent to which research "leads the field"
    - The usefulness of tools developed (see third performance measure)

1.1.3 Objective Three: Conduct and Support Research That May Have a Direct Effect on Health Disparity Populations and Communities

The goal of the NCMHD and the NIH is not merely to better define the nature of health disparities, but to understand root causes and actually to close the “disparity gap.” Intervention studies, which examine the efficacy of specific strategies and methods to improve the health of minorities and other health disparity populations, are a vital component of the overall research strategy. These studies may involve biomedical, behavioral, pharmaceutical, social science, or health care delivery innovations. Through such efforts, the NCMHD will be able to demonstrate what is effective in improving health in disparity cohorts.

1.1.3.1 Action Plan

Action Plan	Milestones	
	Target	**Achieved**
▪ Conduct and/or support intervention trials that test the efficacy of different strategies to close the disparity gap in different populations afflicted with different disorders.	FY06-FY08	
o Based on priorities established as described in Objective 1.1 target diseases and populations	FY06-FY08	
o Identify candidate "interventions"	FY06-FY08	
o Publish Requests for Applications (RFAs)	FY06-FY08	

1.1.3.2 Performance Measures

Performance Measures	Targets*				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in the number of targeted intervention studies			Base	5%	10%
▪ Number of grant awards made to private community-based organizations			Base	5%	10%
▪ Scientific publications that report the progress and results of the intervention trials			Base	5%	10%

***** Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant "ramp-up" time is expected.

Timeline

- Noted in Action Plan

1.1.3.3 Outcome Measures

- Extent to which long-term (20-year) and interim (5-year) goals for the reduction of specific disparities are met. (See Objective 1.1.)
- Health disparity reductions in experimental cohorts compared to control groups.
- Performance as measured by expert review.
- Yearly assessment of the intervention research program by an external panel of experts and community representatives using the following criteria:
    - Quality of research

- Relevance of research
- Extent to which research "leads the field"

1.1.4 Objective Four: Develop Methodologies to Effectively Conduct Outreach and Maximize the Impact of NCMHD's Research Efforts

The research findings will not be fully realized if they are not communicated to the U.S. population in general and specifically to racial and ethnic minorities and other health disparity communities. Furthermore, the nuances of effective communication with minority and health disparity communities are a legitimate area of scholarly investigation. For instance, reaching out to Dominican women regarding breast cancer screening may require a different approach than reaching out to Mexican or Native American women. However, outreach is not merely about effective communication and understanding; it is often about changing behavior. Research that measures the efficacy of outreach in changing behavior of defined populations is important in establishing "best practices."

1.1.4.1 Action Plan

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Conduct and support research to define methods of communication that are most effective in influencing behavior and affecting health status	FY06 -FY08	
▪ Conduct and support research to develop tools and methods for measuring the impact of specific outreach initiatives in altering behavior	FY06-FY08	
▪ Conduct and support research that develops and validates effective tools and methodologies for communicating with defined populations	FY06-FY08	

1.1.4.2 Performance Measures

Performance Measure	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in the number of validated tools				Base	5%
▪ Scientific publications that report progress and results with respect to establishing best communications practices				Base	5%

*Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant "ramp-up" time is expected.

Timeline

- Noted in Action Plan

1.1.4.3 Outcome Measures

- The extent to which the NCMHD and other ICs use these tools and approaches in their outreach effort. The goal is that 50 percent of these approaches are used in NIH-related projects within 5 years of their development.
- Performance as measured by expert review
- Yearly assessment of the intervention research program by an external panel of experts and community representatives using the following criteria:
  - Quality of research
  - Relevance of research
  - Extent to which research "leads the field"

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

Building capacity for minority health and other health disparities research is a high priority for the Center. Accordingly, NCMHD is using a portion of its resources to increase research infrastructure at strategically located institutions committed to addressing and ultimately eliminating disparities in health status. Three key programs are the nucleus of the Center's research infrastructure activities and are NCMHD's highest priority for developing research infrastructure: (1) the Endowment Program for Section 736 Institutions; (2) the Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training (Project EXPORT); and (3) the Loan Repayment Program for Health Disparities Research (HDR-LRP). The NIH director also requested that the NCMHD develop and implement the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP). In addition, the NCMHD will continue its support of RIMI and in FY2004 assume responsibility for administering the Minority International Research Training Program (MHIRT), currently known as the Minority Health and Health Disparities International Research Training (MHIRT) Program.

Overall, the NCMHD programs highlight NIH's commitment to ensuring that the highest quality research, research capacity, and outreach are brought to bear in addressing health disparities throughout the country. As part of the research infrastructure area of emphasis, the NCMHD will examine ongoing efforts developed under the auspice of ORMH and identify key gaps in minority health and other health disparities research infrastructure. In particular, the NCMHD will take the lead in developing a set of tools to be used throughout the research community to collect and analyze epidemiologic and demographic data on racial and ethnic minority and other health disparity populations.

2.1 Area of Emphasis One: Develop a Cadre of Researchers With Expertise in Minority Health and Other Health Disparities Research

P.L. 106-525 also mandated that the NCMHD develop a vehicle for increasing the number of racial and ethnic minority researchers in the biomedical and behavioral field and increase the number of researchers conducting minority health and other health disparities research. It is particularly important to develop and promote a culturally competent cadre of research investigators because the participation of these individuals in the scientific, technological, and engineering workforce enables society to address its diverse needs.

To effectively promote a diverse and strong scientific workforce, it is necessary to expand and create transitioning and financial aid programs that help alleviate barriers that often discourage many students from pursuing a research career. The NCMHD Loan Repayment Programs address this national need by encouraging the recruitment and retention of minority and other scientists in the fields of biomedical, clinical, behavioral, and health services research. Specifically, the HDR-LRP is designed to increase the number of highly qualified health professionals in research careers focused on health disparities. The focus of the ECR-LRP is to increase the participation of highly qualified health professionals from disadvantaged backgrounds in clinical research careers. To develop synergies between the NCMHD programs and ensure emphasis is placed on minority health and other health disparities research efforts, the NCMHD will work to establish links between the LRPs (HDR-LRP and ECR-LRP) and the NCMHD research priorities.

The academic credentials and the various areas of discipline represented by the NCMHD LRP recipients, better known as NCMHD Health Disparities Scholars (Scholars), demonstrate the ability of the programs to tap into the existing pool of talent able to address the diverse and complex needs of society. Academic credentials of the Scholars include Ph.D., M.D., D.M.D., D.N.Sc., and joint degrees such as Ph.D./M.P.H. and M.D./M.P.H. Areas of discipline represented in the programs include Cardiology, Dentistry, Epidemiology, Internal Medicine, Mental Health, Nephrology, Oncology, and Sociology.

The success of the Loan Repayment Programs is illustrated by the array of projects in priority research areas that have been supported across the nation. For example:

Cancer

- Forty-five NCMHD Health Disparities Scholars have set their sights on combating cancer health disparities in 17 states, including Alabama, California, Colorado, Georgia, Illinois, Kansas, Massachusetts, Maryland, Michigan, Minnesota, North Carolina, New York, Pennsylvania, Tennessee, Texas, Virginia, Wisconsin, and in the District of Columbia. Their exciting work includes a community-based health promotion project to prevent cervical cancer in Vietnamese-American women; research on the quality of breast cancer care and the role of Hispanic ethnicity, language, and socioeconomic position; and an epidemiologic cohort study designed to address the disproportionate burden of many major cancers among African Americans.

Cardiovascular Disease

- The NCMHD supports 20 Scholars located across 11 states, including California, Florida, Illinois, Indiana, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, and Texas, who focus on the on the elimination of health disparities in cardiovascular disease. The breadth of research conducted by these individuals includes research on ambulatory blood pressure measures, SES, and their relation to increased left ventricular mass among a normotensive African American cohort; long-term treatment of myocardial infarction among American Indians; and a longitudinal study of neighborhood predictors of cardiovascular disease.

Diabetes

- The NCMHD has 15 Scholars addressing diabetes-related health disparities research in 10 states including Alabama, California, Florida, Georgia, Illinois, Massachusetts, New Hampshire, New York, Texas, and Virginia. These individuals are conducting several important projects including conducting educational interventions to prevent type 2 diabetes in middle school children; diabetes education multimedia for vulnerable populations; and an investigation of the relationship between lower extremity bone mass and measures of peripheral neuropathy in African American and Caucasian type 2 diabetic patients.

Infant Mortality

- The NCMHD supports six Scholars who focus on infant mortality health disparities research. These Scholars' research efforts take place in Florida, Maryland, Michigan, Missouri, North Carolina, and Pennsylvania. Their ongoing research includes evaluating the link between sexually transmitted diseases and infant mortality; determining leading health indicators for women and girls; and creating logic models for maternal, child, and family health programs.

The NCMHD LRPs are an integral part of the success of the NCMHD and will remain cornerstone programs. These programs will continue to serve as an avenue for NIH and the NCMHD to engage in and promote the development of research programs that reflect the variety of issues and problems associated with health disparities. For the NCMHD, the LRPs are more than a vehicle to repay qualified health professionals' educational loan debt. The NCMHD looks forward to developing lasting relationships with its LRP recipients because it is these professionals who will help to create a health disparities and clinical research community that will serve to accomplish the NCMHD mission.

2.1.1 Objective One: Loan Repayment Program for Health Disparities Research (HDR-LRP)

The HDR-LRP program seeks to recruit and retain highly qualified health professionals in research careers that focus on minority health disparities research or research related to the medically underserved. Upon acceptance into the program, participants are obligated to conduct a minimum of 2 years of basic, clinical, or behavioral research. In return for the participant's service, NCMHD will make direct payments to their lenders toward their outstanding educational loan debt. Pursuant to

P.L. 106-525, at least 50 percent of the awards will be made to individuals from health disparity populations. Through this program, the NCMHD will increase the cadre of culturally competent scientists working in minority health and other health disparities research.

Highlights of specific HDR-LRP research projects for the fiscal years 2002 and 2003 include:

- An assessment and cultural competency program involving the delivery of services to American Indians and Alaska Natives;
- Racial and Ethnic Health Disparities in Arkansas;
- Pathways to Health: Depression Symptom Experience and Help Seeking of Low Income Women of Mexican Descent;
- Reducing Syndrome X in Obese/Diabetic Black Women;
- Sisters Talking About Real Solutions (STARS): STD/HIV risk reduction intervention for adult African American females;
- Mental and physical health in Native Hawaiians and Asian/Pacific Islanders in the state of Hawaii;
- Breast and Cervical Cancer Screening in Korean Americans;
- Long-Term Treatment of Myocardial Infarction Among American Indians; and
- Pathways of Alaska Native Adolescents in Substance Abuse.

2.1.1.1 Action Plan

Because this is a newly created program, the NCMHD undertook a number of actions to ensure the program is as effective and efficient as possible.

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Identify and review best practices from well established loan programs throughout the federal government and the private sector o Identify efficient application distribution systems (e.g., via web-based solutions) o Determine best approach for reviewing loan applications	November 2001	X
▪ Promote the HDR-LRP throughout the biomedical and behavioral, research, educational, and minority and medically underserved communities.	March FY02	X
▪ Distribute applications	July FY02	X
▪ Review loan applications	August FY02	X
▪ Make awards	September FY02	X
▪ Host LRP roundtable to identify continuous improvement opportunities for the loan repayment program and its participants	July FY03	X

2.1.1.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ The number of applicants for the LRP (Base = 75)	350	375	400	425	450
▪ Number of LRP recipients who publish peer-reviewed articles	50%	50%	50%	50%	50%
▪ Assure that a significant number of LRP applicants are researchers in training or have recently commenced their research careers	50%	50%	50%	50%	50%
▪ Assure that a significant number of LRP awardees are from health disparity populations	50%	50%	50%	50%	50%
▪ Percent of awardees in their 2nd or 3rd year of the program who attend educational or technical assistance workshops, seminars, and other educational mechanisms and are encouraged to apply for small grant support	25%	30%	35%	40%	40%
▪ Percent of LRP recipients who participate in community outreach efforts	95%	95%	95%	95%	95%

***** Targets subject to change based on collection of baseline data.

Timeline

- The NCMHD began administering loan repayments in FY01. The HDR-LRP is congressionally authorized through FY06. Incremental milestones are listed above in the Action Plan and Milestones table.

2.1.1.3 Outcome Measures

- Twenty percent of awardees are still conducting minority health disparity research 5 years after their award.
- Twenty percent of minority awardees are still conducting minority health disparity research 5 years after their award.

2.1.2 Objective Two: Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP)

The ECR-LRP program provides an incentive for health professionals from disadvantaged backgrounds to conduct clinical research. The emphasis on “clinical research” and on individuals from “disadvantaged” backgrounds is consistent with the trans-NIH Strategic Plan objectives of building a culturally competent cadre of clinical investigators. The growing gap in income between the rich and poor; inequities in health due to race, poverty, substandard housing, and lack of employment opportunities; and an increasing perception of hopelessness and powerlessness among marginalized populations highlight the need for the involvement of a cadre of culturally competent physician scientists in clinical research. Such a cadre of clinical investigators not only has the potential of impacting the medical processes within their communities but can also engage in and promote the development of clinical research programs that reflect an understanding of the variety of issues and problems associated with health status.

An "individual from a disadvantaged background" is defined according to low family income levels set by the U.S. Bureau of the Census, as published in the Federal Register. To be eligible for the program, the candidate must meet the criteria stated above, as well as meet other minimum requirements established by the NIH and the NCMHD. Upon acceptance into the program, candidates are obligated to conduct a minimum of 2 years of clinical research. In return for the participants' service, the NCMHD will make direct payments to the participants' lenders for qualified education loan debt.

Highlights of specific HDR-LRP research projects for the fiscal years 2002 and 2003 include:

- Sickle cell anemia research;
- VIDAS: The Voice Interactive Depression System;
- Oral conditions and health outcomes in frail elders;
- HIV-specific T-helper and CTL responses in infected children;
- Take Charge of Your Oral Health: an oral health promotion program for African American elders;
- REACH 2010 (Racial and Ethnic Approaches to Community Health – reducing disparities among Latino diabetics and associated CVD);
- Clinical neuroimaging studies and neuroendocrine studies in Alzheimer's disease and normal aging;
- HIV-related tuberculosis research – paradoxical reactions (immune reconstitution syndrome); and
- Prevalence of growth hormone deficiency in patients with idiopathic dilated cardiomyopathy.

2.1.2.1 Action Plan

Because this is a newly created program, the NCMHD undertook a number of actions to ensure the program is as effective and efficient as possible.

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Identify and review best practices from well established loan programs throughout the federal government and the private sector. o Identify efficient application distribution systems	November 2001	X

Action Plan	**Milestones**	
	Target	**Achieved**
(e.g., via web-based solutions) o Determine best approach for reviewing loan applications		
▪ Promote the ECR-LRP throughout the biomedical, research, educational, and minority communities.	March FY02	X
▪ Distribute applications	July FY02	X
▪ Review loan applications	August FY02	X
▪ Make awards	September FY02	X
▪ Host LRP roundtable to identify continuous improvement opportunities for the loan repayment program and its participants.	July FY03	X

2.1.2.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ The number of applicants for the LRP	100	110	120	130	140
▪ Number of LRP recipients who publish peer-reviewed articles	50%	50%	50%	50%	50%
▪ Assure that a significant percent of LRP applicants are researchers in training or have recently commenced their research careers	50%	50%	50%	50%	50%
▪ Percent of awardees in their 2nd or 3rd year of the program who attend educational or technical assistance workshops, seminars, and other educational mechanisms and are encouraged to apply for small grant support	25%	30%	35%	40%	45%
▪ Percent of LRP recipients who participate in community outreach efforts	95%	95%	95%	95%	95%

* Targets subject to change based on collection of baseline data.

Timeline

- The NCMHD began administering loan repayments in FY01 and plans to continue the LRP indefinitely. Incremental milestones are listed above in the Action Plan and Milestones table.

2.1.2.3 Outcome Measures

- Twenty percent of awardees are still conducting clinical research 5 years after their award.

2.2 Area of Emphasis Two: Promote and Support Research Capacity Building Activities in Racial and Ethnic Minority and Medically Underserved Communities

In passing P.L. 106-525, the U.S. Congress recognized the need to increase the facilities and workforce supporting and conducting minority health and health disparity research. To meet this need, the U.S. Congress has given the NCMHD extramural funding capabilities and the statutory authority to promote and support research capacity building, workforce building, and training activities through two programs:

- The Centers of **EX**cellence in **P**artnerships for Community **O**utreach, **R**esearch on Health Disparities and **T**raining (Project **EXPORT**)
- An Endowment Program for Section 736 Institutions

In addition, the NCMHD supports two additional capacity-building programs, RIMI and MHIRT.

2.2.1 Objective One: The Centers of Excellence (COEs) in Partnerships for Community Outreach, Research on Health Disparities, and Training (Project EXPORT)

Pursuant to the Public Law, the NCMHD has been developing and implementing through the Project EXPORT grants program a network of COEs in partnerships for Community Outreach, Research on Health Disparities, and Training. The Project EXPORT Centers have been established at academic institutions with a significant number of students from racial and ethnic minority or other health disparity and medically underserved populations.

The NCMHD Project EXPORT Program is central to the investment strategy for addressing disparities in health status. This program poises the NIH and the NCMHD to more completely define the scope of health disparity problems and to identify and evaluate new approaches for preventing, reducing, and eliminating health disparities. Project EXPORT represents an investment for the present and for the future that will:

- Identify the factors that may contribute to health disparities;
- Increase the number of researchers engaging in health disparities research;
- Augment and strengthen the infrastructure and capacity of academic institutions to conduct research (basic, clinical, behavioral, and social sciences);
- Provide research training for the next generation of health disparity researchers; and
- Establish partnerships with health disparity and medically underserved communities.

The Project EXPORT Program builds research capacity at designated institutions enrolling a significant number of students from health disparity populations and promotes participation and training in biomedical and behavioral research among health disparity populations. The program attracts broad participation among institutions and consortia with varying levels of research experience and infrastructure, and engages health disparity and medically underserved communities in the effort to eradicate health disparities and to participate in biomedical and behavioral research and clinical trials.

The Project EXPORT Program will remain central to the NCMHD strategy for addressing disparities in health status. In addition to broadening the NIH commitment to research and research training, the program will continue to strengthen community involvement in understanding the causes/origin of health disparities and increase awareness regarding available treatments.

Through the Project EXPORT Program, the NCMHD will continue to: (1) promote minority health and health disparities research aimed at reducing and eliminating disparities; (2) build health disparities research capacity at minority-serving and other institutions; (3) promote the participation of health disparity populations in biomedical and behavioral research, prevention, and intervention activities; and (4) foster collaboration among investigators in a way that enhances and extends the effectiveness of their research.

During fiscal years 2002 and 2003 the NCMHD funded Project EXPORT awards across the nation focusing on priority research areas. Selected examples include:

- NCMHD Health Disparities COEs in 12 states across the nation are bringing to bear their state-of-the-art research and outreach programs to eliminate the impact of **cancer** on diverse populations. These efforts take place in Alabama, Arizona, California, Colorado, Georgia, Maryland, Mississippi, New York, Pennsylvania, Tennessee, Texas, and Virginia.

- Today, 13 NCMHD Health Disparities COEs, located in nine states across the nation, including California, Georgia, Hawaii, Maryland, Mississippi, North Carolina, New York, Pennsylvania, and Texas, focus on eliminating disparities due to **cardiovascular disease**. Three Health Disparities COEs in Georgia, Mississippi, and New York focus on **stroke** research.

- **Diabetes** is the target of 27 Health Disparities COEs in 17 states, including Alabama, Arizona, California, Colorado, Georgia, Hawaii, Illinois, New York, North Carolina, North Dakota, Maryland, Mississippi, Oklahoma, Pennsylvania, South Carolina, Texas, and Wisconsin, as well as the District of Columbia.

- The NCMHD has Health Disparities COEs in six states, including Alabama, Florida, Georgia, Texas, Iowa, and Wisconsin, that focus their efforts to improve the **health of mothers and their infants**.

Some examples of Project EXPORT initiatives funded in FY2002 include:

- The “Center for Research and Outreach in Hispanic Mental Health” at Carlos Alibzu University in Puerto Rico facilitates research on health disparities with a special focus on the diagnosis, prevention, and treatment of mental health disorders in Hispanics. It also conducts research on hypertension and HIV/AIDS.

- Another project, "Health Disparities Research with Indian Tribes in Montana and Wyoming," with Black Hills State University in North Dakota, will develop a research infrastructure to address health disparities issues affecting the American Indian population of the Northern Plains. The project will integrate cutting-edge research with Tribal custom, leadership, and structure with emphasis on vehicular crash morbidity and mortality and ocular health/diabetes.

- The initiative, "Reducing Health Disparities in Alabama's Black Belt," with Tuskegee University and the University of Alabama, Tuscaloosa, focuses on minority health disparities, bioethics, and rural health in Alabama's African American community. Specifically, this Center will emphasize research on adult immunization, infant mortality, cancer, and diabetes and take a proactive role in collaborations with the University of Alabama Institute for Rural Health Research (IRHR) and community organizations in addressing health disparities.

- "Partnerships for Diabetes Related Disparities in Health" with the University of Hawaii at Manoa and the Medstar Research Institute establish the Hawaii EXPORT Center (HEC), a research center whose mission is to reduce and eliminate diabetes-related health disparities in Native Hawaiians and Pacific peoples. HEC will: (1) seek "grass roots" partnerships with multiple stakeholders through a strategic planning process; (2) improve research in diabetes-related disparities by designing and implementing hypothesis-driven research of high scientific merit and relevance to Native Hawaiians and Pacific peoples; (3) build research capacity by increasing the numbers of studies and investigators pursuing diabetes-related research; (4) improve and facilitate the translation of research to clinical practice by building a community-based network to disseminate scientific information and educate students; and (5) raise public awareness of diabetes-related disparities throughout the state and the United States.

Some examples of Project EXPORT initiatives funded in FY2003 include:

- The "Mexican-American Women's Health Project EXPORT Center" at the University of Texas, El Paso (UTEP), a Hispanic-Serving Institution (HIS), was established by UTEP in partnership with established Hispanic health disparity researchers at the University of Arizona. The focus of this research initiative will be on potentially modifiable health behaviors disproportionately affecting Mexican-American women (i.e., alcohol use; maternal health and nutrition; smoking cessation; and the pursuit of the recommended Pap and human papillomavirus (HPV) screening tests.

- Clemson University, a land grant institution in South Carolina, established an EXPORT Center in collaboration with Voorhees College, a Historically Black Institution (HBI) also in South Carolina. The purpose of the EXPORT Center is to build capacity for research and training and outreach to address health disparities in minority and rural underserved communities in South

Carolina. This project primarily focuses on African Americans and Hispanics, who form the largest racial/ethnic minority groups living in the state.

- The establishment of the Center for Excellence in Minority Health at Jackson State University in Jackson, Mississippi, is built on a partnership with the University of Mississippi Medical Center, the University of Pittsburgh, and the Jackson Medical Mall Foundation. This Center's research agenda emphasizes cancer, cardiovascular disease, and stroke in the African American population of Mississippi. Additional research sub-cores will be developed in areas of maternal-child health, diabetes and injury/violence.

- Another program funded in FY2003 is the UNI (University of Northern Iowa) Project EXPORT Center in Cedar Falls, Iowa. The purpose of this initiative is to strengthen and build the University's existing institutional infrastructure to increase its capacity to address the special health needs of Iowa's pre-existing minority groups (which include urban African Americans and the Meskwaki Indian Tribe) and rural families, as well as the state's growing populations of Latino immigrants, Bosnian refugees, East African immigrants, refugees from the former Soviet Union, and others. Through applied research, the Center will seek to identify effective ways to reduce health disparities within the parameters of a low-resource environment experiencing rapid ethnic diversification. The research agenda for the UNI Project EXPORT Center focuses on maternal and child health disparities and issues concerning cultural conflict and adaptation.

2.2.1.1 Action Plan

In developing Project EXPORT, the NCMHD undertook a number of actions to ensure the program would be as effective and efficient as possible.

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Promote awareness of and increase understanding of the NCMHD Project EXPORT COEs (e.g., Technical Assistance Workshops, RFAs, NCMHD web site)	January FY03	FY2003 and FY2004
▪ Identify and implement best practices from established public and private grant-making organizations (e.g., grant making, peer review process, program review/evaluation)	FY05	Ongoing
▪ Make awards	FY04-FY08	Ongoing
▪ Monitor grantee performance including: o Publication of scientific and technical articles about their research in peer-reviewed journals o Recruitment and retention of scientists from	Annually, due at end of each fiscal year	Ongoing: Progress reports are currently

Action Plan	**Milestones**	
	Target	**Achieved**
minority and other underrepresented populations in the fields of biomedical and behavioral research at NCMHD Project EXPORT COEs o Recruitment and retention of qualified individuals trained at institutions with NCMHD Project EXPORT COEs who are currently underrepresented in the scientific, technological, and engineering workforce in public and private sector organizations o Use of endowment funds		being analyzed for this information.

2.2.1.2 Performance Measures

Performance Measures	**Target***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ An increase in the number of applications for NIH research project grants being submitted by researchers from institutions with NCMHD Project EXPORT COEs		Base	15%	15%	20%
▪ An increase in the number of NIH research project grants awarded to researchers at institutions with NCMHD Project EXPORT COEs		Base	10%	10%	15%
▪ Percent increase in the number of minority research-related articles published by individuals training or being trained at Project EXPORT COEs			Base	5%	10%
▪ Percent increase in the number of students trained at institutions with NCMHD Project EXPORT COEs who continue work in the field of minority health disparity research			Base	5%	10%
▪ Increase the number of basic and clinical researchers representative of minority and other health disparity populations		Base	10%	15%	20%
▪ Percent increase in the number of community-based efforts established in association with an NCMHD Project EXPORT COE		Base	15%	20%	25%

* Targets subject to change based on collection of baseline data.

Timeline

- The NCMHD began the Project EXPORT COE program in FY02, and plans to continue it indefinitely. Incremental milestones are listed above in the Action Plan and Milestones table.

2.2.1.3 Outcome Measures

- Increase over baseline in the number of capital improvement projects supporting health disparity research, over 5 years. Increases will be itemized and included in the NCMHD portion of the NIH Annual Report.
- Number of Project EXPORT grantees evolving from a R24 funded Center to a P20 funded Center, and from a P20 funded Center to a P60 funded Center.
- Number of new NIH-funded health disparity related grants at institutions receiving NCMHD Project EXPORT funding.

2.2.2 Objective Two: NCMHD Research Endowment Program for Section 736 Institutions

The NCMHD Research Endowment Program specifically targets "Section 736 [PHS Act] Institutions with currently funded Programs of Excellence in Health Professions Education for Underrepresented Minority Individuals." Congress determined that the establishment of federally supported endowment funds is an appropriate method of building research and training capacity in institutions that make significant investments in the education and training of underrepresented minority and socioeconomically disadvantaged individuals.

Through the Endowment Program, the NCMHD will help to:

- Address the disparities in the burden of illness and death experienced by African Americans, Hispanics, Native Americans, Alaska Natives, Asians/Pacific Islanders, and other underserved populations as compared to the Nation as a whole
- Expand or add programs that effectively overcome educational and financial resource barriers to promote a diverse and strong scientific, technological, and engineering workforce for the 21st century
- Work in concert with the private and nonprofit sectors to emphasize the recruitment and retention of qualified individuals from health disparities populations that are currently underrepresented in the scientific, technological, and engineering workforce
- Assist in the recruitment of more scientists from health disparities populations in the fields of biomedical and behavioral research and other areas of the scientific, technological, and engineering workforce

The objective of the Endowment Program is to facilitate a decrease in reliance on governmental financial support and encourage reliance on endowments and private sources. Eligible institutions include only those institutions with corporate or total institutional endowment assets of less than half the national average for section 736 institutions that conduct similar biomedical research or training of health professionals. Regarding partnerships, collaborating institutions that meet these criteria may independently apply for endowment support.

Additionally, as part of the guidelines for receiving an endowment, institutions must develop and measure outreach mechanisms to educate and inform their constituents. The NCMHD will monitor endowments throughout the life of the award.

The Research Endowment Program is an important priority and represents one of the NCMHD cornerstone programs. NCMHD-endowed institutions are using endowment funds to enhance research capacity and infrastructure for research and training, which includes: strengthening teaching programs in the biomedical and behavioral sciences and related areas; making physical plant improvements; establishing endowed chairs and programs; obtaining equipment for instruction and research; enhancing student recruitment and retention; providing merit-based scholarships; recruiting and retaining faculty; developing instruction delivery systems and information technology in areas that enhance minority health and health disparities research activities; and training minority and disadvantaged scientists in the behavioral and biomedical sciences.

Some highlights of the fiscal year 2002 Research Endowment Program awards include:

- The University of Montana has had a long-standing history and commitment to the recruitment and training of American Indians and other minorities for degrees in pharmacy and physical therapy. Through participation in the Research Endowment Program, the University of Montana will expand its infrastructure capacity to offer graduate degrees with an increased focus on minority health disparities research. Additionally, funds generated from the endowment award will be used to establish new tenure-track faculty positions and to support the continued emphasis on recruitment and retention of individuals from minority and other populations that are currently underrepresented in the scientific, technological, and engineering workforce.

- Support received from this program by Charles R. Drew University of Medicine and Science, a HBCU and a Hispanic-Serving Health Professional School (HSHPS) in California, will enable the university to acquire personnel and state-of-the-art information technologies that will strengthen and grow three of its highly productive infrastructure components, thereby increasing its capacity in research and training.

- The University of New Mexico (UNM) is a Hispanic-Serving Institution (HSI). Through participation in the Research Endowment Program, UNM will use the generated funds to support research on health disparities in New Mexico and the Southwest. UNM's overarching goal is not only to identify and analyze disparities, but also to design interventions that will lead to the reduction of disparities. UNM intends to use assistantships for minority and other underrepresented health professions students and pre-professional students to attract diverse students to science research careers.

Some highlights of the fiscal year 2003 Research Endowment awards include:

- Florida A&M University, located in Tallahassee, Florida, will use the income earned from its Research Endowment to provide resources to enhance the health professions and graduate programs in the Colleges of Pharmacy and Pharmaceutical Sciences and Arts and Sciences (Biology, Chemistry, and Physics) and Schools of Nursing and Allied Health and Environmental Sciences. This objective will be achieved through the expansion of efforts to recruit outstanding qualified individuals from minority and other populations that are currently underrepresented in the scientific, technological, and engineering workforce and the retention of existing health professions and graduate science faculty.

- Xavier University of Louisiana, in New Orleans, will use the funds generated from the Research Endowment to support ongoing projects to increase the research capability of the College of Pharmacy in the area of diabetes, to promote health disparities research, and to increase the pool of well-educated individuals from minority and other underrepresented populations who pursue advanced education in biomedical and behavioral research. The initiative will invest in programs that enhance recruitment, research development, continuing education, faculty retention, student training, and retention.

- Tuskegee University (TU), in Tuskegee, Alabama, will use Research Endowment income to implement a nationally recognized, interdisciplinary Ph.D. program in the Integrative Biosciences (with an emphasis in molecular and cell biosciences, dedicated to the development and application of genomics, proteomics, and bioinformatics). This research program will be conducted by faculty from the TU’s College of Veterinary Medicine, Nursing, and Allied Health and College of Agriculture, Environment, and Natural Sciences. The research infrastructure built by this award will be used to train African American and other minority and disadvantaged scientists in the behavioral and biomedical sciences. Funds also will be used to support the recruitment and retention of highly qualified faculty from minority and other underrepresented populations and to provide merit-based scholarships to students and competitive stipends to graduate science students.

2.2.2.1 Action Plan

Because this is a newly created program, the NCMHD undertook a number of actions to ensure the program is as effective and efficient as possible.

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Identify and implement best practices from established public and private grant-making organizations (e.g., grant making, peer review process, program review/evaluation)	FY02	
▪ Make endowment awards	End of FY02	
▪ Monitor grantee performance including: o Publication of scientific and technical articles about their research in peer-reviewed journals o Recruitment and retention of scientists from minority and other underrepresented populations in the fields of biomedical and behavioral research at Section 736 institutions o Recruitment and retention of qualified individuals trained at Section 736 institutions who are currently underrepresented in the scientific, technological, and engineering workforce in public and private sector organizations o Use of endowment funds	Annually, due at end of each fiscal year	
▪ Promote awareness of and increase understanding of the NCMHD Endowment Program among Section 736 institutions with currently funded Programs of Excellence in Health Professions Education through Technical Assistance Workshops, RFAs, and the NCMHD web site	FY03	

Timeline

- NCMHD began the Endowment program in FY01. Incremental milestones are listed in the Action Plan and Performance Milestones table.

2.2.2.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Percent increase in the number of applications for competitive research awards being submitted by researchers from NCMHD-endowed Section 736 institutions		Base	10%	15%	20%
▪ Percent increase in the number of NIH research project grants awarded to researchers at NCMHD-endowed Section 736 institutions		Base	5%	10%	15%
▪ Percent increase in the number of minority research-related articles published in peer-reviewed journals by individuals training or being trained through endowment funding			Base	5%	10%
▪ An increase in the number/percent of students trained at NCMHD-endowed institutions who continue work in the fields of minority health and health disparity research			Base	5%	10%

* Targets subject to change based on collection of baseline data. (Baseline data comprises the data collected in the Endowment Program's first year.)

2.2.2.3 Outcome Measures

- Increase the number of capital improvement projects and itemize them in the annual report
- A 50 percent increase over 5 years in the number of researchers focusing on minority health and health disparity research as a result of graduating from or teaching at a section 736 institution with an NCMHD endowment
- A 30 percent increase over 5 years in articles published in research journals focusing on minority health disparities originating at Section 736 institutions that have an NCMHD endowment

2.2.3 Objective Three: Research Infrastructure in Minority Institutions Program (RIMI)

RIMI was originally created by the NIH National Center for Research Resources (NCRR) and the NIH ORMH, the predecessor to the NCMHD. The RIMI research infrastructure grant program is designed to strengthen the research environment of predominantly minority-serving academic institutions through grant support to develop and/or expand existing capacities for institutional and/or individual faculty initiated basic, biomedical, social, and/or behavioral research programs. The program is flexible and allows institutions to pursue, for example, research efforts that address health disparities among racial and ethnic minorities and the medically underserved, including those who reside in the Southwest Border States, rural communities, Appalachia Region, Mississippi Delta, Frontier States, and urban centers of the United States. Further, the RIMI Program helps nondoctoral degree institutions to develop and enhance their capacity and competitiveness to conduct biomedical or behavioral research and develop their research infrastructure, primarily through collaborations with research-intensive universities.

The RIMI Program is now administered solely by the NCMHD. In FY2002, the objectives of the competition were to provide extension grants to institutions that seek to: (1) establish a RIMI activity that enhances the institution's biomedical research infrastructure; and (2) utilize collaborative agreements with institutions granting doctoral degrees in the health sciences to encourage and facilitate research and mentoring interactions between the biomedical research faculty in grantee and collaborating institutions. In FY2002, the NCMHD issued RIMI awards to six biomedical and behavioral research institutions. In fiscal year 2003, the NCMHD issued new RIMI awards to five qualified biomedical and behavioral research institutions.

The effectiveness of the RIMI Program is highlighted by Morgan State University, which took advantage of the support provided by the program and successfully established its own doctoral degree programs. Morgan State University entered the RIMI program in 1995 with the goal of establishing a biomedical research center through the creation of an interdisciplinary environment that fostered collaborative biomedical research in biology, chemistry, and psychology with Johns Hopkins University. Morgan State proposed specific research to address stress and cardiovascular disease, HIV/AIDS, and neurodevelopmental/neurological disorders. Morgan State has successfully implemented its doctoral programs in biomedical sciences.

The Charles R. Drew University is working to improve the detection and characterization of brain tumors, and researchers at San Francisco University are examining the impact of social support, spirituality, and depression on quality of life among breast cancer survivors from diverse populations.

2.2.3.1 Action Plan

Since the transfer of the RIMI to the NCMHD, the NCMHD has established a number of actions to ensure that the program meets the goal of solidifying and strengthening the infrastructure and capacity of non-research intensive minority-serving institutions to establish biomedical and behavioral science research degree programs, including: (1) developing faculty sustainable research programs; and (2) enhancing the overall quality of the educational experience for students in biomedical and behavioral sciences as well as related research areas.

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Expand the RIMI grant program to include capacity-building opportunities for community/junior colleges	FY05	
▪ Make RIMI awards	End of FY05	
▪ Monitor grantee performance including:		

Action Plan	**Milestones**	
	Target	**Achieved**
o Recruitment and retention of scientists from health disparities populations in the fields of biomedical and behavioral research o Recruitment and retention of qualified teaching faculty who are able to establish collaborative partnerships with individuals who are currently underrepresented in the scientific, technological, and engineering workforce in public and private sector organizations o Publication of scientific and technical articles about their research in peer-reviewed journals o Recruitment, retention, and graduation of students who select a major concentration in life or behavioral sciences	Annually, due at end of each fiscal year	
▪ Promote awareness of and increase understanding of the NCMHD RIMI Program among minority-serving institutions, including 2-year minority serving institutions, through Technical Assistance Workshops, RFAs, and the NCMHD web site	FY05	

Timeline

- The RIMI Program was transferred to NCMHD in 2002, but not expanded until FY04 to include a focus on the elimination of health disparities. Incremental milestones are listed in the Action Plan and Performance Milestones table.

2.2.3.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Percent increase in the number of applications for competitive research awards being submitted by minority-serving institutions		Base	10%	15%	20%
▪ Percent increase in the number of NIH research		Base	5%	10%	15%

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
capacity-building project grants awarded to minority-serving institutions					
▪ Percent increase in the number of minority research-related articles published in peer-reviewed journals by faculty being trained through RIMI funding			Base	5%	10%
▪ An increase in the number/percent of students trained at NCMHD RIMI institutions who continue to pursue a scientific research degree and/or work in the fields of minority health and health disparity research			Base	5%	10%

***** Targets subject to change based on collection of baseline data. (Baseline data comprises the data collected in the Endowment Program’s first year.)

2.2.3.3 Outcome Measures

- An increase by at least 30 percent over 5 years in the number of capital improvement and scientific research infrastructure projects at minority-serving institutions and itemizing of them in the annual report
- An increase by 35 percent over 5 years in the number of minority-serving institutions’ students who graduate with a degree focus on basic or behavioral science and research as a result of RIMI research support
- An increase by 30 percent over 5 years in the number of minority-serving institutions’ faculty researchers focusing on minority health and health disparity research as a result of RIMI program support
- A 25 percent increase over 5 years in faculty published articles in research journals focusing on minority health disparities originating at minority-serving institutions that have an NCMHD RIMI grant award.

2.2.4 Objective Four: Minority Health and Health Disparities International Research Training Program (MHIRT)

In FY2004, the NCMHD assumed responsibility for administering the Minority Health and Health Disparities International Research Training Program (MHIRT), previously known as the Minority International Research Training Program (MHIRT). This program was previously managed by the NIH Fogarty International Center (FIC) with co-funding from the NCMHD. The MHIRT Program supports innovative international research training opportunities for undergraduate, graduate, and health profession students who are from health disparity populations and groups and/or groups underrepresented in basic science, biomedical, clinical, and behavioral health research career fields.

MHIRT awards also enable U.S. institutions to offer mentored research training opportunities to qualified non-research students to participate in short-term international biomedical, clinical, social, or behavioral research programs abroad for at least 10-12 weeks during the summer or one semester during the academic year.

2.2.5 Objective Five: Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

The SBIR and Small Business Technology Transfer (STTR) Programs are set-aside programs for small businesses to engage in federal research and development with a potential for commercialization. For the NCMHD, these programs foster and encourage the participation of minority-owned small businesses and businesses owned by disadvantaged persons in technological innovation through cooperative research and technology transfer with research institutions that focus on health disparities issues. Moreover, they illustrate NCMHD's commitment to combine science, technology, and business into a collective effort that explores and solves health disparities.

Highlights of NCMHD's SBIR/STTR funded projects are illustrated by the following examples:

Real-Time Multinational System for Home Telehealth

This project focuses on the creation of a real-time multifunctional digital system for home telehealth by utilizing a single telephone line connection. Further, the product will facilitate verbal communication between health care providers and patients while simultaneously transmitting biosignals (e.g., electroencephalograms, electrocardiograms) in real time. This product has the potential to assist rural and isolated patients in receiving multiple types of health care and in obtaining physiological monitoring by a physician.

visiBabble

This project consists of the development of visiBabble, sound recognition software that provides real-time contingent visual reinforcement of vocalizations produced by infants and pre-school children who are delayed in frequency and variety of pre-speech vocalization. In an effort to prevent these children from becoming non-speakers, visiBabble may be used to encourage infants to vocalize and explore a large repertoire of phonetic patterns that help to foster later language and cognitive development. In addition, visiBabble can also be used by teachers, clinicians, and parents as a tool tailored to a child's particular problem (e.g., syllable starts, pitch variation, duration of voicing, particular consonant types, or syllable complexity).

Tissue Dissociation Enzymes for Islets and Other Cells

This project focuses on the improvement of the composition and purity of collagenase, the tissue dissociation enzyme used in islet isolation procedures, in an effort to increase the islet yield. This project is particularly important because transplantation of islet cells offers exciting treatment possibilities for diabetes mellitus, which is the third-leading cause of death in the United States and disproportionately affects minorities and other medically underserved populations.

Novel Platform for NO_x Reduction from Furnaces

This project seeks to reduce nitrogen oxides (NO_x) in the air by improving membrane technology and existing burner technology to reduce NO_x emissions from combustion processes. The reduction of NO_x in the air is particularly important because they are well-known environmental pollutants that inhibit lung function, increase susceptibility to bacterial and viral pulmonary infections, and are harmful for asthmatics, children, the elderly, and individuals with chronic obstructive pulmonary diseases. This project holds great promise in improving current technology and significantly impacting the health field.

2.2.5.1 Action Plan

The SBIR/STTR Program will focus on increasing the NCMHD portfolio. The strategy is to employ a stepwise process that will result in an 80 percent increase in the number of SBIR/STTR projects supported and administered by NCMHD by FY2008. The process will involve revising the SBIR/STTR Solicitation Manual, increasing participation in Regional and National SBIR/STTR conferences, developing outreach material that advertises NCMHD priorities in the business community (including web site material and promotional brochures), convening a workshop to brainstorm potential areas of collaboration between NCMHD and business enterprises, and ultimately offering Program Announcements or RFAs that will support a targeted need in one or more of our scientific priority areas.

Action Plan	Milestones	
	Target	Achieved
▪ Revise SBIR/STTR Solicitation Manual	FY05	
▪ Attend regional and national SBIR/STTR conferences	FY05-FY08	
▪ Develop outreach material	FY06	
▪ Convene outreach workshop	FY07	
▪ Develop targeted RFA	FY07	
▪ Develop targeted, ongoing Program Announcement	FY08	

2.2.5.2 Performance Measures

Performance Measures	Targets*				
	FY04	FY05	FY06	FY07	FY08
▪ Percent increase in the number of SBIR/STTR applications supported and administered by NCMHD	Base	20%	40%	60%	80%

***** Targets subject to change based on collection of baseline data. (Baseline data comprises the data collected in Fiscal Year 2004.)

2.2.5.3 Outcome Measures

- Increase in the number of supported and administered SBIR/STTR applications by 80 percent over the base year by FY2008.

2.3 Area of Emphasis Three: Develop and Refine Research Tools, Survey Instruments, and Databases That Are Culturally Sensitive, Culturally Competent, and Specifically Designed for Minority and Other Health Disparity Populations

As the coordinator of minority health and health disparity activities and information, the NCMHD will implement a knowledge repository database, or interconnected series of databases, to facilitate the retrieval, analysis, and dissemination of minority health and other health disparity research, infrastructure, and outreach information. A sophisticated mechanism of information sharing, leveraging the newest technologies, must be established to ensure all stakeholders can benefit from the multiple sources of information.

2.3.1 Objective One: Improve the Infrastructure for Collecting and Analyzing Epidemiological and Demographic Data on Minority Populations

The NCMHD will improve the infrastructure for collecting and analyzing epidemiological and demographic data on minority populations by developing and refining research tools, survey instruments, and databases. This knowledge repository must be culturally sensitive, culturally competent, and specifically designed for minority and other health disparity populations. The NCMHD will also support efforts to improve the Surveillance, Epidemiology, and End Results (SEER) data system at the NCI.

2.3.1.1 Action Plan

To lead the development of enhanced mechanisms for collecting and analyzing epidemiological and demographic data on minorities, the NCMHD will:

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Explore opportunities for partnerships with the private sector, particularly genomics and pharmaceutical companies, to develop better mechanisms to collect and analyze data on minorities' health and diseases of minorities and other populations.	FY06	
▪ Encourage knowledge sharing and cross-disciplinary research between NIH ICs, as well as the CDC. This will include reviewing ongoing infrastructure development efforts funded by the NCMHD.	FY06-FY08	

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Identify requirements to develop the most effective and efficient mechanisms of creating a data management solution to benefit research on three fronts: o NCMHD research o Intramural research (within NIH ICs) o Extramural research (NIH partnering institutions and community groups)	FY06	
▪ Standardize and improve record keeping on minority and ethnic groups and the underserved by states. The SEER data system should improve and refine descriptors for minority groups to reflect the number of minority and ethnic groups and the diversity within minority populations.	FY06-FY08	
▪ Examine the practices of institutions that have effective mechanisms of collecting data, developing research tools and survey instruments, and leveraging information among various studies.	FY06	

Timeline

- NCMHD will begin this effort in FY06.

2.3.1.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Percent increase of studies utilizing newly developed tools				Base	30%
▪ Increase in the number of tools				Base	20%

* Targets subject to change based on collection of baseline data.

2.3.1.3 Outcome Measures

- An improvement in methods for collection and dissemination of data and the promotion of surveillance studies with the development of data banks, databases, and “registries” of information on minority populations.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

Effective community outreach is bi-directional. Consequently, the NCMHD is committed to creating communication channels that lend themselves to the interactive nature of effective outreach. Different communities require different modes of communication. The word "community" is used broadly here since the NCMHD must reach out not only to constituent communities, but to the community of advocates, health professionals, and institutions as well. Accordingly, the NCMHD divides its outreach efforts into three major objectives:

- Outreach to communities and their community-based organizations
- Outreach to health and social service professionals
- Outreach to health, research, and social service institutions; professional organizations; and the business sector

In each of these categories the NCMHD may take on the role of partner, leader, or resource. The nature of that role defines the nature of the relationship, and consequently, the nature of communication and outreach required. However, the NCMHD is a new Center and before it can pursue the outreach objectives described above, it must create the institutional infrastructure to plan and lay the groundwork for the outreach effort.

Laying the Groundwork for Effective Outreach

In reaching out to communities and stakeholders, it is critical to convey a message that faithfully communicates the identity and mission of the organization. Therefore, it is important that the Center go through the necessary steps to establish its identity in order to create greater public understanding of the mission of the NCMHD. This will help develop unified thinking within the Center and its stakeholder community. The NCMHD also must develop a comprehensive communications strategy. This strategy will help identify the target audience, determine the communications objectives, design the message, manage the communications mix, and measure the communication results. Developing an effective communications strategy, implementing the plan, and developing the infrastructure to implement the plan are significant undertakings.

The NCMHD currently is establishing and launching its Office of Community-Based Participatory Research and Outreach (OCBPRO). Activities under consideration for this Office include the three objectives delineated below. The OCBPRO also will assist the Center in continuing to develop its branding approach and enhancing its communications strategy.

In the process of building an outreach infrastructure, the Center will continue to reach out to communities, community-based organizations, and other stakeholders because it is vital that the Center have a solid understanding of the communications needs of those it serves. Those needs vary in urban and rural environments, and among different health disparity populations. In the process of gathering input, the OCBPRO may use various means, from stakeholder meetings, focus groups, and workshops to larger conferences, surveys, and ethnographic studies. Although this is a time-consuming process, it is the essential foundation for an effective outreach program. The funding cycle and performance measures in this section reflect the necessary time required to gather this input and build the appropriate information foundation.

In measuring outreach performance we used both milestones tied to action plans and performance measures that capture improvements over time. The performance measures focus on two primary dimensions: (1) volume, or the number of groups and individuals touched; and (2) quality, or the efficacy of communications. In the case of volume, merely tallying up the number of leaflets distributed and similar gross measures are not satisfying measures. Where possible, we tried to emphasize capacity for volume, such as in the size of a database, or meaningful interactions, such as the number of inquiries to a database or web site. In the case of quality, the best and simplest measure is to ask a random sample of users and stakeholders how we are performing communication efforts. The outcome measure in each outreach category is to establish a high-quality, nationwide outreach network by a specified date.

3.1 Area of Emphasis One

3.1.1 Objective One: Outreach That Engages Communities and Their Community-Based Organizations

An understanding of affected communities drives minority health and other health disparity research priorities. The research findings cannot be fully realized until they are communicated to these same communities and translated into practice. Therefore, developing a strategic relationship with community-based organizations is of the highest priority. However, developing and implementing an effective outreach effort is a daunting task. There are many people to reach, and often they are among the most difficult-to-reach members of our society. Barriers of language, literacy, mobility, money, geography, vision, and hearing all conspire to thwart communication efforts. To succeed in this endeavor, the NCMHD will partner with multiple agencies and leverage existing channels, including individual health and social service providers. However, in many cases it will have to develop new methods and new channels to enhance the depth, breadth, and efficacy of its outreach efforts. As noted in the “Research Areas of Emphasis,” some research resources will be devoted to developing innovative and effective means of outreach. The research will be leveraged in the outreach effort described in this section as the Center identifies and implements best practices.

3.1.1.1 Action Plan

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Explore with the NCMHD Advisory Council and stakeholders the most appropriate means for establishing effective outreach to minority and underserved communities (e.g., Tribal Consultation Plan).	FY05	
▪ Continue to reach out to communities, community-based organizations, and other stakeholders to collect input regarding their communications needs and the best methods of maintaining a communications relationship. This may include methods such as town hall meetings, workshops, focus groups, conferences, surveys, and other studies. (This could also serve as an infrastructure for ongoing quality improvement and satisfaction measurement.)	FY05-FY08	
▪ Explore the feasibility of establishing a national database of effective and strategically located community-based organizations, churches, and faith communities that may be marshaled in an outreach effort. The database should be part of the broader knowledge management effort and should have a Geographic Information Systems (GIS) component. This GIS component will permit pinpointing of specific outreach messages to well-defined areas of disparity. (This has significant overlap with the coordination function and the Infrastructure Area of Emphasis.)	FY06	
▪ As outreach-focused research begins to reveal effective and innovative means of outreach, explore the feasibility of holding conferences to showcase that work and serve as a focal point of exchange with other scholars and practitioners working in this domain. (See Section 1.4)	FY05 – FY08	

Timeline

- As described in Action Plan.

3.1.1.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in volume of communications as measured by an increase in number of community-based organizations included in database and other indicators of volume		Base	10%	20%	30%
▪ Increase in satisfaction of community-based organizations with communications efforts as measured by surveys and other quantitative means		Base	10%	15%	20%

* Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant "ramp-up" time is expected.

3.1.1.3 Outcome Measures

An established communications network that provides research-based information and responds to the information needs of existing and future community-based organizations in all 50 states by the end of FY05.

3.1.2 Objective Two: Outreach That Engages Health and Social Service Professionals

Individual caregivers provide a vital link in the outreach chain. They have the opportunity to speak with patients and clients one-on-one in the context of a special relationship. It is extremely important to have a network that reaches these professionals, who in turn can share information with individuals in their care. In keeping with the principle of bi-directionality, health care providers must have the means to communicate with NCMHD so they can relay their concerns and provide their insights.

3.1.2.1 Action Plan

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Explore the feasibility of creating a research database of scientific articles relevant to minority health and other health disparities that could be easily accessed by health care professionals. This would be analogous to a Medline service and could be done in partnership with the National Library of Medicine.	FY05	

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Explore with the NCMHD Advisory Council the creation of minority health and other health disparity curricula that can be adapted and used by schools of nursing, medicine, and social work. In a parallel effort, Continuing Medical Education courses may be created for practicing professionals.	FY05	
▪ Explore with the NCMHD Advisory Council the creation of a textbook on minority health and health disparities that can be used in conjunction with the curricula cited above.	FY05	
▪ Explore with the NCMHD Advisory Council the creation of *Journal of Minority Health and Health Disparities* that can not only be used as a venue for publication but also as a tool of communication.	FY05	

Timeline

- As described in Action Plan

3.1.2.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in volume of communications to individual professionals as measured by an increased number of hits/page views/inquiries to literature database and other indicators of communication volume		Base	10%	20%	30%
▪ Increase in satisfaction of professionals with regard to communications as measured by surveys and other quantitative means		Base	10%	15%	20%

* Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant “ramp-up” time is expected.

3.1.2.3 Outcome Measures

- An established communications network that provides research-based information and responds to the information needs of health and social service professionals in all 50 states by the end of FY05.

3.1.3 Objective Three: Outreach That Engages Health, Research, and Social Service Institutions; Professional Organizations; and the Business Sector

Health care and social service institutions often play an important role in the lives of health disparity populations. Because of their presence in the community as both providers and employers, and because they often have pre-existing networks, it is important to leverage their capabilities in outreach efforts. The other NIH ICs all have an outreach infrastructure that could be coordinated and leveraged in the outreach effort. Enhanced communication between research institutions, such as the various NIH ICs, would enhance the health disparity research endeavor and is also a legitimate objective of the outreach function. The for-profit sector is an important part of the institutional outreach effort. Large employers and small businesses play an important role in the life of a community and will require special outreach strategies to enlist them in the health disparity effort.

3.1.3.1 Action Plan

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Explore acquisition or establishment of a database of hospitals, clinics, and other key institutions in minority/health disparity communities. Database should include the names of key information/public relations staff, and have a strong GIS component. These institutions could be leveraged in disseminating information, developing behavior change programs, and recruiting research subjects. (This has significant overlap with Infrastructure Area of Emphasis and related Objectives.)	FY05	
▪ Identify and consider reaching out to other institutions and systems that may not be traditionally thought of in this effort such as state and federal prison systems; the Veterans Affairs hospital system; and large employers, small businesses, Health Maintenance Organizations, and health insurance companies active in minority and health disparity communities. These may be included in the database.	FY05	
▪ Create relationships and collaborate with other federal agencies, including other ICs, who may wish to reach the same populations. The messages of different organizations need to be coordinated and consistent. The NCMHD can play a role in coordinating messages so that the database and the community-based partners are used most efficiently and effectively.	FY05	

Action Plan	**Milestones**	
	Target	**Achieved**
▪ Identify best practice outreach tools and techniques among the other ICs.	FY05	
▪ Require strategically located COE award recipients to take a leadership role in coordinating and leading outreach and information dissemination in a specified geographic area.	FY02	X

Timeline

- As described in Action Plan

3.1.3.2 Performance Measures

Performance Measures	**Targets***				
	FY04	**FY05**	**FY06**	**FY07**	**FY08**
▪ Increase in volume of communications to institutional partners as measured by an increase in the size of the database and other indicators of volume		Base	10%	20%	30%
▪ Increase in satisfaction of institutions with regard to communications as measured by surveys and other quantitative means		Base	10%	15%	20%

***** Targets subject to change based on collection of baseline data. Percentages refer to increase over base year unless otherwise stated. Base year is deferred to out years when significant "ramp-up" time is expected.

3.1.3.3 Outcome Measures

- An established outreach network that provides research-based information and responds to the information needs of health, social service, and other institutions in all 50 states by the end of FY05.

The National Eye Institute

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL EYE INSTITUTE

MISSION/VISION STATEMENT

Congress established the National Eye Institute (NEI) in 1968 with the mission to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the individuals who are visually impaired. Inherent in the NEI's mission is the investigation of normal visual processes and health information dissemination activities to conduct activities related to the prevention of blindness through public and professional education programs and through the encouragement of regular eye examinations.

The NEI will continue to protect and improve the visual health of the Nation through the support and performance of the highest quality laboratory and clinical research aimed at increasing our understanding of the eye and visual system in health and disease and developing the most appropriate and effective means of prevention, treatment, and rehabilitation, and through the timely dissemination of research findings and information that will promote visual health.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NEI is the principal federal agency concerned with the support of basic and clinical research aimed at the improved prevention, diagnosis, and treatment of eye diseases and visual disorders that cause visual impairment and blindness. Vision research is supported by the NEI through approximately 1,600 research grants and training awards made to scientists at more than 250 medical centers, hospitals, universities, and other institutions across the country and around the world. The NEI also conducts laboratory and patient-oriented research at its own facilities located on the National Institutes of Health (NIH) campus in Bethesda, Maryland.

The NEI's latest strategic plan, the National Plan for Eye and Vision Research, was developed in conjunction with experts from all fields of vision research, who were assembled to make recommendations on research priorities. Additionally, the National Eye Health Education Program (NEHEP) Partnership met to review and evaluate progress, identify new critical areas for applied research, and make recommendations regarding the NEHEP. Both the research priorities and NEHEP recommendations were included in the strategic plan. Several of the priority recommendations made by these groups were related to health disparities. They included research on glaucoma, diabetic retinopathy, myopia, health services research, and eye health education. More than 60 professional, scientific, or advocacy organizations that support vision research were asked to review the draft plan to ensure that important areas of research or specific issues of importance to vision research had not been overlooked. The final plan reflects the comments and input received during that process and can be found on the NEI web site at http://www.nei.nih.gov/strategicplanning.

NATIONAL EYE INSTITUTE

For this document, the areas of research priority related to health disparities that were identified in the full strategic plan were extracted. These areas were used to revise and update the NEI strategic plan for addressing health disparities. In addition, the NEI's activities as a co-lead agency for the new focus area on Vision and Hearing in Healthy People 2010 are highlighted.

An NIH committee developed strict definitions of minority health and health disparities research so that funding levels can be tracked for clinical or basic research related to diseases, conditions, or biological processes that are either exclusively or almost exclusively found in specific designated minority or health disparities populations. Eye diseases and conditions, however, are neither found exclusively nor nearly exclusively in minority or health disparities populations. Nonetheless, some eye diseases and conditions have a greater prevalence in minority populations and result in increased blindness or visual impairment compared to other populations. These include glaucoma, diabetic retinopathy, cataract, and refractive errors. A recent study of causes and prevalence of visual impairment suggested that glaucoma and cataract account for more than 60 percent of the blindness in Black adults in this country, and in spite of a highly effective surgical treatment, cataract causes approximately 50 percent of the bilateral low vision in Blacks, Hispanics, and Whites.[i] By conducting basic and clinical research into these diseases and ensuring that NEI-supported clinical trials have appropriate inclusion of minority populations, the NEI and the vision research community are trying to improve treatment of those afflicted, particularly those who have a disproportionate share of the disease burden.

In preparing this plan, the public comments concerning the *NIH Strategic Plan and Budget to Reduce and Ultimately Eliminate Health Disparities* were reviewed. Although no specific comments were found concerning the research, research capacity, or outreach activities discussed in the NEI Minority Health Strategic Plan, some of the major themes are relevant to the interests and concerns of the NEI in conducting its activities related to minority health and health disparities.

With regard to the theme of using culturally sensitive and appropriate communications, the NEI, through its NEHEP, convenes work groups and conducts focus groups and key informant interviews to ensure the sensitivity of its education programs in addressing the needs and perspectives of minority populations. These activities have resulted in culturally appropriate educational materials for the Glaucoma Education Program, the Low Vision Program, and the Diabetic Eye Disease Program, which includes the American Indian and Alaska Native Diabetic Eye Disease Outreach Program. The *Ojo Con Su Visión* (Watch Out for Your Vision) program provides Spanish-language outreach on diabetic eye disease, glaucoma, and low vision.

The theme of strengthening the capacity of minority communities is being addressed through the NEHEP with its efforts to expand the number of partnership organizations involved in the planning and conduct of its educational and outreach activities. The NEI's efforts for the Department of Health and Human Services (HHS) health promotion and disease prevention initiative, Healthy People 2010, also are aimed at strengthening the capacity of minority communities. The NEI has established a Healthy Vision 2010 Awards Program that is intended to stimulate collaborative community health education initiatives. The NEI recognizes the importance of strengthening the capacity of community-based organizations by providing “seed money” to begin or continue vision-related health education projects. The NEI provides leadership to promote health and prevent disease among Americans through management and coordination of the implementation of the vision objectives in Healthy People 2010, the Nation’s health agenda. These awards provide NEI with opportunities to establish partnerships that extend the reach and effectiveness of its work.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Glaucoma

Glaucoma is not a single disease but rather a heterogeneous group of disorders that share a distinct type of optic nerve damage that can lead to blindness caused by the death of retinal ganglion cells. These diseases involve several tissues in the front and back of the eye. Commonly, but not always, glaucoma begins with a defect in the front of the eye. Fluid in the anterior portion of the eye, the aqueous humor, forms a circulatory system that brings nutrients to various tissues. Aqueous humor enters the anterior chamber via the ciliary body epithelium (inflow); flows through the anterior segment bathing the lens, iris, and cornea; and then leaves the eye via specialized tissues known as the trabecular meshwork and Schlemm’s canal to flow into the venous system. Intraocular pressure (IOP) is maintained by a balance between fluid secretion and fluid outflow. Almost all glaucomas are associated with defects that interfere with aqueous humor outflow and, hence, lead to a rise in IOP. The consequence of this impairment in outflow and elevation in IOP is that optic nerve function is compromised. The result is a distinctive optic nerve atrophy, which clinically is characterized by excavation and cupping of the optic nerve, indicative of loss of optic nerve axons.

Rationale and Priority

Primary open-angle glaucoma, the most common form of the disease, is characterized by relatively high IOPs believed to arise from a blockage of the outflow drainage channel or trabecular meshwork in the front of the eye. However, another form of primary open-angle glaucoma, normal-tension glaucoma, is characterized by a severe optic neuropathy in the absence of abnormally high IOP. Patients with normal-tension glaucoma have pressures within the normal range, albeit often in the high normal range. Both these forms of primary open-angle glaucoma are considered to be late-onset diseases in that, clinically, the disease first presents itself around midlife or later. However, among African Americans, the disease may begin earlier in middle age. In contrast, juvenile open-angle glaucoma is a primary glaucoma that affects children and young adults. Clinically, this rare form of glaucoma is distinguished from primary open-angle glaucoma not only by its earlier onset but also by the very high IOP associated with this disease. Although there are a number of other forms of glaucoma, the major focus of NEI-supported research remains on primary open-angle glaucoma because of the large number of people affected and its public health impact.

Primary open-angle glaucoma can be insidious. The disease is manifest as a progressive optic neuropathy that, if left untreated, leads to blindness. It usually begins in midlife and progresses slowly but relentlessly. If detected, disease progression can frequently be arrested or slowed with medical and surgical treatment. However, without treatment, the disease can result in absolute, irreversible blindness. Even though the initial site is believed to occur in the outflow drainage channels at the front of the eye, vision loss from primary open-angle glaucoma is the result of damage to the retinal ganglion cells, whose axons form the optic nerve at the back of the eye.

An estimated 66.8 million people worldwide have glaucoma, and nearly 6.7 million will be bilaterally blind as a result.[ii] Glaucoma is a major public health problem in this country, as well. A recent meta-analysis of population-based data from several studies estimated that as many as 2.2 million Americans have the disease, and by the year 2020 this number is expected to increase to nearly 3.4 million.[iii] Furthermore, the study found that glaucoma is three times more prevalent in African Americans than in Whites,[iii] and it is the number one cause of blindness in African Americans.[iv] Epidemiological studies conducted in the United States and the West Indies have improved the prevalence and incidence estimates of primary open-angle glaucoma among White and Black populations. One strength of these studies is the adoption of more inclusive definitions of primary open-angle glaucoma that require the presence of visual field loss or optic disc damage but do not necessarily require the presence of elevated IOP. The Beaver Dam (Wisconsin) Eye Study, which studied nearly 5,000 individuals between the ages of 43 and 84, reported a prevalence rate of 2.1 percent in a predominantly Caucasian sample.[v] The Baltimore Eye Study, with more than 5,000 participants age 40 and older, reported a prevalence rate of 1.7 percent among Caucasian Americans and 5.6 percent among African Americans.[vi] The Barbados Eye Study, which studied more than 4,000 Black Barbadians ages 40 to 84, reported a prevalence rate of 7 percent.[vii] The Barbados Eye Study and the Baltimore Eye Study confirmed the substantially higher prevalence of primary open-angle glaucoma in Caribbean Blacks and African Americans than in Whites. Recent prevalence estimates of primary open angle glaucoma in Hispanics indicate rates lower than African Americans and similar to Whites except for the group over 65 years old, which had higher rates.[3]

Treatments to slow the progression of the disease are available; however, at least half of those who have glaucoma are not receiving treatment because they are unaware of their condition[viii]. In some patients, the beneficial effect of eye drops lessens with time, and "advanced glaucoma" develops. Findings from the NEI-supported Advanced Glaucoma Intervention Study suggest that Black and White patients with advanced glaucoma respond differently to two surgical treatments for the disease. Although both groups benefit from treatment, scientists found that Blacks with advanced glaucoma benefit more from a regimen that begins with laser surgery, while Whites benefit more from one that begins with an operation called a trabeculectomy[ix].

Results from three other clinical trials confirmed the value of reducing IOP in patients with ocular hypertension or glaucoma to prevent the onset of glaucoma in the former case and the progression of disease in the latter. The Ocular Hypertension Treatment Study (OHTS), a study co-sponsored by the NEI and National Center for Minority Health Disparities (NCMHD), noted that lowering IOP at least

20 percent produced a 50 percent protective benefit over baseline among those individuals who had elevated IOP without optic disc or visual field deterioration.[x] Analysis of the African American subgroup in the OHTS revealed that daily pressure-lowering eye drops also reduced the development of primary open-angle glaucoma in African Americans by almost 50 percent.[xi] The Early Manifest Glaucoma Trial determined that patients with newly diagnosed glaucoma progressed less often than untreated patients when IOP was reduced at least 20 percent compared with baseline.[xii] The Collaborative Initial Glaucoma Treatment Study demonstrated that patients with glaucoma who undergo either medical or surgical therapy were equally likely to avoid progression of disease after 5 years of follow-up.[xiii]

Analyses of key baseline, clinically important factors among ocular hypertensive patients enrolled in the OHTS also uncovered or affirmed a number of risk factors for the development of glaucomatous damage, including IOP, large cup-to-disc ratio, age, and central corneal thickness.[xiv]

Significant advances in identifying glaucoma-causing or associated genes have been made with the mapping of more than a dozen glaucoma loci and the cloning of more than a half dozen glaucoma genes. New studies involving genome-wide screening are beginning to identify alleles that may play a combinatorial role in complex primary open-angle glaucoma. Identification of trabecular meshwork glucocorticoid response/myocilin, optineurin, cytochrome P450 1B1 (*CYP1B1*), and other genes that play a less prominent role in disease causation promises a better understanding of normal eye development and of the molecular pathophysiology of glaucoma in general. Defining roles for these genes with respect to glaucoma should indicate pathways that are disrupted and thereby help increase our understanding of the pathology of all forms of glaucoma.

Progress also has been made in the development of new pharmacological agents that might protect axons from damage due to glaucoma. Elevated IOP frequently is associated with glaucoma, and explanations for how axons become damaged usually are based on the mechanical effects of elevated IOP. However, optic nerve damage can occur without abnormally high pressures and conversely, elevated pressure does not necessarily lead to optic nerve damage. Discovering the basis of optic nerve degeneration is essential for the development of the next generation of glaucoma drugs, neuroprotective agents. Scientists now have evidence that the molecule nitric oxide (NO) is directly involved in mediating the degeneration of axons in the optic nerve head.[xv] Research is being aimed at identifying and developing neuroprotective agents as a new class of glaucoma drugs.

An important aim of current research is to develop methods of diagnosis to detect the disease in the early stages, when treatment is most effective in minimizing irreversible vision loss. This is made more critical by the apparent absence of symptoms in the early stages of glaucoma. Because elevated IOP is not always accompanied by pathology, nor does elevated IOP always lead to optic neuropathy, the diagnosis of glaucoma now emphasizes the presence of visual field loss and observable characteristic optic nerve damage. Individuals with ocular hypertension present a unique dilemma for clinicians. In the absence of any overt pathology, clinicians must decide whether or not to treat these individuals with IOP-lowering medications that can pose a considerable expense and often have side effects. This dilemma can be avoided with a more thorough understanding of the natural history of the disease and whether early treatment can prevent the onset of glaucoma.

Because characteristic visual field changes in glaucoma patients are due to degeneration of retinal ganglion cells, clinical progress goes hand-in-hand with progress in understanding how retinal ganglion cell loss occurs and the role played by elevated IOP in this process. New approaches to treatment are essential because not all patients respond to current treatments, and vision that is lost currently cannot be restored. Because ganglion cell death is the common feature of glaucoma, it has become increasingly important to understand the fundamental pathophysiology of the retina. For this reason, the NEI sponsored a workshop on ganglion cell death and optic nerve degeneration to help stimulate the development of new paradigms and neuroprotective methodologies for the clinical treatment of glaucoma.

Clinical and laboratory research will continue to provide a greater understanding of the normal functions of the ocular tissues involved in glaucoma. Such studies already have led and will continue to lead to the introduction of new drugs to reduce IOP, the development of new diagnostic tools, better estimates of disease prevalence and incidence, and the identification of glaucoma genes.

1.1.1 Objective One: Understanding Glaucoma

Elucidate the prevalence, pathophysiology, natural history, and history of intervention results of optic neuropathies such as glaucoma and optic neuritis over the full time course of these diseases and within ethnic subgroups.

1.1.1.1 Action Plan

Improve our understanding of the nature and course of glaucoma, incorporating studies of comorbidity, natural history, and genetics.

Results from the Baltimore Eye Study, the Beaver Dam Eye Study, and the Barbados Eye Study firmly established race as a significant risk factor for primary open-angle glaucoma. Though there is variation in estimates that reflects the different populations studied, all of these studies confirm a substantially higher prevalence of primary open-angle glaucoma in Blacks. Furthermore, the rates for blindness due to primary open-angle glaucoma in African-Americans are six times higher than the rates for the Caucasian population, reflecting not only an increased rate of the disease but also more severe disease. A recent report estimated the prevalence of glaucoma in Latinos of Mexican ancestry to be higher than Whites in the ages older than 65 years.[iii] This could account in part for the high age-specific rates of visual impairment seen in the Los Angeles Latino Eye Study.[xvi] Several lines of research need to be continued to increase our understanding of the nature and course of the disease and to provide new knowledge upon which to base preventive measures or improved treatments.

Questions of comorbidity have not been adequately resolved. Studies that sought to investigate the relationship between glaucoma and myopia have yielded ambiguous results. There is also incomplete and equivocal epidemiologic information available on the relationship between glaucoma and vascular disease. The need to resolve the question of comorbidity is highlighted by the fact that the rate of hypertension is often high in minority populations.

Risk factors for glaucoma need to be identified and verified. The question of whether there are susceptibility genes that can affect the course of the disease is being actively pursued. With advances in genetics, environmental effects also need to be understood so that researchers can better determine the interaction of genetics and environment in the natural history of this disease. Currently, important known risk factors for glaucoma include elevated IOP, advanced age, optic disc abnormalities, and family history of primary open-angle glaucoma. However, the contribution of each of these known risk factors to the progression of glaucoma is unknown. Questions remain concerning whether or not a compromised vascular system contributes to glaucomatous pathology. The difficulty of measuring ocular blood flow hampers progress in understanding its impact on the survival of retinal neurons and visual function.

Rigorous epidemiologic studies need to be conducted to reduce the number of gaps in knowledge about the nature and course of glaucoma. Well-designed studies that use systematically selected sample sizes (from census tract data, for example) have high rates of participation by the study sample, and use standard procedures for assessing disease and measuring risk factors needed to address these issues. There is also a critical need for better population-based screening procedures that are simple, inexpensive, portable, and effective. Developing such methods will be useful for testing populations that historically have limited access to formal health care systems, for determining more accurately the incidence and prevalence of glaucoma in epidemiologic studies, and for screening large populations in remote regions of the world.

1.1.1.2 Performance Measures

The NEI will continue to support the very best and highest quality research identified through the peer-review process. The NEI research portfolio will continue to be evaluated periodically through the strategic planning process to determine whether the needs and opportunities for glaucoma research are being adequately addressed. When necessary to stimulate research areas not adequately addressed in the portfolio, research solicitations in the form of Program Announcements, Requests for Proposals, or Requests for Applications will be issued. Research advances in the form of scientific publications will be reviewed yearly and assessed for progress in the following areas: adding to the body of knowledge about normal and abnormal biological functions related to glaucoma; developing new or improved approaches for preventing or delaying the onset of glaucoma and associated visual disability; developing new or improved methods for diagnosing glaucoma and related visual disability; and developing new or improved approaches for treating glaucoma and its related visual disability.

1.1.1.3 Outcome Measures

The NEI will support research that will build on the knowledge gained from its investment in the highest quality science and translate the findings of this research program to develop new treatments and diagnosis for glaucoma. The outcome of this support should be significant progress towards improving our understanding of the nature and course of glaucoma, incorporating studies of comorbidity, natural history, and genetics.

1.2 Area of Emphasis Two: Myopia

Myopia, or nearsightedness, is a common condition in which images of distant objects are focused in front of, instead of on, the retina, usually because the eye is too long. More than 30 years ago, scientists found that raising a variety of animals with a closed eyelid led to the development of myopia because the eye became elongated. Similar observations were made in human infants in whom trauma or some other disorder resulted in neonatal eyelid closure. Over the next three decades a clearer picture of some of the processes involved in the control of refractive error in growing eyes has emerged.

Rationale and Priority

Myopia occurs in approximately 25 percent of the population of the United States.[xvii,xviii] Myopia is an important public health problem, which entails substantial societal and personal costs. It is highly prevalent in our society and even more frequent in Asian countries; furthermore, its prevalence may be increasing over time. The most common form of myopia is childhood myopia, which begins after age 6 and progresses rapidly until age 16. Myopia progression results from excessive growth of the eye, primarily by enlargement of the vitreous chamber. Excessive elongation of the eye is a major risk factor for retinal detachment. A clinical study of myopia in first and second generation Hispanic, White, Asian, and Black immigrant students in this country demonstrated that Asian immigrants have a significantly higher prevalence of myopia.[xix] Increased prevalence of myopia among Alaskan Eskimos and some American Indian tribes also has been reported.[xx, xxi]

High myopia contributes to significant loss of vision and blindness. At present, the mechanisms involved in the etiology of myopia are unclear, and there is no way to prevent the condition. Current methods of correction require lifelong use of lenses or surgical treatment, which is expensive and may lead to complications.

After extensive argument about whether to attribute myopia to visual factors or genetic factors, experimentation on animals in the past two decades has provided a clearer, but as yet incomplete, picture of some of the processes involved in the control of refractive error in growing eyes. Two insights are especially important. First, images not focused on the retina guide the developing eye to correct for this defocus. Thus, animals with either hyperopia (farsightedness) or myopia imposed by spectacle lenses alter the shape of their eyes to bring the images back into focus. Second, changes in focus of images on the retina can cause changes in eye growth directly by a cascade of chemical signals from the retina to the sclera. Thus, in animals, normal refractive development and myopia of moderate severity may involve a visual feedback mechanism that controls eye growth. Recent evidence that this feedback occurs in primates suggests that these discoveries have substantial practical implications for the clinical treatment of myopia and other refractive disorders in humans, affording opportunities for testing this hypothesis in clinical trials.

The NEI is currently conducting a number of studies designed to provide more information on the development and prevention or treatment of myopia. One such study is the Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) Study. It is a multi-center, observational investigation of ocular development and refractive error development in schoolchildren. It adds three clinical centers to the Orinda Longitudinal Study of Myopia (OLSM), begun in 1989, specifically to describe normal ocular growth in children ages 6 to 14 years, and to develop the ability to predict juvenile onset myopia before it is clinically evident. In addition to the more than 1,300 predominantly Caucasian children enrolled in the OLSM, three additional clinical sites enroll African American, Hispanic, and Asian children. The children are examined annually for at least 4 years. The OLSM investigators have reported from their cross-sectional data that heredity is more important than the amount of near work or educational achievement in the development of myopia.[xxii] These investigators also were unable to link regions of chromosomes 12 and 18 that had previously been postulated to be linked to severe or high myopia to juvenile myopia.[xxiii]

Another study, the Correction of Myopia Evaluation Trial (COMET), is a multicenter, randomized, double-masked clinical trial designed to evaluate whether progressive addition lenses (PALs) slow the progression of juvenile-onset myopia as compared with single vision lenses. The primary outcome of the study was progression of myopia, defined as the magnitude of the change relative to baseline in spherical equivalent refraction, determined by cycloplegic autorefraction. The secondary outcome of the study was axial length measured by A-scan ultrasonography. Researchers found that the use of PALs slowed the progression of myopia by a small but statistically significant amount only during the first year, even though the size of the effect remained stable for the next 2 years.[xxiv] The size of the effect was insufficient to warrant a change in clinical practice. Additional analysis of the data from this study has suggested that a subset of children with myopia who are prescribed PALs or bifocal lenses because they do not accommodate adequately may have the additional benefit of slowed progression of their myopia.[xxv]

In a similar study being conducted in Oklahoma, the hypothesis that correction with bifocal spectacle lenses rather than single-vision lenses will slow the progression of myopia in children with near-point esophoria was tested. The primary outcome variable is refraction as measured with an automated refractor. Axial length was measured with ultrasound in order to test the corollary hypothesis that use of bifocals would slow ocular growth in these myopic children. The results of this study were similar to those of the COMET in that the progression of myopia was slowed by the use of bifocal lenses during the first 2 years of the study and the difference in myopia was maintained during a subsequent 2.5 years of study.[xxvi]

1.2.1 Objective Two: Risk Factors for Myopia

Determine the etiology of human myopia and identify the risk factors associated with this and other refractive errors so as to prevent their occurrence or progression.

1.2.1.1 Action Plan

Expand the knowledge of myopia by further characterizing the visual signals that govern eye growth. Identify the genes and gene products associated with these signaling mechanisms. Identify the human risk factors, environmental and genetic, for myopia and abnormal eye growth. Evaluate the efficacy of potential treatments, such as pharmacological approaches, special spectacles, and contact lenses, for slowing the progression of myopia.

In animal models, it is now accepted that visual circumstances can influence refractive error, and that this influence involves modification of the growth of the eye. Thus, a feedback mechanism is at work in ocular growth: visual input influences growth, which in turn modifies the visual input. Importantly, the influence of vision on growth can be communicated directly from the retina to the sclera without involvement of the brain. This view of the mechanisms of refractive adjustments has provoked a search for the visual cues the retina uses to discern whether to accelerate or retard the axial growth of the eye and for the signals, presumably chemical, by which the retina communicates to the sclera the appropriate direction of growth. The most provocative candidates are dopamine and acetylcholine because agonists and antagonists, respectively, reduce form-deprivation myopia in both birds and primates.

As knowledge of the underlying mechanisms that control eye growth and refractive compensation increases, the ability to assess the risk factors that predict the development of myopia in children or adults has increased as well. Reading is the most established risk factor for myopia. More recent observations have strengthened the association of the amount of near work with the rate of myopic progression. Several additional lines of research need to continue to be pursued.

Additional research is needed into how accommodation and convergence are related to myopia. Because the sharpness of the image during reading depends on the precision of accommodation, it is significant that myopic children have poorer accommodation than others.

The role that genetic factors play in the cause of myopia should be more fully explored. Refractive errors of monozygotic twins are more closely aligned than they are for dizygotic twins. A greater prevalence of myopia exists among the children of myopic parents than among the children of non-myopic parents. Recent studies of the eye in infancy have also shown that the seeds of myopia may appear early in development. Longitudinal studies of refractive error have suggested that some myopic children may have previously been myopic as infants.

There is a pressing need to determine how similar the biological mechanisms of eye growth are in different species, and how similar experimental models of myopia (by visual deprivation or the imposition of hyperopia by spectacle lenses) are to the myopia that develops in schoolchildren. Enough is presently known to begin to evaluate promising treatments for preventing the onset or slowing the progression of myopia and systematically investigate the risk factors associated with the development of myopia.

1.2.1.2 Performance Measures

The NEI will continue to support the very best and highest quality myopia research identified through the peer-review process. The NEI myopia research portfolio will continue to be evaluated periodically through the strategic planning process to determine whether the needs and opportunities for myopia research are being adequately addressed. When necessary to stimulate research areas not adequately addressed in the portfolio, research solicitations in the form of Program Announcements, Requests for Proposals, or Requests for Applications will be issued. Research advances in the form of scientific publications will be reviewed yearly and assessed for progress in the following areas: adding to the body of knowledge about normal and abnormal biological functions related to the development of myopia; developing new or improved approaches for preventing or slowing the onset or progression of myopia; and developing new or improved approaches for treating myopia.

1.2.1.3 Outcome Measures

The NEI will support research that will build on the knowledge gained from its investment in the highest quality science and translate the findings of this research program to develop new treatments and preventive strategies for myopia. The outcome for this support should be in increased knowledge about the identity of the visual error signals that govern eye growth during correction for refractive error. Progress also should be made in identifying human risk factors for myopia and abnormal eye growth and evaluating promising treatments for preventing the onset of or slowing the progression of myopia, such as special spectacles, contact lenses, or pharmacological treatments.

1.3 Area of Emphasis Three: Health Services Research

To understand the impact of eye disease and visual impairment on the Nation’s health, data are needed on the number and characteristics of people with various eye conditions, the effects of these conditions on quality of life, and the economic burden of these conditions. This information will serve to increase public awareness of the personal and societal costs of visual impairment and be useful to those who are interested in allocating adequate resources to Americans most in need of vision care services.

NATIONAL EYE INSTITUTE

Rationale and Priority

The NEI defines the field of health services research broadly to include such diverse topics as: increasing patient access to and utilization of vision care services, improving the delivery of vision services by eye care professionals, and measuring the visual health of patients receiving eye care services. Various studies have demonstrated the need to ensure patient access and utilization of vision care services particularly where treatments are available to improve or preserve vision. In Blacks, undertreatment has been reported for cataract, diabetic retinopathy, and glaucoma.[xxvii,xxviii,xxix,xxx]

A number of different scientific methodologies are used in conducting health services research projects. These include but are not limited to: clinical outcomes research of new or existing data, survey research techniques, translational research methods, decision and utility analytic methods, health economics, traditional epidemiologic methods, and randomized clinical trials. The selection of design methodology should be scientifically justified as appropriate for the research objectives of a given study.

Quality-of-life assessments have been incorporated into the design of several NEI-funded epidemiologic studies and clinical trials, therein recognizing that a patient’s quality of life is an important facet to consider in assessing visual health. In response to the need to more completely understand the impact of clinical interventions specifically on vision-related quality of life from a patient perspective, the NEI fostered the development and testing of a questionnaire, the NEI-Visual Functioning Questionnaire (NEI-VFQ), to collect this important information.

Findings from recent studies have shown that the majority of people having cataract extraction surgery subsequently report substantial improvement in their ability to see and to perform common, necessary daily activities.

Numerous studies have reported that a large number of people who have diabetes do not obtain an annual dilated eye examination. Currently funded projects are attempting to identify specific reasons why the medical system is failing to reach this population at increased risk of visual impairment. Other studies are testing specific interventions geared toward the patient or the eye care provider to increase the rates of ophthalmic screening among people with diabetes.

The NEI currently is supporting the Ophthalmic Complications Prevention Trial, designed to evaluate the efficacy of an inexpensive telephone-based educational intervention to promote annual ophthalmic screening among low-income African Americans with diabetes. This intervention doubled the dilated ophthalmic examinations in the intervention group compared with the standard care group.[xxxi]

As stated above, the NEI and NCMHD supported a major research project in Los Angeles County, California, the Los Angeles Latino Eye Study, to gain a greater understanding of the prevalence and incidence of eye disease among Latinos. Researchers have conducted in-depth interviews with study participants on their medical and ophthalmic histories, use of medications, tobacco and alcohol consumption, and utilization of health care services. Because so little is known about the visual health needs of this segment of the population, the data collected from this study will be instrumental in determining the prevalence of cataract, glaucoma, age-related macular degeneration, and diabetic retinopathy among Latinos in this community. The study also will determine the proportion of blindness and visual impairment that is caused by these diseases, and will explore the association of various risk factors, such as smoking or sun exposure, with ocular disease. The study also will examine the effect of eye diseases and disorders on quality of life and will assess the cost/benefit of eye care services and the utilization of those services in the Los Angeles Latino community. Results from the various components of this study are just beginning to appear in the medical literature. The first series of reports confirms a high rate of visual impairment in this population compared to other racial or ethnic groups, particularly in female and older Latinos.[xvi] Future reports may help clarify the reasons for this increased prevalence of visual impairment in urban Latinos.

The NEI and NCMHD also funded the Midwest Latino Health Research, Training, and Policy Center to develop a Spanish/English diabetic eye disease module to be included in the Diabetes Health Promoters train-the-trainer curriculum developed to train community lay persons who have diabetes to become diabetes educators/outreach workers.

Another study supported by the NEI that is designed to improve our understanding of eye disease and visual impairment in the Hispanic population in this country is a study known as Proyecto VER (Vision Evaluation and Research). This study collected data to determine the prevalence of diabetic retinopathy, cataract, and other causes of blindness and visual impairment in 4,500 Mexican Americans age 40 years and older residing in Arizona. The study reported that the leading cause of blindness in this population was open-angle glaucoma.[xxxii] Additionally, those with low income seemed to be at higher risk for diabetes and its ocular complications than those with higher incomes.[xxxiii] The NEI and NCMHD are currently supporting the Multiethnic Pediatric Eye Disease Survey, a population-based study designed to improve understanding of the extent and the causes of eye diseases in African-American, Latino, Asian, and non-Hispanic White children. This survey will assess the demographic, biological, and behavioral risk factors associated with refractive error, strabismus, and amblyopia and the consequences of these diseases from a health-related quality of life perspective.

1.3.1 Objective One: Impact of Vision Impairment on the Nation's Visual Health

Assess the impact of eye disease and visual impairment on the Nation's health and determine the most appropriate use of diagnostic strategies and treatments scientifically demonstrated to improve vision and preserve sight.

1.3.1.1 Action Plan

Determine the number of Americans with eye disease and visual impairment and measure the impact on medical costs and costs to society associated with these conditions. Identify the factors associated with the most effective delivery and use of vision care services. Basic information on the visual health of the U.S. population is critical for increasing public awareness of the effects and costs of visual impairment, assessing the need for eye care services, evaluating the delivery of vision care, and setting priorities for vision research. However, gathering detailed ophthalmic data on a large, nationally representative sample, while scientifically preferred, is not practical. During the past decade, studies on three large ethnically and geographically different populations have generated information on the prevalence of and risk factors associated with eye disease and vision loss. Long-term follow-up of these groups of Caucasians and African Americans is providing additional information on the frequency of new cases of eye disease. Similar information is needed on children and minority populations of all ages, particularly Hispanics and East Asians. Continued emphasis on several important lines of health services research is needed.

Complete estimates of the economic and social costs of Americans with eye disease and visual impairment are needed. Previous economic analyses of the costs associated with eye conditions have generally been limited to consideration of direct medical costs to the patient or third-party payers, and to indirect costs to society in the form of tax deductions or disability payments. Given that the onset of visual loss can be gradual and that the loss can worsen over time, the true costs of visual impairment are difficult to estimate. The magnitude of direct and indirect medical costs, as well as the costs to society, depends on a number of factors, including: the nature and severity of the visual impairment; the nature and severity of other illnesses; a patient's age, socioeconomic status, and family setting; cultural expectations regarding self-reliance and independence; attitudes about health and health care; and the part of the country where the person lives. All of these factors need to be considered in subsequent research efforts. Also of importance are costs associated with changes required in the home or workplace that allow visually impaired persons safely to go about their daily activities and income lost by family members who may have to reduce their hours of gainful employment or quit their jobs to care for a family member who has a visual deficit.

It is particularly important to study ethnically diverse populations because there are both genetic and environmental determinants of eye disease. Additional epidemiologic studies on Hispanic, East Asian, and American Indian and Alaska Native populations are needed to provide regional estimates of disease and to identify risk factors, quality-of-life considerations, and access to care issues, which may differ by ethnic group. National estimates of disease burden among Caucasians and African Americans may be more readily available using methods like mathematical modeling techniques to extrapolate these data from rates of disease found in NEI-funded community-based studies.

Research to examine the delivery and utilization of vision care is of the utmost importance due to the increasing number of Americans covered by managed care plans. Little is known about the quantity and quality of eye care services offered to different segments of the American population, or how the changing patterns of delivering vision care services influence a person's access to and utilization of appropriate, high-quality vision care. With a characterization of the eye care services offered by providers in different health systems, it may be possible to design and test specific interventions to improve the delivery and utilization of vision care and thereby reduce rates of blindness and visual impairment.

Analytical studies are needed to evaluate the movement toward fully automated medical records. These analyses may provide a cost-efficient opportunity to study patterns of care across a variety of health care delivery settings. Automated systems may be especially useful for monitoring changes in the content, cost, and use of vision care services. It is important to note, however, that persons in systems of care with automated records may be different from the general population.

1.3.1.2 Performance Measures

The NEI will continue to support the very best and highest quality health services research identified through the peer-review process. The NEI health services research portfolio will continue to be evaluated periodically through the strategic planning process to determine whether the needs and opportunities for health services research are being adequately addressed. When necessary to stimulate research areas not adequately addressed in the portfolio, research solicitations in the form of Program Announcements, Requests for Proposals, or Requests for Applications will be issued. Research advances in the form of scientific publications will be reviewed yearly and assessed for progress in the following areas: development of new or improved instruments and technologies that will aid in the delivery of medicine to all Americans; development of new or improved approaches for preventing or delaying the onset of disease and disability that will reduce the burden of disease in all ethnic and racial groups; development of new or improved methods for diagnosing disease and disability that will reduce the burden of disease in all ethnic and racial groups; and development of new or improved approaches for treating disease and disability that will reduce the burden of disease in all ethnic and racial groups.

1.3.1.3 Outcome Measures

The NEI will support health services research that will build on the knowledge gained from its investment in the highest quality science and translate the findings of this research program to improve health services. The outcome of this research will help determine the number of Americans with eye disease and visual impairment and measure the impact on medical costs and costs to society associated with these conditions. It will also help identify the factors associated with the most effective delivery and use of vision care services.

1.4 Area of Emphasis Four: Diabetic Retinopathy

Diabetes mellitus is one of the leading causes of death in this country and throughout the world and is also a major cause of blindness. One of the ocular complications of diabetes is diabetic retinopathy.

Diabetic retinopathy causes excessive vascular permeability and is typically accompanied by neovascularization with ballooning of the retinal capillaries to form microaneurysms. The blood-retinal barrier may break down within these microaneurysms, causing leakage of blood proteins with subsequent hemorrhage into the retina and visual loss. Newly formed blood vessels tend to break through the retinal surface, which may result in hemorrhage into the vitreous and in traction retinal detachment, where the retina is pulled away from the underlying choroid. Because of the prevalence of diabetes, diabetic retinopathy is a major cause of blindness.

Rationale and Priority

The Centers for Disease Control and Prevention (CDC) estimated that there were 18.2 million Americans with diabetes in the year 2002, but that only 13 million have been diagnosed. Almost 800,000 new cases are diagnosed annually. The CDC also reports that African Americans, Hispanic/Latino Americans, American Indians, and some Native Hawaiians and other Pacific Islanders are at particularly high risk for type 2 diabetes.[xxxiv] Although the incidence of insulin-dependent diabetes mellitus (IDDM) in Whites is nearly twice the incidence in Blacks, the prevalence of non-insulin-dependent diabetes mellitus (NIDDM) is between 1.4 and 2.3 times higher in Blacks than in Whites. Similarly, the prevalence of NIDDM is two to three times higher in Hispanics than in non-Hispanic Whites. The prevalence of the disease in U.S. Hispanics varies by geographic location and education.[xxxv,xxxvi]

A meta-analysis of data from eight population-based surveys indicated that there are 4.1 million adults in the U.S. with diabetic retinopathy, or one person for every 12 with diabetes. This study also found that diabetic retinopathy was more prevalent in Hispanics and Blacks compared to Whites and that vision-threatening diabetic retinopathy was likewise more prevalent in these groups compared to Whites.[xxxvii]

With the increased prevalence of NIDDM in Mexican Americans, studies have shown that there is also a significantly increased risk of severe retinopathy.[xxxviii] Diabetic retinopathy has also been shown to occur more often in Blacks than in Whites, but this difference was not explained by differences in risk factors alone. Rather, the results suggested that the differences may be due to a greater susceptibility to the adverse effects of hyperglycemia and/or high blood pressure.[xxxix] A recent study suggested that a high percentage of Blacks with type 1 diabetes do not receive adequate care, and improvements in screening and access to eye care professionals is needed.[xl] Another study found that being eligible both for Medicare and Medicaid was associated with not receiving routine diabetes care.[xli]

Although these associations may help explain the increased prevalence and severity of diabetic retinopathy in Blacks, it does not explain the excess prevalence and disease severity in Mexican Americans with NIDDM.[xlii] Previous studies have demonstrated that disease duration, increased hyperglycemia, diagnosis at an earlier age, and the need for insulin treatment are associated with increased prevalence of diabetic retinopathy in both Mexican Americans and Caucasians.

Interestingly, no association was found with socioeconomic status.[xliii] The finding that a high percentage of Blacks and Hispanics have severe diabetic retinopathy at initial presentation for treatment strongly argues for earlier referral from primary care physicians and increased public education efforts.[xliv] Although currently recommended treatments are over 95 percent effective in preventing further vision loss, about half of those who could benefit from treatment are being treated.

Vascular endothelial growth factor (VEGF) has become a leading candidate for the long-sought agent responsible for neovascularization in retinal diseases. Retinal neovascularization is often associated with retinal ischemia and hypoxia. Hypoxia induces VEGF production. VEGF is present at high concentrations in the vitreous fluid of patients with proliferative diabetic retinopathy and is low to absent in the vitreous of patients with nonvasoproliferative disease. VEGF levels are high in the retina and vitreous of animals with experimental retinal or iris neovascularization, and methods that block VEGF action (e.g., neutralizing antibodies, soluble receptors, or antisense DNA) prevent neovascularization. In human eyes with retinal and choroidal vascular diseases, and in experimental animals, VEGF is localized primarily in the glial cells of the retina and optic nerve, and in the retinal pigment epithelium (RPE) cells. Although hypoxia has not been identified in choroidal neovascular diseases, VEGF has been reported in the RPE cells of choroidal neovascular membranes. Although macular edema and neovascularization apparently result when VEGF is upregulated during certain pathologic processes, the normal function of VEGF may be to stimulate blood vessel growth in fetal development. Mice with a targeted disruption of the VEGF gene die in embryo due to defective vascular development.

Another growth factor that has shown promise in the control of angiogenesis is pigment epithelium-derived growth factor (PEDF), a protein found in the healthy eye. PEDF is secreted by the retinal pigment epithelial cells that underlie and nourish the neural retina. Recently, a team of scientists demonstrated that PEDF can transiently delay the death of photoreceptors in mouse models of inherited retinal degenerations. This protein has also been shown to promote neurite-outgrowth and protect spinal cord motor neurons against natural and induced death using cell culture and animal model systems. Another group of scientists has shown that PEDF can prevent the growth of endothelial cells that form new blood vessels. Thus, PEDF behaves as a potent neurotrophic factor for the retina and nerves of the central nervous system, as well as a potent inhibitor of angiogenesis. Continued research to learn how PEDF works may provide information that will contribute to the development of effective treatments for several neural degenerative and angiogenic diseases, such as retinitis pigmentosa, macular degeneration, and diabetic retinopathy.[xlv, xlvi]

Another new therapeutic agent has been developed that may be important in treating blindness in humans caused by diabetic retinopathy or macular degeneration. The new drug, called PKC 412, can be taken orally and appears to have several actions on growth factors and their receptors within the retina. Although PKC 412 blocks new abnormal vessel growth, it has no apparent adverse effects on normal, fully mature vessels. Additional research is needed to determine whether PKC 412 is a viable therapeutic alternative in the treatment of diabetic retinopathy.[xlvii]

In diabetic retinopathy, glucose may exert its deleterious effects by directly modifying the expression of genes. Cultured retinal pericytes grown in high glucose show differences in gene expression when compared to cells grown in normal glucose. Basement membranes of blood vessels from diabetic or galactosemic animals contain a profile of collagens different than basement membranes of control animals, suggesting altered expression of genes. Similarly, when animals in poor diabetic "control" or those maintained on high-galactose diets for a short time are switched to "tight" control or a normal diet, it is possible to delay by several years the development of diabetic retinopathy. The Diabetes Control and Complications Trial and its follow-up showed that the delay of onset and possible prevention of diabetic eye disease was due to tight control of glycemic levels. This study has made a significant contribution to patient welfare and quality of life.

A role for pituitary-associated factor in diabetic retinopathy has been appreciated for many years. Several decades ago, retinal neovascularization was found to regress after pituitary ablation in diabetic patients and appeared to be related to postsurgical growth hormone (GH) deficiency. In addition, insulin-like growth factor-1 (IGF-1) appears to be associated with proliferative retinopathy. To investigate the role of GH and IGF-1 in ischemia-induced retinal neovascularization and its interaction with VEGF, transgenic mice were studied. It was found that systemic inhibition of GH, IGF-1, or both may have therapeutic potential in preventing some forms of retinopathy.

Current research efforts continue to focus on the development of improved pharmacologic agents that will prevent or cause the regression of retinal or choroidal neovascularization. Studies are continuing to determine the role of tissue hypoxia in VEGF upregulation and expression. The role of oxidation products in the pathogenesis of retinal vascular diseases also is being studied, as well as the role of antioxidants that may be used therapeutically to retard this pathogenesis.

In spite of the finding that laser therapy has been highly successful in preventing vision loss from proliferative diabetic retinopathy, it has been estimated that up to 50 percent of patients that could benefit from treatment are not receiving appropriate treatment. This suggests that current public and professional education efforts are essential to preserving the vision of diabetic patients. The NEI has also established a clinical research network of core centers and participating clinics that will help satisfy the need to evaluate promising new approaches to treat diabetes-induced retinal disorders and to investigate other approaches as they become available. This network approach will provide a framework for rapid initiation of important studies, efficient use of pooled clinical expertise in idea generation and protocol development, and efficient use of central resources for data management, quality control, and endpoint evaluation.

1.4.1 Objective One: Preventing and Treating Diabetic Retinopathy

Understand the pathogenesis of diabetic retinopathy and other vascular diseases of the retina and develop strategies for primary prevention and improved treatment.

NATIONAL EYE INSTITUTE

1.4.1.1 Action Plan

Investigate the pathogenesis of vascular diseases of the retina and choroid, including diabetic retinopathy; develop better methods of prevention and therapy. Recent advances have provided the identification and characterization of factors and proteins that may play a critical role in the management of diabetic retinopathy. Research needs to continue on a variety of fronts.

There is a need to test new therapeutic approaches with potentially useful agents such as VEGF neutralizing agents, inhibitors of isoform of protein kinase C (PKC), aminoguanidine, and inhibitors of aldose reductase. Collaborations between NIH investigators and the private sector should be encouraged.

It is important to understand the metabolism of these cells in diabetes, because neural cells in the retina are primary sources of vasoactive compounds such as VEGF.

Molecular techniques and animal models need to be developed to allow study of genetic factors involved in the disease to increase the pace of discovery of genetic factors involved in diabetic retinopathy. It is important to identify key genes as well as the mechanisms involved in hyperglycemia. Chronic hyperglycemia is the hallmark event for the development and progression of the disease, and hyperglycemia can act through its effect on genetically controlled mechanisms.

It is important to undertake molecular studies of the embryonic development of the blood-retinal barrier, the molecular mechanisms of its maintenance in adult life, and its breakdown in diseased states, because the blood-retinal barrier is often compromised in the diabetic state. Since oxidative processes may be involved in diabetic retinopathy, the measurement of toxic oxidation products in tissues and evaluation of antioxidant enzymes by direct enzyme assay of small tissue samples are needed. The preventive effects of antioxidant compounds on lesions putatively caused by toxic oxidation products need to be tested in experimental animals or in human clinical trials.

1.4.1.2 Performance Measures

The NEI will continue to support the very best and highest quality diabetic retinopathy research identified through the peer-review process. The NEI diabetic retinopathy research portfolio will continue to be evaluated periodically through the strategic planning process to determine whether the needs and opportunities for diabetic retinopathy research are being adequately addressed. When necessary to stimulate research areas not adequately addressed in the portfolio, research solicitations in the form of Program Announcements, Requests for Proposals, or Requests for Applications will be issued. Research advances in the form of scientific publications will be reviewed yearly and assessed for progress in the following areas: adding to the body of knowledge about normal and abnormal biological functions related to the development of diabetic retinopathy; developing new or improved approaches for preventing or slowing the onset or progression of diabetic retinopathy; and developing new or improved approaches for treating diabetic retinopathy.

1.4.1.3 Outcome Measures

The NEI will support research that will build on the knowledge gained from its investment in the highest quality science on diabetic retinopathy and translate the findings of this research program to improved treatments and prevention strategies for the ocular complications associated with diabetes. The outcome of this line of research will be to understand the pathogenesis of vascular diseases of the retina and choroid, including diabetic retinopathy, and develop better methods of prevention and therapy to improve the visual health of those with diabetic retinopathy.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Training of Minority Scientists

The strategies of developing a well-trained pool of laboratory and clinical scientists for the future must include the achievement of scientific literacy through innovative science education programs at the elementary level through high school for all students regardless of age, gender, or cultural, racial, or ethnic background. The NEI must take full advantage of the changes in the demographic patterns of the workforce and make special efforts to foster the scientific careers of women and minorities and other underrepresented groups. Programs of support for specific training in visual sciences at graduate and postgraduate levels must convince students that their educational endeavors will be rewarded with opportunities for productive careers and research support. Therefore, the NEI's emphasis on individual investigator-initiated research project grants must continue to be given high priority.

2.1.1 Objective One: Career Development

Ensure the proper resource requirements through training/career development.

2.1.1.1 Action Plan

Continue to attract a greater diversity of scientists into vision research using the NIH-wide program of Research Supplements to Promote Diversity in Health-Related Research. New vision researchers must come in greater measure from members of groups that have been shown to be underrepresented. Members of groups that are underrepresented in science in this country are an important source of talent, and outreach efforts should be continued. Since the National Advisory Eye Council's (NAEC) last major planning effort, lack of marked success in increasing diversity of the workforce in biomedical science, including vision research, clearly makes the case for the need for new strategies. The NEI has enthusiastically participated in NIH-wide special programs, such as the Research Supplements to Promote Diversity in Health-Related Research Program, that reach out to underrepresented groups to increase the diversity of the scientific workforce. The Council reaffirms its recognition that progress in this area can come only if potential laboratory and clinical scientists seek and obtain sufficient grounding in fundamental levels of biological, physical, and mathematical sciences. This means that programs must begin at the elementary school and junior high school levels. The vision community must become involved in vision science programs at local schools, sharing the excitement and enthusiasm of science. Vision research organizations may be able to assist with these outreach programs nationwide. A school program called “Vision,” for children in grades 4 through 8, was developed by the NEI in cooperation with The Association for Research in Vision and Ophthalmology. This program is a series of three lessons that was designed for vision researchers and eye care professionals for school classroom visits.

2.1.1.2 Performance Measures

The NEI will monitor the number of supplements that are awarded each year to support underrepresented minorities who are pursuing careers in eye and vision research.

2.1.1.3 Outcome Measures

The NEI will build on successful strategies that have recruited minorities and other underrepresented groups into basic and clinical eye and vision research.

2.2 Area of Emphasis Two: Minority Representation in Clinical Trials

The NEI and NAEC fully endorse and support the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. Because the primary aim of research is to provide scientific evidence leading to a change in health policy or a standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently. To this end, the NIH guidelines are intended to ensure that all future NIH-supported biomedical and behavioral research involving human subjects will be carried out in a manner sufficient to elicit information about individuals of both genders and diverse racial and ethnic groups and, in the case of clinical trials, to examine differential effects on such groups. Increased attention, therefore, must be given to gender, race, and ethnicity in earlier stages of research to allow for informed decisions at the Phase III clinical trial stage. The guidelines reaffirm NIH’s commitment to the fundamental principles of inclusion of women and racial and ethnic minority groups and their subpopulations in research. This policy will continue to provide a variety of new research opportunities to address significant gaps in knowledge about health problems that affect women and racial/ethnic minorities and their subpopulations.

The guidelines require that when a Phase III clinical trial is proposed, evidence must be reviewed to show whether or not clinically important gender or race/ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology, and other relevant studies.

2.2.1 Objective One: Inclusive Clinical Trials

Continue to ensure that all clinical trials that are funded by the NEI adhere to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

2.2.1.1 Action Plan

Ensure that all clinical trials funded by the NEI adhere to the NIH Guidelines on the inclusion of Women and Minorities as Subjects in Clinical Research. This will be an ongoing effort that will continue throughout the period of this plan and not incur any significant costs.

2.2.1.2 Performance Measures

The NEI will closely monitor all clinical trials and applications to assure that appropriate numbers of women and minorities are included.

2.2.1.3 Outcome Measures

The NEI will strongly enforce the tenets of the NIH Guidelines on the inclusion of women and minorities, and the NEI will communicate to clinical research applicants the need to include women and minorities in their clinical protocols.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: National Eye Health Education Program

In 1989, the NEI launched the NEHEP, with the goal of increasing awareness among health care professionals and the public of scientifically based health information that can be applied to preserving sight and preventing blindness. Numerous organizations (more than 70 in all) from both the public and private sectors joined in partnership with the NEHEP. Working together, these partners endeavor to reach select target audiences, informing them of the importance of early detection and treatment of eye diseases, particularly glaucoma and diabetic retinopathy, and persuading them to make an appropriate change in behavior. The NEHEP currently has three major ongoing education/outreach programs.

3.1.1 Objective One: Outreach for Visual Health

Continue to increase awareness among health care professionals and the public of scientifically based health information that can be applied to preserving sight and preventing blindness.

3.1.1.1 Action Plan

Provide culturally specific and appropriate messages for all NEHEP content areas and materials; increase the representation of racial and ethnic populations and organizations in the NEHEP partnership and continue to facilitate the national dialogue among current and future NEHEP partnership members.

The NEHEP partnership initially identified two target audiences for the diabetes education program: people with diabetes and health care professionals. They also recommended that messages be directed to family members and other groups, including educators and clergy. Subsequent phases of the Program included groups in which diabetes is more prevalent than in the general population, including American Indians and Alaska Natives, Hispanics/Latinos, and African Americans. The NEHEP has developed the Educating People with Diabetes Kit for health professionals and *Ojo Con Su Visión* (Watch Out for Your Vision), a Spanish-language booklet, designed to educate Hispanics/Latinos with diabetes about the ocular complications of the disease. The Ojo Con Su Visión Program, launched in 1995, has expanded to include culturally and linguistically appropriate outreach for all three of the NEHEP Program areas. Most recently, a Spanish-language general eye health brochure was developed to provide information to Hispanics/Latinos about eye health and eye diseases. This unique brochure covers information on comprehensive eye exams, four common diseases that can affect vision, refractive errors, and myths and facts about eye care, among other topics.

Participants in the NEHEP Planning Conference identified three target audiences for glaucoma education: glaucoma patients, the general public, and health care professionals. The current general primary target groups are African Americans over age 40 and anyone over age 60. It also will be important to reach eye care and other health care professionals to help motivate the at-risk populations to have regular eye exams. Educating the general public is a means to ensuring long-term success. The Glaucoma Public Education Program consists of a *Glaucoma Community Education Kit* that community agencies can use to conduct glaucoma awareness activities and comprehensive public service campaigns emphasizing early detection.

In late 1999, the NEHEP launched a new program for the purpose of addressing the impact of low vision on those who have it and to bring the message to them, their families, and the health and service professionals who care for them that information and help are available. The two primary audiences are: (1) people age 65 and older who have decreased visual function that interferes with their activities of daily living; and (2) people under age 65 who are particularly at risk for low vision (i.e., Hispanic/Latino and African American populations). NEHEP is an ongoing activity of the NEI that will continue on to 2006 and beyond.

In June 2002, the NEI formed an ad hoc working group on American Indian and Alaska Native Outreach, with representation from diverse regions, tribes, eye care professionals, and national organizations including NEHEP partners. The goal of the meeting was to obtain input and guidance on developing a diabetic eye disease education and outreach program for American Indians and Alaska Natives. Research with American Indians and Alaska Natives was conducted to gain a better understanding of the knowledge, awareness, and approaches related to diabetic eye disease among these populations and their communities.

In January 2004, the NEHEP launched its American Indian and Alaska Native Diabetic Eye Disease Outreach Program. The specific objectives of this Program are to:

- Increase awareness of diabetic eye disease, particularly diabetic retinopathy, among American Indians and Alaska Natives with diabetes.
- Increase knowledge of diabetic retinopathy among American Indians and Alaska Natives with diabetes, stressing that the disease does not present symptoms during its early stages and that it can lead to blindness.
- Increase knowledge that the risk of vision loss from diabetic eye disease can be reduced with early detection and timely treatment.
- Encourage American Indians and Alaska Natives with diabetes to have annual comprehensive eye examinations with dilated pupils by trained eye care professionals.
- Encourage American Indians and Alaska Natives with diabetic eye disease to adhere to the recommended treatments.
- Provide culturally appropriate information on diabetic eye disease to accomplish more easily the objectives mentioned above.
- Provide information on diabetic eye disease in adaptable materials to accomplish more easily the objectives mentioned above.

3.1.1.2 Performance Measures

The NEHEP partnership will pretest the materials that it plans to distribute with focus groups to determine the effectiveness of the materials used to communicate NEHEP’s message to its target populations. An analysis of public queries to the NEI Office of Health Education, Communication, and Public Liaison also will be conducted to determine if the products that NEHEP produces are having a positive impact on the public’s knowledge of eye health.

3.1.1.3 Outcome Measures

The NEHEP partnership will make changes based on the results of its evaluation of the program to ensure that the program continues to be effective in communicating to the public information about eye health and eye disease.

3.2 Area of Emphasis Two: *Healthy People 2010*: Vision and Hearing Chapter

Healthy People 2010 represents the ideas and expertise of a diverse range of individuals and organizations concerned about the Nation’s health. The Healthy People Consortium—an alliance of more than 350 national organizations and 250 state public health, mental health, substance abuse, and environmental agencies—conducted three national meetings on the development of *Healthy People 2010*. Members of the voluntary, scientific, and professional organizations that comprise the vision research community joined forces to recommend the inclusion of a section on the visual health needs of the Nation. The NEI agreed to serve as a co-lead agency and support the inclusion of a chapter on vision. Both vision and hearing were selected to share the lead of a new chapter on Vision and Hearing in *Healthy People 2010*. A workgroup already has been formed, and the initial focus of the group is to develop the necessary data sources to assess progress in accomplishing the program's objectives.

As a means of stimulating collaborative community health education initiatives related to vision, the NEI established the Healthy Vision 2010 Awards Program in an effort to accomplish the vision-related objectives in *Healthy People 2010.* This program was designed to strengthen the capacity of community-based organizations by providing "seed money" to begin or continue vision-related health education projects. These awards provide NEI with opportunities to establish partnerships that extend the reach and effectiveness of its work. The following are examples of awards made in FY2003:

- A Hispanic outreach project will increase awareness of and referrals for vision rehabilitation services and adaptive devices and will use its existing Project Eye Care network of community sites to target underserved and uninsured populations in the Greater Rochester area and Finger Lakes region.
- One center's educational program will educate Chinese Americans who have diabetes about diabetic retinopathy and the importance of early detection and treatment. The program will feature educational workshops, a media campaign, and collaboration with Asian community organizations.
- Health professionals will provide education, referral, and follow-up services to American Indians with diabetes in tribal locations in three southwestern Oklahoma counties. A train-the-trainer approach will be used to train project staff in delivering culturally and linguistically sensitive information about eye disease.
- One program targets people with diabetes, primarily African Americans and uninsured, underinsured, and medically underserved people, in three counties. Planned activities include health fairs and workshops, patient counseling, and media relations.
- One project will use its food distribution centers, which serve 43,000 people a month, to provide educational materials about glaucoma and diabetic retinopathy. Cards attached to food bags will promote free screening clinics. The organization serves primarily older African Americans who are economically disadvantaged and medically underserved.
- A center will conduct outreach to older adults in seven Choctaw communities and provide onsite vision screening and follow-up, patient transportation, eye health education, and referrals. Collaborative efforts will include community centers and other tribal programs.
- One project will raise awareness of age-related eye diseases and provide screening for Hispanic, African American, and American Indian residents of three rural communities.

- Older adults and Hispanics/Latinos with diabetes in a small rural community 20 miles from the Mexican border will receive professional eye health services as well as information and educational materials about diabetic retinopathy and other eye diseases.
- A broad-based media and outreach campaign will feature culturally sensitive brochures and public service announcements for stations serving the Lake Traverse Reservation. To address the rapid increase in diabetes and its complications among tribal youth, the campaign will demonstrate a human eye model in school presentations and at health fairs.
- A project will provide low-income Hispanic/Latino immigrants who have diabetes with information about diabetic retinopathy and glaucoma, which disproportionately affects people with diabetes. The center's five clinics will facilitate access to annual comprehensive dilated eye exams.

3.2.1 Objective One: Increasing Quality of Life

Increase quality and years of healthy life and eliminate health disparities.

3.2.1.1 Action Plan

- *Increase the proportion of persons who have a dilated exam at appropriate intervals.*
- *Increase the proportion of preschool children aged 5 years and under who receive vision screening.*
- *Reduce uncorrected visual impairment due to refractive errors.*
- *Reduce blindness and visual impairment in children aged 17 and under.*
- *Reduce visual impairment due to diabetic retinopathy.*
- *Reduce visual impairment due to glaucoma.*
- *Reduce visual impairment due to cataract.*
- *Reduce occupational eye injury.*
- *Increase the use of appropriate personal protective eyewear in recreational activities and hazardous situations around the home.*
- *Increase the use of vision rehabilitation services and adaptive devices by people with visual impairments.*

Healthy People 2010 is a 10-year plan to improve the health of the American people.

3.2.1.2 Performance Measures

A mid-course evaluation will be performed in 2005 to assess of the progress that has been made toward achieving the goals set forth in *Healthy People 2010*.

3.2.1.3 Outcome Measures

Based on the results of the mid-course review, strategies for achieving the goals of *Healthy People 2010* will be adjusted to enhance the probability of achieving those goals by 2010.

REFERENCES

---

i. The Eye Diseases Prevalence Research Group: Causes and prevalence of visual impairment among adults in the United States. Arch Ophthalmol 122:477-485, 2004.

ii. Coleman AL: Glaucoma. Lancet 354(9192):1803-1810, 1999.

iii. The Eye Diseases Prevalence Research Group: Prevalence of open-angle glaucoma among adults in the United States. Arch Ophthalmol 122:532-538, 2004.

iv. Higginbotham EJ: Glaucoma: A preventable cause of blindness. Md Med J 46(8):412-414, 1997.

v. Klein BE, Klein R, Sponsel WE, Franke T, Cantor LB, Martone J, Menage MJ: Prevalence of glaucoma. The Beaver Dam Eye Study. Ophthalmology 99(10):1499-1504, 1992.

vi. Tielsch JM, Sommer A, Katz J, Royall RM, Quigley HA, Javitt J: Racial variations in the prevalence of primary open-angle glaucoma. The Baltimore Eye Survey. JAMA 266(3):369-374, 1991.

vii. Leske MC, Connell AM, Schachat AP, Hyman L: The Barbados Eye Study. Prevalence of open angle glaucoma. Arch Ophthalmol 112(6):821-829, 1994.

viii. Javitt JC: Preventing blindness in Americans: the need for eye health education. Surv Ophthalmol 40(1): 41-44, 1995.

ix. The AGIS Investigators: Advanced Glaucoma Intervention Study (AIGS): 4. Comparison of treatment outcomes within race. Ophthalmology 105(7):1146-1164, 1998.

x. Kass MA, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JL, Miler JP, Parrish II RK, Wilson MR, Gordon MO, for the Ocular Hypertension Treatment Study Group: The ocular hypertension treatment study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. Arch Ophthalmol 120:701-713, 2002.

---

xi. Higginbotham EJ, Gordon MO, Beise JA, Drake MV, Bennett GR, Wilson MR, Kass MA, for the Ocular Hypertension Treatment Study Group: The ocular hypertension treatment study: topical medication delays or prevents primary open-angle glaucoma in African American individuals. Arch Ophthalmol 122:813-820, 2004.

xii. Heijl A, Leske MC, Bengtsson B, Hyman L, Bengtsson B, Hussein M, for the Early Manifest Glaucoma Trial Group: Reduction of intraocular pressure and glaucoma progression: results from the early manifest glaucoma trial. Arch Ophthalmol 120:1268-1279, 2002.

xiii. Lichter PR, Musch DC, Gillespie BW, Guire KE, Janz NK, Wren PA, Mills RP, CIGTS Study Group: Interim clinical outcomes in the collaborative initial glaucoma treatment study (CIGTS) comparing initial treatment randomized to medications or surgery. Ophthalmology 108:1943-1953, 2001.

xiv. Gordon MO, Beiser JA, Brandt JD, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JL, Miller JP, Parrish II RK, Wilson MR, Kass MA, for the Ocular Hypertension Treatment Study Group: The ocular hypertension treatment study: baseline factors that predict the onset of primary open-angle glaucoma. Arch Ophthalmol 120:714-720, 2002.

xv. Neufeld AH, Sawada A, and Becker B: Inhibition of nitric-oxide synthase 2 by aminoguanidine provides neuroprotection of retinal ganglion cells in a rat model of chronic glaucoma. Proc Natl Acad Sci USA 96:9944-9948, 1999.

xvi. Varma R, Mei Ying-Lai MS, Klein R, Azen S, Los Angeles Latino Eye Study Group: Prevalence and risk indicators of visual impairment and blindness in Latinos. Ophthalmology 111(6):1132-1140, 2004.

xvii. Sperduto RD, Seigel D, Roberts J, Rowland M: Prevalence of myopia in the United States. Arch Ophthalmol 101:405-407, 1983.

xviii. The Eye Diseases Prevalence Research Group: The prevalence of refractive errors among adults in the United States, western Europe, and Australia. Arch Ophthalmol 122:495-505, 2004.

xix. Voo I, Lee DA, Oelrich FO: Prevalences of ocular conditions among Hispanic, White, Asian, and Black immigrant students examined by the UCLA Mobile Eye Clinic. J Am Optom Assoc 69(4):255-261, 1998.

xx. Van Rens GH, Arkell SM: Refractive errors and axial length among Alaskan Eskimos. Acta Ophthalmol (Copenh) 69(1):27-32, 1991.

xxi. Maples WC, Atchley J, Ashby W, Ficklin T: An epidemiological study of the ocular and visual profiles of Oklahoma Cherokees and Minnesota Chippewas. J Am Optom Assoc 61(10):784-788, 1990.

xxii. Mutti DO, Mitchell GL, Moeschberger ML, Jones LA, Zadnik K: Parental myopia, near work, school achievement, and children's refractive error. Invest Ophthalmol Vis Sci 43:3633-3640, 2002.

xxiii. Mutti DO, Semina E, Marazita M, Cooper M, Murray JC, Zadnik K: Genetic loci for pathological myopia are not associated with juvenile myopia. Am J Med Genet 112:355-360, 2002.

xxiv. Gwiazda J, Hyman L, Hussein M, Everett D, Norton TT, Kurtz D, Leske MC, Manny R, Marsh-Tootle W, Scheiman M, and the COMET Group: A randomized clinical trial of progressive addition lenses versus single vision lenses on the progression of myopia in children. Invest Ophthalmol Vis Sci 44:1492-1500, 2003.

xxv. Gwiazda J, Hyman L, Norton TT, Hussein MEM, Manny R, Marsh-Tootle W, Manny R, Wang Y, Everett D, and the COMET Group: Accommodation and related risk factors associated with myopia progression and their interaction with treatment in COMET children. Invest Ophthalmol Vis Sci 45:2143-2151, 2004.

xxvi. Fulk GW, Cyert LA, Parker DE: A randomized clinical trial of bifocal glasses for myopic children with esophoria: results after 54 months. Optometry 73(8):470-476, 2002.

xxvii. Javitt JC, McBean AM, Nicholson GA, Babish JD, Warren JL: Undertreatment of glaucoma among Black Americans. N Engl J Med 325(14):1418-1422, 1991.

xxviii. Rahmani B, Tielsch JM, Katz J, Gottsch J, Quigley H, Javit J, Sommer A: The cause-specific prevalence of visual impairment in an urban population. Ophthalmology 103(11):1721-1726, 1996.

xxix. West SK, Munoz B, Schein OD, Duncan DD, Rubin GS: Racial differences in lens opacities: the Salisbury Eye Evaluation (SEE) project. Am J Epidemiol 148(11):1033-1039, 1998.

xxx. Devgan U, Yu F, Kim E, Coleman AL: Surgical undertreatment of glaucoma in Black beneficiaries of Medicare. Arch Ophthalmol 118:253-256, 2000.

xxxi. Basch CE, Walker EA, Howard CJ, Shamoon H, Zybert PA: The effect of health education on the rate of ophthalmic examinations among African Americans with diabetes. Am J Public Health 89:1878-1882, 1999.

xxxii. Rodriguez J, Sanchez R, Munoz B, West SK, Broman A, Snyder RW, Klein R, Quigley H: Causes of blindness and visual impairment in a population-based sample of U.S. Hispanics. Ophthalmology 109(4)737-743, 2002.

xxxiii. West SK, Munoz B, Klein R, Sanchez R, Rodriguez J, Snyder R: Risk factors for type II diabetes and diabetic retinopathy in a Mexican-American population: Proyecto VER. Am J Ophthalmol 134(3):390-398, 2002.

xxxiv. Centers for Disease Control and Prevention: National diabetes fact sheet: United States, 2003. DHHS, CDCP Publication. 8 pp.

xxxv. Centers for Disease Control and Prevention: Self-reported prevalence of diabetes among Hispanics–United States, 1994-1997. MMWR 48(1):8-12, 1999.

xxxvi. Hamman RF, Mayer EJ, Moo-Young GA, Hildebrandt W, Marshall JA, Baxter J: Prevalence and risk factors of diabetic retinopathy in non-Hispanic Whites and Hispanics with NIDDM. San Luis Valley Diabetes Study. Diabetes 38(10):1231-1237, 1989.

xxxvii. The Eye Diseases Prevalence Research Group: The prevalence of diabetic retinopathy among adults in the United States. Arch Ophthalmol 122:552-563, 2004.

xxxviii. Haffner SM, Fong D, Stern MP, Pugh JA, Hazuda HP, Patterson JK, vanHeuven WA, Klein R: Diabetic retinopathy in Mexican Americans and non-Hispanic Whites. Diabetes 37(7):878-884, 1988.

xxxix. Harris EL, Sherman SH, Georgopolous A: Black-White differences in risk of developing retinopathy among individuals with type 2 diabetes. Diabetes Care 22(5):779-783, 1999.

xl. Roy MS: Eye care in African Americans with type 1 diabetes: the New Jersey 725. Ophthalmology 111(5):914-920, 2004.

xli. McCall DT, Sauaia A, Hamman RF, Reusch JE, Barton P: Are low-income elderly patients at risk for poor diabetes care? Diabetes Care 27(5):1060-1065, 2004.

xlii. Harris MI, Klein R, Cowie CC Rowland M, Byrd-Holt DD: Is the risk of diabetic retinopathy greater in non-Hispanic Blacks and Mexican Americans than in non-Hispanic Whites with type 2 diabetes? A U.S. population study. Diabetes Care 21(8):1230-1235, 1998.

xliii. Haffner SM, Mitchell BD, Moss SE, Stern MP, Hazuda HP, Patterson J, Van Heuven WA, Klein R: Is there an ethnic difference in the effect of risk factors for diabetic retinopathy? Ann Epidemiol 3(1):2-8, 1993.

xliv. Appiah AP, Ganthier R Jr, Watkins N: Delayed diagnosis of diabetic retinopathy in Black and Hispanic patients with diabetes mellitus. Ann Ophthalmol 23(4):156-158, 1991.

xlv. Dawson DW, Volpert OV, Gillis P, Crawford SE, Xu HJ, Benedict W, Bouck NP: Pigment epithelium-derived factor: a potent inhibitor of angiogenesis. Science 285:245-248, 1999.

xlvi. Houenou LJ, D’Costa AP, Li L, Turgeon VL, Enyadike C, Alberdi E, and Becerra P: Pigment epithelium-derived factor promotes the survival and differentiation of developing spinal motor neurons. J Compar Neurol 412(3):506-514, 1999.

xlvii. Seo MS, Kwak N, Ozaki H, Yamada H, Fabbro D, Hofmann F and Campochiaro PA: Dramatic inhibition of retinal and choroidal neovascularization by oral administration of a kinase inhibitor. Am J Path 154(6):1743-1753, 1999.

The National Heart, Lung, and Blood Institute

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

MISSION/VISION STATEMENT

The mission of the National Heart, Lung, and Blood Institute (NHLBI) is to provide leadership for a national program in diseases of the heart, blood vessels, lung, and blood; sleep disorders; and blood resources management. The Institute:

- Plans, conducts, fosters, and supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases and sleep disorders conducted in its own laboratories and by other scientific institutions and individuals supported by research grants and contracts.
- Plans and directs research to develop and evaluate interventions and devices related to prevention of heart, lung, and blood diseases and sleep disorders and to treatment and rehabilitation of patients suffering from them.
- Conducts research on clinical use of blood and all aspects of the management of blood resources.
- Supports career training and development of new and established researchers in fundamental sciences and clinical disciplines to enable them to conduct basic and clinical research related to heart, blood vessel, lung, and blood diseases; sleep disorders; and blood resources through individual and institutional research training awards and career development awards.
- Coordinates relevant activities with other research institutes and all federal health programs in the above areas, including the causes of stroke.
- Conducts educational activities, including development and dissemination of materials for health professionals and the public in the above areas, with emphasis on prevention.
- Maintains continuing relationships with institutions and professional associations, and with international, national, state, and local officials as well as voluntary agencies and organizations working in the above areas.
- Oversees management of the Women’s Health Initiative.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

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’s outstanding efforts in this area have been publicly recognized in Congressional hearings and validated and supported by the National Advisory Council on Minority Health and Health Disparities. The Institute not only has initiated research projects with significant minority participation to compare health status between various populations, but also given high priority to programs that focus exclusively on minority health issues. These projects have produced a wealth of information that enables identification of health disparities and provides clues about their causes.

In addition, research programs that focus exclusively on minority health issues have been and continue to be a high priority for the NHLBI. Institute programs address diseases, conditions, and risk factors that disproportionately affect minorities, including high blood pressure, coronary heart disease, obesity, physical inactivity, diabetes, asthma, sarcoidosis, tuberculosis, sickle cell disease, and Cooley's anemia.

The NHLBI reviewed public comments received in response to the NIH FY2002 Strategic Plan for Health Disparities and was encouraged to find that the public's recommendations correspond well with the Institute's long-standing efforts to reduce health disparities. For example, one comment was that resources should be equitably distributed across population groups. Since FY1991, the Institute has had procedures in place to ensure full compliance with the NIH Policy on Inclusion of Minorities and Women in Research. As a result, all NHLBI-supported research that involves human subjects includes strong minority representation, with the exception of a very few projects for which a strong justification for limiting the diversity of the study population exists. Currently the NHLBI's programs include research and outreach to Americans of Black, Hispanic, American Indian and Native Alaskan, and Asian and Pacific Islander heritage.

Another recommendation from the public was to improve research infrastructure at minority academic institutions. It has long been a goal of the NHLBI to increase the number of underrepresented minorities in scientific research. The Institute supports a variety of research awards such as the Historically Black Colleges and Universities (HBCU) Research Scientist Award and the Research Scientist Award for Minority Institutions to develop and strengthen research programs at minority-serving institutions. In addition, the Institute supports a variety of training programs to encourage diverse groups that currently are underrepresented in the biomedical field to pursue careers in research.

Two additional suggestions were to use racially and culturally sensitive and appropriate communication and to strengthen the capacity of minority communities. Through its outreach and education programs, the NHLBI disseminates health-related information to physicians, health care professionals, patients, and the general public. Strong emphasis is placed on outreach to minority populations using culturally sensitive, innovative, community-based approaches, such as the Cardiovascular Outreach and Education in Public Housing Communities Program, which empowers Blacks in Baltimore City public housing to improve their cardiovascular health. Spanish-language health education campaigns such as *Salud para su Corazón* distribute health information in Hispanic communities. The NHLBI-Indian Health Service Partnership to Strengthen the Heartbeat of American Indian and Alaska Native communities works with these populations. Many additional examples of NHLBI's commitment to reducing health disparities are described in the following sections.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Development and Progression of Heart, Lung, and Blood Diseases and Sleep Disorders that Contribute to Health Disparities

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Some diseases of the heart, lung, and blood develop and progress differently in minorities than in Whites, and disproportionately affect some subgroups of the U.S. population, such as minorities, individuals living in rural areas, and those of low socioeconomic status.

A major example is cardiovascular disease (CVD) and its risk factors. Recent data show that heart disease mortality is 24 percent higher in Black males than in White males and 35 percent higher in Black females than in White females, and the prevalence of stroke is higher in Blacks than in Whites at all ages. The Stroke Belt, a largely rural area in the southeastern United States with a high proportion of Black residents, experiences stroke mortality rates approximately 25 percent higher than those in the rest of the country. High blood pressure, a risk factor for CVD, tends to be more common, develops at an earlier age, and is more severe for Blacks than Whites in the United States. Two other risk factors for CVD—lack of physical activity and obesity—are particularly problematic for minority populations.

Asthma is a chronic lung condition that disproportionately affects children, Blacks, and low-income individuals. Since 1980, the age-adjusted asthma death rate for Blacks has increased 62 percent, compared to a 32 percent increase for Whites. In 2002, the age-adjusted asthma death rate for Blacks was almost three times that of Whites. In 2000, hospitalization rates for asthma were more than three times higher for Blacks than for Whites. The cost of asthma in 2004 is estimated to be $16.1 billion, with direct costs amounting to $11.5 billion and lost earnings due to illness and death totaling $4.6 billion.

Sarcoidosis─an inflammatory disease that usually starts in the lungs or lymph nodes─also affects minorities disproportionately. In the United States, it occurs more often and more severely among Blacks than Whites, with an incidence of about 10 per 100,000 among Whites and about 35 per 100,000 among Blacks.

Much scientific opportunity exists today for investigators to pursue research in the development and progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities. New tools, skills, and knowledge in molecular biology, genetics, and genomics make possible research into the mechanisms of disease development. Computational tools are available with which to perform epidemiological studies and analyze genetic and environmental factors that contribute to health disparities. Involving community groups in such epidemiological studies and training lay community health workers as links between research and the community not only benefits the research study but also leads to more effective community outreach efforts for health promotion and disease prevention in health disparities populations.

This Area of Emphasis, one component of a coordinated and interdependent effort to reduce and eliminate health disparities, is of equal priority with others in the plan.

As described above under “Strategy for Addressing Health Disparities,” the NHLBI has long maintained a commitment to minority health and health disparities research. Public comments on the

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

"NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006" validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute's comprehensive research portfolio.

1.1.1 Objective One

Support research to increase understanding of the development and progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities.

Emphasis is on identifying genetic and environmental factors that influence development and progression of diseases that disproportionately affect minorities; determining mechanisms responsible for the progression of such diseases; and clarifying processes by which environmental, developmental, and psychosocial factors early in life contribute to health disparities later in life.

This is the only objective in this Area of Emphasis. Public comments validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute's comprehensive research portfolio.

1.1.1.1 Action Plan

The NHLBI will continue to support ongoing research programs that address this objective. In addition, as applications for research that focus on this objective are received, and as new initiatives are developed, additional research grants and contracts will be awarded.

(1) Steps to achieve objective

Current Major Programs

Epidemiological Studies

Atherosclerosis Risk in Communities (ARIC): Investigates the association of CHD risk factors with development of atherosclerosis and CVD in an adult population; 38 percent of the participants are Black.

Coronary Artery Risk Development in Young Adults (CARDIA): Determines the evolution of coronary heart disease (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.

Genetics of Atherosclerosis in Mexican-Americans: Seeks to identify and map specific genes that contribute to CVD risk in Mexican-Americans.

Genetics of Coronary Artery Disease in Alaskan Natives (GOCADAN): Documents CVD risk factors and measures of subclinical disease in approximately 40 extended Alaska Native families. Identifies and characterizes genes that contribute to CVD.

Hemochromatosis and Iron Overload Screening Study (HEIRS): Determines the prevalence of iron overload and hereditary hemochromatosis; identifies genetic and environmental determinants and potential clinical, personal, and societal impact of iron overload in an adult population consisting of 28 percent Blacks, 13 percent Asians, and 13 percent Hispanics.

Jackson Heart Study: Identifies environmental and genetic factors influencing evolution and progression of CVD in Blacks.

Multi-Ethnic Study of Atherosclerosis (MESA): Investigates the prevalence, correlates, and progression of subclinical cardiovascular disease (i.e., disease detected non-invasively before it has produced clinical signs and symptoms), in a population consisting of 38 percent Whites, 28 percent Blacks, 22 percent Hispanics, and 12 percent Asians.

National Longitudinal Mortality Study (NLMS) – Follow-up: Analyzes socioeconomic, demographic, and occupational differences in mortality in the United States among a study population of approximately 1.4 million people that reflects the composition of the U.S. population.

Strong Heart Study: Compares risk factor levels and morbidity and mortality from CVD among American Indians from three different geographic locations.

High Blood Pressure

Family Blood Pressure Program: Uses a network of investigators to identify genes associated with high blood pressure and to examine interactions between genetic and environmental determinants of hypertension; approximately two-thirds of participants are from minority populations.

Molecular Genetics of Hypertension: Determines the etiology and pathogenesis of hypertension and its complications 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.

Ischemic Heart Disease

Ischemic Heart Disease in Blacks: Elucidates the pathophysiological basis for excess morbidity and mortality from ischemic heart disease in Blacks, and subsequently develops therapeutic strategies to address these problems.

Diabetes

Insulin Resistance and Atherosclerosis Study (IRAS) Family Study: Identifies the genetic determinants of insulin resistance and abdominal obesity and determines the extent to which insulin resistance, visceral adiposity, and metabolic cardiovascular disease risk factors share common genetic influences; participants are Black and Hispanic.

Asthma

Severe Asthma Research Program: Investigates the mechanistic basis for severe asthma and determines how it differs from mild-to-moderate asthma. Recent publications indicate that severe asthma is more prevalent in Blacks than Whites.

Sarcoidosis

Sarcoidosis Genetic Linkage Consortium: Identifies genes linked to sarcoidosis susceptibility and determines how they interact with environmental risk factors to cause sarcoidosis; all of the participants are Black.

New Initiatives

Asthma Exacerbations: Biology and Disease Progression: Elucidate the biologic mechanisms of asthma exacerbation pathobiology and resolution and their effect on lung function, physiology, and disease state.

Granulomatous Lung Inflammation in Sarcoidosis: Investigate the mechanisms leading to development of nontuberculous granulomatous inflammation in the lungs found in sarcoidosis. In the United States, sarcoidosis disproportionately affects Blacks and individuals of low socioeconomic status who are underinsured.

Specialized Centers of Clinically Oriented Research (SCCOR) in Cardiac Dysfunction and Disease: Foster multi-disciplinary research on clinically relevant questions enabling basic science findings related to dysfunction and disease of the myocardium to be applied more rapidly to clinical problems; emphasize research that addresses health disparities related to heart disease and the translation of research findings to clinical practice for affected minority populations.

(2) Timeline for objective

Current Major Programs
Expected end date of FY2004:

Insulin Resistance and Atherosclerosis Study (IRAS) Family Study
Ischemic Heart Disease in Blacks

Expected end date of FY2005:

- Family Blood Pressure Program
- Genetics of Coronary Artery Disease in Alaskan Natives (GOCADAN)
- Hemochromatosis and Iron Overload Screening Study (HEIRS)
- Jackson Heart Study
- Sarcoidosis Genetic Linkage Consortium
- Strong Heart Study

Expected end date of FY2006:

- Molecular Genetics of Hypertension
- Severe Asthma Research Program

Expected end date of FY2007:

- Atherosclerosis Risk in Communities (ARIC)
- Genetics of Atherosclerosis in Mexican-Americans

Expected end date of FY2008 and beyond:

- Coronary Artery Risk Development in Young Adults (CARDIA)
- Multi-Ethnic Study of Atherosclerosis (MESA)
- National Longitudinal Mortality Study (NLMS) - Follow up

New Initiatives

Expected end date of FY2006:

- Granulomatous Lung Inflammation in Sarcoidosis

Expected end date of FY2008 and beyond:

- Asthma Exacerbations: Biology and Disease Progression
- Specialized Centers of Clinically Oriented Research (SCCOR) in Cardiac Dysfunction and Disease

(3) This objective is ongoing. See previous section for dates by which specific activities within this objective are expected to be completed.

1.1.1.2 Performance Measures

To assess performance of the NHLBI portfolio of current activities that “support research to increase understanding of the development and progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities,” NHLBI scientific staff track and assess the success of Institute-supported investigators in publishing articles related to this objective in peer-reviewed, high-quality scientific journals. Another measure of the performance of ongoing research is whether a grant is renewed once its initial period of support ends. Applications for competing renewal grants are reviewed carefully by peer reviewers and the National Heart, Lung, and Blood Advisory Council for past performance and published results, as well as future potential.

In addition, the NHLBI portfolio is assessed frequently to ensure that it addresses newly identified scientific needs and opportunities. New initiatives are developed with input from the scientific and health care-related communities and the general public, and reviewed by the Institute’s Board of

Extramural Advisors and the National Heart, Lung, and Blood Advisory Council before being announced.

1.1.1.3 Outcome Measures

A measure of the outcome of NHLBI-supported activities to “support research to increase understanding of the development and progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities” is the publication in peer-reviewed, high-quality scientific journals of articles reporting science advances based on the results of NHLBI-supported research toward this objective. NHLBI scientific staff continually assesses Institute objectives and research programs in terms of the results reported in such articles. In fact, as part of its annual budget justification submitted to the U.S. Congress, the NHLBI consistently reports on scientific advances pertaining to this objective that have resulted from Institute-supported research, the results of which have been published in high-quality scientific journals during the previous year. For example, as recently published in an abstract in the *American Journal of Respiratory and Critical Care Medicine* and reported to Congress in the NHLBI FY2005 budget justification, investigators have found polymorphisms, or variants, in DNA that are associated with an increased risk of developing acute lung injury or acute respiratory distress syndrome from sepsis (commonly known as blood poisoning). Strikingly, the investigators also determined that these polymorphisms are more common in Black patients than in White patients.

1.2 Area of Emphasis Two: Diagnosis and Treatment of Heart, Lung, and Blood Diseases and Sleep Disorders that Contribute to Health Disparities

Some diseases of the heart, lung, and blood react to treatment differently in minorities than in Whites. In addition, diagnosis of disease often occurs at a later stage in individuals who are members of minority groups, live in rural areas, or are of low socioeconomic status. Moreover, standard clinical practice guidelines for heart, lung, and blood diseases are often inadequately used, especially in the treatment of minorities, women, and the elderly. By supporting clinical trials, clinical studies, and networks of clinical research centers, and by striving for high levels of minority participation in its clinical studies, the NHLBI focuses on diagnostic and treatment issues that contribute to health disparities.

Sickle cell disease (SCD) is unusual in that it occurs almost exclusively in minority individuals. It is an inherited blood disorder that produces chronic anemia, end organ damage, and periodic episodes of pain. It affects approximately 72,000 people in the United States, most of whom trace their ancestry to Africa. It occurs in about one of every 500 Black births and one of every 1,000-1,400 Hispanic births. Tremendous progress has been made since NHLBI-supported research programs on SCD began about 30 years ago. Patients with SCD now live longer on average; and care is more coordinated, beginning with screening of newborns, provision of appropriate infection prophylaxis, and prevention of stroke in high-risk children through transfusion therapy. Yet treatment options remain limited and a widely applicable cure remains elusive. For example, the drug hydroxyurea, which reduces the rate of painful crises in SCD, is effective in only two-thirds of patients. Continued progress can be expected from further studies in areas of ongoing research, such as pursuing new therapeutic targets and strategies; examining the long-term effects of hydroxyurea; and optimizing treatment for prevention of stroke in children with SCD.

Improving diagnosis and treatment strategies for other diseases that contribute substantially to health disparities, such as CVD, asthma, and diabetes, also is essential. Diabetes, for example, is having a devastating effect on minority populations. Rates of type 2 diabetes are about twice as high among Blacks and Hispanics as among Whites and are even higher in American Indian communities. The number of individuals with end-stage renal disease has doubled over the past decade; minority populations, especially Blacks and American Indians, have been particularly affected.

This Area of Emphasis, one component of a coordinated and interdependent effort to reduce and eliminate health disparities, is of equal priority with others in the plan.

As described above under “Strategy for Addressing Health Disparities,” the NHLBI has long maintained a commitment to minority health and health disparities research. Public comments on the “NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006” validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute’s comprehensive research portfolio.

1.2.1 Objective One

Support research to develop new or improved approaches for diagnosing and treating heart, lung, and blood diseases and sleep disorders that contribute to health disparities.

Emphasis is placed on understanding differences in disease presentation in subsegments of the population; achieving accurate and timely diagnosis; predicting the likely clinical course in individuals; establishing the effectiveness, safety, and cost-effectiveness of treatments; and improving use of clinical practice guidelines.

This is the only objective in this Area of Emphasis. Public comments validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute’s comprehensive research portfolio.

1.2.1.1 Action Plan

(1) Steps to achieve objective

The NHLBI will continue to support ongoing research programs that address this objective. In addition, as new initiatives are developed that focus on this objective, additional research grants and contracts will be awarded.

Current Major Programs

Cardiovascular Disease

Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL): Evaluates whether medical therapy with stenting of hemodynamically significant (angiographically documented) renal artery stenoses in patients with systolic hypertension reduces the incidence of adverse cardiovascular and renal events compared with medical therapy alone; 30 percent of the participants will be from minority populations.

Clinical Research in Peripheral Arterial Disease: Develops improved therapeutic and preventive approaches for atherosclerotic arterial diseases of the peripheral vasculature through integrated, multi-disciplinary clinical research projects. The development and progression of peripheral arterial disease (PAD) is affected by age, ethnicity, and the presence of other medical conditions. Elderly individuals and those with diabetes are at increased risk for PAD. In the United States, minorities suffer disproportionately from PAD.

Evaluation Study of Congestive Heart Failure and Pulmonary Catheterization Effectiveness (ESCAPE): Evaluates whether treatment guided by pulmonary artery catheterization or treatment guided by clinical assessment offers an advantage to severe heart failure patients; 29 percent of participants are from minority populations.

Diabetes

Action to Control Cardiovascular Risk in Diabetes (ACCORD): Evaluates the benefits of different therapies to reduce CVD in Type 2 diabetes; 33 percent of the participants will be from minority populations.

Bypass Angioplasty Revascularization Investigation in Type 2 Diabetics (BARI 2D): Evaluates 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, determines if insulin-providing drugs offer advantages or risks compared to insulin-sensitizers (drugs that enhance insulin action); 33 percent of the participants will be from minority populations.

Stop Atherosclerosis in Native Diabetics Study (SANDS): Compares a treatment of aggressively lowering low-density lipoprotein (LDL) cholesterol (goal less than or equal to 75 mg/dL) and blood pressure (goal less than or equal to 115/75 mmHg) to standard care in a population of diabetic American Indians with CVD who have relatively low levels of LDL cholesterol and blood pressure.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Asthma

Asthma Clinical Research Network, Phase II: Phase I established an interactive network of asthma clinical research groups to assess new therapies and management strategies and ensure that findings are rapidly disseminated to the medical community. A new program was funded in 2003 as a result of national competition for participation in the successful 10-year-old asthma clinical research network. The minority patient population will be approximately 33 percent for each protocol.

Childhood Asthma Management Program (CAMP): Evaluates the long-term effects of anti-inflammatory therapy compared to bronchodilator therapy on the course of asthma, particularly on lung function and bronchial hyperresponsiveness, and on physical and psychosocial growth and development. Results showed that 4½ to 6 years of daily treatment with inhaled corticosteroids was safe and provided superior control of asthma compared to a different anti-inflammatory medication or treatment only when symptoms occurred. The CAMP study will continue to observe children for 5 years to determine the effect of early treatment on maximum lung growth and on height.

Childhood Asthma Research and Education Network (CARE): Establishes a network of pediatric clinical care centers to determine optimal treatment and management strategies for children with asthma. Customizes therapy based on specific asthma phenotypes and genotypes; 30 percent of the participants will be minorities.

Sickle Cell Disease

Comprehensive Sickle Cell Centers Program: Supports coordination of resources, facilities, and personnel to expedite development and application of new knowledge for improved diagnosis and treatment of SCD and prevention of its complications. In the 2003-2008 funding cycle, the program included, for the first time, a clinical research network component to provide for rapid evaluation of promising new treatments for SCD.

Multicenter Study of Hydroxyurea (MSH) Patients' Follow-up: Seeks 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; all the participants are Black.

Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG): Determines the effectiveness of hydroxyurea in preventing onset of chronic organ damage in young Black children with sickle cell anemia.

Sibling Donor Cord Blood Banking and Transplantation: Establishes 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 sickle cell disease or thalassemia. A majority of the participants are Black.

Stroke Prevention in Sickle Cell Anemia (STOP2): Determines when the primary prevention treatment strategy proven effective in STOP 1 in a minority pediatric population may be safely discontinued.

Cooley's Anemia

Thalassemia (Cooley's Anemia) Clinical Research Network: Accelerates research in the management of thalassemia, standardizes existing treatments, and evaluates new ones in a network of clinical centers; minority participation will be approximately 48 percent in the thalassemia registry being developed by the network.

Use of Clinical Practice Guidelines

Trials Assessing Innovative Strategies to Improve Clinical Practice Through Guidelines: Investigates reasons for inadequate use of standard clinical practice guidelines for heart, lung, and blood diseases, particularly in treatment of racial and ethnic minorities, women, and the elderly; evaluates remedial interventions.

New Initiatives

Pulmonary Complications of Sickle Cell Disease: Elucidate mechanisms of the pulmonary complications of SCD (e.g., acute chest syndrome, a complex of symptoms including severe chest pain, dyspnea, and fever; and chronic sickle cell pulmonary disease, characterized by perfusion and diffusion lung abnormalities); and develop new treatments.

Sickle Cell Disease Clinical Research Network: Establish a network of clinical centers to address critical issues in the care of persons with SCD by developing a registry and completing Phase I-III clinical trials (with emphasis on Phase III trials).

(2) Timeline for objective

Current Major Programs
Expected end date of FY2004:
  Evaluation Study of Congestive Heart Failure and Pulmonary Catheterization Effectiveness (ESCAPE)
Expected end date of FY2005:
  Sibling Donor Cord Blood Banking and Transplantation
  Stroke Prevention in Sickle Cell Anemia (STOP2)
  Thalassemia (Cooley's Anemia) Clinical Research Network
Expected end date of FY2006:
  Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG)

Expected end date of FY2007:
- Bypass Angioplasty Revascularization Investigation in Type 2 Diabetics (BARI 2D)
- Childhood Asthma Management Program (CAMP)
- Stop Atherosclerosis in Native Diabetics Study (SANDS)
- Trials Assessing Innovative Strategies to Improve Clinical Practice through Guidelines

Expected end date of FY2008 or beyond:
- Asthma Clinical Research Network, Phase II
- Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL)
- Clinical Research in Peripheral Arterial Disease
- Comprehensive Sickle Cell Centers Program
- Multicenter Study of Hydroxyurea (MSH) Patients' Follow-up
- Childhood Asthma Research and Education Network (CARE)
- Action to Control Cardiovascular Risk in Diabetes (ACCORD)

New Initiatives

Expected end date of FY2008 and beyond:
- Pulmonary Complications of Sickle Cell Disease
- Sickle Cell Disease Clinical Research Network

(3) This objective is ongoing. See previous section for dates by which specific activities within this objective are expected to be completed.

1.2.1.2 Performance Measures

To assess performance of the NHLBI portfolio of current activities that "support research to develop new or improved approaches for diagnosing and treating heart, lung, and blood diseases and sleep disorders that contribute to health disparities," NHLBI scientific staff track and assess the success of Institute-supported investigators in publishing articles related to this objective in peer-reviewed, high-quality scientific journals. Another measure of the performance of ongoing research is whether a grant is renewed once its initial period of support ends. Applications for competing renewal grants are reviewed carefully by peer reviewers and the National Heart, Lung, and Blood Advisory Council for past performance and published results, as well as future potential.

In addition, the NHLBI portfolio is assessed frequently to ensure that it addresses newly identified scientific needs and opportunities. New initiatives are developed with input from the scientific and health care-related communities and the general public, and reviewed by the Institute's Board of Extramural Advisors and the National Heart, Lung, and Blood Advisory Council before being announced.

1.2.1.3 Outcome Measures

A measure of the outcome of NHLBI-supported activities to "support research to develop new or improved approaches for diagnosing and treating heart, lung, and blood diseases and sleep disorders that contribute to health disparities" is the publication in peer-reviewed, high-quality scientific journals of articles reporting science advances based on the results of NHLBI-supported research toward this objective. NHLBI scientific staff continually assesses Institute objectives and research programs in terms of the results reported in such articles. In fact, as part of its annual budget justification submitted to the U.S. Congress, the NHLBI consistently reports on scientific advances pertaining to this objective that have resulted from Institute-supported research, the results of which have been published in high-quality scientific journals during the previous year. For example, as published in an article in the November/December 2002 edition of the *Journal of Clinical Hypertension* and as reported to Congress in the NHLBI FY2005 budget justification, blood pressure control rates among participants in the NHLBI-supported Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) increased from 27.4 percent at the beginning of the trial to 66 percent after 5 years of follow-up. Perhaps most notably, the ALLHAT gains in blood pressure control were achieved in a variety of clinical practice settings and in subgroups of people known to have difficulty controlling their blood pressure, such as Blacks, the elderly, and patients with diabetes. In another article recently published in the *Journal of the American Medical Association*, researchers reported results showing that hydroxyurea not only protects adults who have SCD from painful crises and acute chest syndrome, but also prolongs their lives.

1.3 Area of Emphasis Three: Prevention or Delay of Onset or Progression of Heart, Lung, and Blood Diseases and Sleep Disorders That Contribute to Health Disparities

The continuing rise in obesity and overweight in the United States carries major public health consequences because obesity is a risk factor for many chronic conditions, including hypertension, diabetes, and heart disease. Healthier lifestyles and improved behaviors related to diet and physical activity could help prevent or delay the onset of these serious conditions. Data from a series of national surveys conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention show increases in overweight and obesity between 1988-1994 and 1999-2000 for both men and women in all age groups and for Whites, Blacks, and Mexican-Americans (the racial/ethnic groups of special interest to the survey). Overweight and obesity are particularly serious problems among minority women. In fact, the 1999-2000 survey cited above shows that more than half of Black women aged 40 years or older are obese (compared with about a third of White women) and more than 80 percent are overweight (compared with slightly under two-thirds of White women). Mexican-American women are also much more likely to be overweight or obese than White women. Other data show the prevalence of obesity in American Indian/Alaska Native populations to be about 50 percent higher than in the general U.S. population.

Perhaps even more alarming is the continuing rise in obesity and overweight among children and adolescents, since it puts them at risk for diabetes and other disorders later in life. The current increase is particularly noticeable among minority young people. Data from the survey mentioned above show that the prevalence of overweight and obesity among Black and Mexican-American adolescents increased more than 10 percentage points between 1988-1994 and 1999-2000 (compared with 5 percentage points in the overall adolescent population). Survey data also show that slightly more than 23 percent of Black and Mexican-American adolescents were overweight in 1999-2000, compared with almost 13 percent of White adolescents. Research is needed to elucidate the reasons for disparities in overweight and obesity, and to determine which interventions are most effective in reducing them.

Opportunities also exist for improving other risk factors for disease, in addition to obesity. For example, results of ALLHAT provide physicians with new information about approaches to controlling hypertension, a risk factor for CVD that disproportionately affects Blacks. Opportunities also exist to disseminate culturally sensitive information about health promotion and disease prevention to minority communities by developing new interventions and by continuing or expanding ongoing ones that involve community groups in health care issues, train lay community health care workers, and partner with health care systems that serve minorities.

Minority and lower socioeconomic populations encounter multiple barriers (e.g., financial constraints, logistical and cultural barriers, and environmental stressors) when attempting to follow health and treatment recommendations. Effective interventions for improving adherence to medical and lifestyle regimens for these underserved groups are needed so that the full benefits of medical advances in the treatment of heart, lung, and blood diseases and sleep disorders can be realized for all segments of the U.S. population.

This Area of Emphasis, one component of a coordinated and interdependent effort to reduce and eliminate health disparities, is of equal priority with others in the plan.

As described above under “Strategy for Addressing Health Disparities,” the NHLBI has long maintained a commitment to minority health and health disparities research. Public comments on the “NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006” validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute’s comprehensive research portfolio.

1.3.1 Objective One

Support research to develop new or improved approaches for preventing or delaying the onset or progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities.

Abundant evidence exists that many diseases can be forestalled or prevented entirely through appropriate medical regimens (e.g., blood pressure control, cholesterol lowering) or through healthy lifestyles (e.g., prudent diet, abstinence from smoking, physical activity). Research is needed to identify and test approaches that can be used successfully in minority populations.

This is the only objective in this Area of Emphasis. Public comments validate ongoing NHLBI efforts by recommending action in several thematic areas currently addressed by the Institute’s comprehensive research portfolio.

1.3.1.1 Action Plan

Steps to achieve objective:

The NHLBI will continue to support ongoing research programs that address this objective. In addition, as new initiatives are developed that focus on this objective, additional research grants and contracts will be awarded.

Current Major Programs

Obesity and Diet

Girls Health Enrichment Multi-Site Studies (GEMS): Tests 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.

Nutrient Database for American Indian and Alaska Native Foods: Establishes a set of comprehensive, high-quality databases on the nutrient content of traditional foods and other foods commonly eaten by American Indians and Alaska Natives.

Weight Loss Maintenance Trial: Evaluates the effectiveness of two strategies to maintain weight loss for 2½ years in approximately 800 overweight or obese adults; 40 percent of the participants will be Black.

Physical Inactivity

Trial of Activity for Adolescent Girls (TAAG): Tests the effectiveness of a school-community linked intervention to prevent the decline in physical activity and cardiorespiratory fitness seen during adolescence in girls; approximately 30 percent of the participants will be minorities.

Asthma

Centers for Reducing Asthma Disparities: Establishes 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 socioeconomic populations. Reciprocal training is encouraged to ensure culturally sensitive projects and enhance research capabilities.

Treatment Adherence

Overcoming Barriers to Treatment Adherence in Minorities and Persons Living in Poverty: Evaluates innovative methods to overcome patient, provider, and medical system barriers that obstruct treatment adherence among racial and ethnic minorities and persons living in poverty.

New Initiatives

Community-Responsive Interventions to Reduce Cardiovascular Risk in American Indians and Alaska Natives: Test the effectiveness of behavioral interventions to promote the adoption of healthy lifestyles and/or improve behaviors related to cardiovascular risk (such as interventions that promote weight reduction, regular physical activity, and smoking cessation).

Interventions to Improve Hypertension Control Rates in African Americans: Evaluate interventions to change the delivery of medical care so as to increase the proportion of treated hypertensive African American patients whose blood pressure is controlled to levels specified by Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines. The goal is to prevent complications of hypertension in Blacks.

Partnership Programs to Reduce Cardiovascular Disparities: Create partnerships between research-intensive medical centers and health care systems that serve minority populations to investigate complex biological, behavioral, and societal factors that contribute to cardiovascular disease health disparities; facilitate research within the health care system to improve minority cardiovascular health and reduce health disparities; and provide training and development of investigators to study cardiovascular disease in minorities.

(2) Timeline for objective

Current Major Programs
Expected end date of FY2005:
  Overcoming Barriers to Treatment Adherence in Minorities and Persons Living in Poverty
Expected end date of FY2006:
  Girls Health Enrichment Multi-Site Studies (GEMS)
Expected end date of FY2007:
  Centers for Reducing Asthma Disparities
  Nutrient Database for American Indian and Alaska Native Foods
  Trial of Activity for Adolescent Girls (TAAG*)*
Expected end date of FY2008 or beyond:
  Weight Loss Maintenance Trial
New Initiatives
Expected end date of FY2008 or beyond:
  Community-Responsive Interventions to Reduce Cardiovascular Risk in American Indians

and Alaska Natives
Interventions to Improve Hypertension Control Rates in African Americans
Partnership Programs to Reduce Cardiovascular Disparities

(3) This objective is ongoing. See previous section for dates by which specific activities within this objective are expected to be completed.

1.3.1.2 Performance Measures

To assess performance of the NHLBI portfolio of current activities that "support research to develop new or improved approaches for preventing or delaying the onset or progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities," NHLBI scientific staff track and assess the success of Institute-supported investigators in publishing articles related to this objective in peer-reviewed, high-quality scientific journals. Another measure of the performance of ongoing research is whether a grant is renewed once its initial period of support ends. Applications for competing renewal grants are reviewed carefully by peer reviewers and the National Heart, Lung, and Blood Advisory Council for past performance and published results, as well as future potential.

In addition, the NHLBI portfolio is assessed frequently to ensure that it addresses newly identified scientific needs and opportunities. New initiatives are developed with input from the scientific and health care-related communities and the general public, and reviewed by the Institute's Board of Extramural Advisors and the National Heart, Lung, and Blood Advisory Council before being announced.

1.3.1.3 Outcome Measures

A measure of the outcome of NHLBI-supported activities to "support research to develop new or improved approaches for preventing or delaying the onset or progression of heart, lung, and blood diseases and sleep disorders that contribute to health disparities" is the publication in peer-reviewed, high-quality scientific journals of articles reporting science advances based on the results of NHLBI-supported research toward this objective. NHLBI scientific staff continually assesses Institute objectives and research programs in terms of the results reported in such articles. In fact, as part of its annual budget justification submitted to the U.S. Congress, the NHLBI consistently reports on scientific advances pertaining to this objective that have resulted from Institute-supported research, the results of which have been published in scientific journals during the previous year. For example, as recently published in an article in *Circulation* and as reported to Congress, NHLBI-supported research suggests that thiazolidinediones─a class of insulin-sensitizing drugs often prescribed for diabetics to enable their cells to use insulin more efficiently─may also reduce CVD risk; the results offer hope that treatment with insulin-sensitizing drugs might prevent or delay progression of CVD in patients with diabetes. In another article, published in the *Journal of the American Medical Association* in 2003, researchers reported findings from a recent clinical trial that indicate that an all-in-one approach to lifestyle changes is feasible and effective in lowering blood pressure, which in turn can reduce CVD risk.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis: Research Workforce and Research Resources

For many years, the NHLBI has been particularly concerned with increasing the participation of underrepresented minority individuals in biomedical research careers. Continuing development of the research workforce and research resources remains a high priority with the NHLBI. As described in the overview, the NHLBI's ongoing commitment to provide support for underrepresented minority researchers and institutions agrees in large part with priorities expressed in public comments received in response to the FY2002 Health Disparities Strategic Plan. The Institute adheres to the premise that increasing the number of highly trained minority individuals whose basic or clinical research interests are in cardiovascular, lung, and blood diseases and sleep disorders and improving the research infrastructure at minority institutions are crucial elements in eliminating health disparities.

These activities are extremely important to the elimination of health disparities. Participation of minority investigators in the biomedical research enterprise has been shown to have several positive effects: it improves the recruitment and retention rates of minorities in population-based research studies because some individuals prefer to work with researchers and health care providers of a similar race, ethnicity, or gender, or who speak their language, and are more likely to participate in a trial if such providers and researchers are available; it encourages more minority students to pursue careers in the biomedical and behavioral sciences because they have role models and potential mentors with whom they can identify; it improves access to health care because minority clinicians tend to establish practices in minority communities; and it adds to the body of knowledge about diseases that have a disproportionate impact on minorities because minority investigators tend to pursue research related to minority populations.

2.1.1 Objective One

Expand the opportunities in research training and career development for underrepresented minorities.

The NHLBI emphasizes increasing the number of highly trained minority investigators through support of a range of programs designed to help investigators to develop research careers. The focus of these programs is on helping minority investigators to develop research careers through participation in research relevant to the Institute's mission and through a process of mentoring by established investigators. The NHLBI also fosters collaborative partnerships between research-intensive and minority-serving institutions.

2.1.1.1 Action Plan

The NHLBI will continue to review and transition, when appropriate, its programs to ensure a diverse future research workforce. We have made significant modifications in our diversity portfolio since the fFY2003 submission of this plan as indicated below.

(1) Steps to Achieve Objective

Current Major Programs

Historically Black Colleges and Universities (HBCU) Research Scientist Award: Provides an opportunity for HBCUs offering masters, Ph.D., or professional degrees to recruit established scientists to help expand their research base and to train students in and expose them to the latest scientific advances.

Sickle Cell Research Scholars Program: Supports career development for young or new investigators in SCD research.

(The programs described below have been renamed and reannounced to reflect broadened eligibility criteria for the recruitment and participation of diverse individuals in research and research training programs.) The new names of the programs are Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research, Biomedical Research Training Program for Individuals from Underrepresented Groups, Short-Term Research Education Program to Increase Diversity in Health-Related Research, Research Supplements to Promote Diversity in Health-Related Research for Undergraduate Students.

Renamed "NHLBI Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research" when reissued in April 2005. Provides support to faculty members from racial and ethnic groups and individuals with disabilities who are currently underrepresented on faculty at academic institutions in health-related research on a national or institutional basis.

Renamed "NHLBI Biomedical Research Training Program for Individuals from Underrepresented Groups (BRTPUG)" when reissued in October 2006. Provides research-training opportunities to students from health disparities groups, individuals with disabilities, and those from disadvantaged backgrounds that are underrepresented in health-related research.

Renamed "NHLBI Short-Term Research Education Program to Increase Diversity in Health-Related Research" when reissued in April 2007. Provides research opportunities for undergraduate and health professional students from disadvantaged backgrounds, racial and ethnic groups, and individuals with disabilities.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

NIH-wide Program – Renamed “Research Supplements to Promote Diversity in Health Related Research” when reissued in November 2004. Encourages research opportunities from high school to faculty levels for individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds.

(The NHLBI is in the process of reviewing and updating existing programs identified below to ensure the announcements reflect diverse program eligibility. If any of the programs identified below are reissued, the word “minority” or “minorities” will be replaced with Office of the General Counsel (OGC)-approved language and the program content revised accordingly.)

Mentored Career Award for Faculty at Minority Institutions:
RFA Announcement expires January 3, 2008

Minority K-12 Initiative for Teachers and Students (MKITS):
Last Application Receipt Date of RFA: March 19, 2003

Minority Institutional Research Training Program:
Last Application Receipt Date of RFA: June 21, 2007

Minority Undergraduate Biomedical Education Program:
Last Application Receipt Date of RFA: November 17, 2005

Research Scientist Award for Minority Institutions:
Last Application Receipt Date of RFA: January 16, 2004

The NHLBI provides funds directly to the National Institute of General Medical Sciences (NIGMS) to support the Minority Biomedical Research Support Program. The NHLBI will defer to the NIGMS (primary institute) for modification in program title and content after OGC concurrence.

Minority Biomedical Research Support Program (NIH-wide): Offers opportunities for underrepresented minority undergraduate and graduate students to receive training in fundamental biomedical sciences and clinical research disciplines to enhance career opportunities in biomedical research, including clinical and laboratory medicine, epidemiology, and biostatistics as applied to the etiology and treatment of heart, blood vessel, lung, and blood health and diseases and sleep disorders.

(Although the NHLBI supported the NIGMS-MARC U* Star Program in FY2003, the Institute did not support the award in FY2004 and no future support is anticipated.)

*NHLBI-Sponsored MARC U*STAR Program:* Offers honor students participating in the Minority Access to Research Careers Undergraduate Student Training in Academic Research (MARC U*STAR) program a 10-week summer research experience in the NHLBI intramural laboratories.

New Initiative

Cultural Competence and Health Disparities Academic Award: Supports medical institutions in the United States to develop core curricula and other educational materials that will increase the overall knowledge and skills of medical students, house staff, practicing physicians, and other professionals related to ethnic, cultural, religious, socioeconomic, linguistic, and other factors that contribute to health disparities and to culturally competent approaches to mitigating these disparities.

(2) Timeline for Objective

Current Major Programs

Expected end date of FY2008 or beyond:

Historically Black Colleges and Universities (HBCU) Research Scientist Award
Sickle Cell Research Scholars Program
NHLBI Mentored Minority Faculty Development Award
NHLBI Biomedical Research Training Program for Underrepresented Minorities
NHLBI Short-Term Training for Minority Students Program
Research Supplements for Underrepresented Minorities
Mentored Career Award for Faculty at Minority Institutions
Minority K-12 Initiative for Teachers and Students (MKITS)
Minority Institution Research Training Program
Minority Undergraduate Biomedical Education Program
Research Scientist Award for Minority Institutions
Minority Biomedical Research Support Program
NHLBI-Sponsored MARC U*STAR Program

New Initiative

Expected end date of FY2008 or beyond:

Cultural Competence and Health Disparities Academic Award

(3) This objective is an ongoing effort by the NHLBI that is being addressed through the programs listed above.

2.1.1.2 Performance Measures

The NHLBI has consistently, over the years, increased its funding for these programs and continues to add new programs. The Institute closely scrutinizes the programs to ensure that institutions and mentors alike meet the needs of underrepresented minority investigators, thereby providing underrepresented minority researchers with opportunities to further their scientific training and achieve their research career goals. Applications are carefully evaluated to make sure the proposed training meets the needs of the underrepresented minority trainee and the Institute. Only those applications considered to be of sufficiently high quality to provide an exceptional training experience are considered. In addition, the NHLBI takes into account an institution's or mentor's track record of providing a positive training experience when considering whether to make an award.

2.1.1.3 Outcome Measures

The number of underrepresented minority investigators participating in NHLBI-sponsored training opportunities continues to increase. The NHLBI also has added new programs that have expanded the opportunities for underrepresented minorities to develop a career in the biomedical sciences. The Institute continues to measure the progress of training experiences through required progress reports. Although their outcomes may not be fully appreciated for years, it is already evident that an increasing number of underrepresented minority individuals are using the programs to develop careers in biomedical research, often by entering programs as undergraduates and receiving further training through the doctoral, postdoctoral, and investigator levels of research.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis: Outreach and Education

Outreach and education activities are critical to NHLBI efforts to increase the quality and years of healthy life for all Americans and to end racial and ethnic disparities in the burden of disease. The NHLBI recognizes that access to information, especially information that is relevant and culturally sensitive, is essential to aid individuals in making healthy choices. The Institute's interest in outreach and education encompasses not only the behavior of patients and the general public, but also the behavior of health care providers who dispense advice and prescribe medications.

3.1.1 Objective One

Expand and strengthen our programs of outreach and education for minority populations.

National education programs of the NHLBI have greatly increased public awareness and control of hypertension and high blood cholesterol. However, further progress is needed, especially in vulnerable subsets of the U.S. population. To address this need, the NHLBI established Cardiovascular Disease Enhanced Dissemination and Utilization Centers (EDUCs) as a means of extending the health benefits associated with the implementation of clinical practice guidelines in health care settings and promoting heart healthy behaviors in communities at high risk for CVD. The EDUCs use information generated by the Institute's education programs to inform their communities of the public health burdens of CVD and to develop, implement, and evaluate educational strategies to reduce the burden. The Institute believes that the EDUC approach will provide a solid foundation for further efforts to address Healthy People 2010 goals of eliminating racial/ethnic and geographic disparities in underserved high-risk populations and to support the Department's *Steps to a Healthier US Initiative*.

3.1.1.1 Action Plan

(1) Steps to Achieve Objective

Current Major Programs

Salud para su Corazón (SPSC): This is an ongoing community-based heart health education and outreach initiative to improve cardiovascular health among Latinos/Hispanics. Communities across the United States are implementing SPSC as a result of a variety of strong partnerships with the National Promotores Network, the National Council of la Raza, the Health Resources and Services Administration (HRSA), and other agencies. SPSC has established its validity for heart health education driven by promotores (lay health workers), centered around the family, and involving community-wide partners. Trained teams of *promotores*, using culturally and language-appropriate health messages, teach and empower families to promote healthy lifestyle changes. As community leaders, they can assess community needs, understand the priorities and challenges people face, gain the community's support, and influence values that affect behavior. They connect the community with health care centers by referring participants for screening procedures (blood pressure checks and blood cholesterol and glucose tests).

Honoring the Gift of Heart Health: The NHLBI and the Indian Health Service (IHS) work collaboratively to plan, develop, and implement effective approaches to improve cardiovascular health of American Indians and Alaska Natives (AI/AN). The program has developed a variety of culturally appropriate materials including a video, brochures, and a 10-session curriculum on heart health. A national train-the-trainer program was conducted with a group of 50 participants that included health educators, nutritionists, nurses, and community health representatives from various tribes across the country. The objective is to develop a highly skilled core group of trainers from around the country, who will in turn conduct training workshops in their regions. The first in the series of regional training sessions will be held from August 31 to September 3, 2004, in Scottsdale, Arizona.

Treasure Your Heart for a Healthy Asian American and Pacific Islander (AAPI) Family Project: This is a community outreach and education program to reduce the burden of CVD in Asian American and Pacific Islander (AAPI) populations by increasing awareness of CVD and its risk factors in a culturally and linguistically sensitive manner. It has gained support and interest from community-based organizations, national AAPI advocacy organizations, health clinics and centers, hospitals, state and local health departments, and local parks and recreation centers as a result of national dissemination of targeted publications for the public, patients, health care professionals, and researchers.

Public Health in Public Housing—Community-Based Outreach Initiative for Asthma and CVD: The NHLBI is developing concepts for a new public health initiative for residents of public housing. Planning activities have included the NHLBI Asthma Coalition Contract Awards (ACCAs), completed in 2003, which used multiple strategies to conduct asthma educational projects in high-risk communities; a demonstration project using lay health educators to provide cardiovascular health information in Baltimore City public housing; a qualitative assessment of the cardiovascular health awareness, knowledge, attitudes, and behaviors of public housing residents; and an education strategy development workshop on health and housing involving a multidisciplinary group of experts, practitioners, and residents. The NHLBI will use lessons learned from the ACCAs and the results of the cardiovascular health education activities to work collaboratively with public health and public housing agencies at the federal, state, and local levels, and with other interested organizations and stakeholders to increase the adoption of health promotion, disease prevention, and disease management and control behaviors among public housing residents at high risk for asthma and CVD.

Cardiovascular Disease EDUCs: The NHLBI has funded 12 CVD EDUCs to conduct performance-based education projects to prevent and control CVD and promote heart healthy behavior in high-risk communities. Six were funded in 2001 (Phase I), and an additional six in 2002 (Phase II). A Phase III of EDUCs is scheduled to be awarded in 2005.

Although they serve geographically and ethnically diverse populations, the EDUCs all use common, research-based health education strategies to improve their communities. These strategies include influencing health care provider practices to increase awareness of the latest NHLBI clinical guidelines related to controlling blood pressure and cholesterol and reducing overweight/obesity; educating patients on CVD risk reduction; working with elementary and middle school students and their families to screen for CVD risk factors and implement healthy lifestyle changes; recruiting and training community health workers; conducting community-based CVD risk factor screenings, referral, and follow-up; and stimulating partnerships to build sustainability.

NHLBI Women's Heart Health Education Initiative: The objective of this health education effort is to reduce death and disability from CVD in women. A recent planning workshop developed goals for the women's heart health education effort, identified the primary target audiences, identified the needs of minority target audiences who are at greater risk for CVD, and developed programmatic recommendations and methods for implementation and dissemination.

Native Hawaiian Heart Healthy Curriculum: In partnership with Na Pu'uwai Native Hawaiian Health Care System, the NHLBI is developing a culturally and linguistically appropriate heart health curriculum for Native Hawaiian elementary school age children. This early intervention strategy is expected to establish healthy behaviors in Native Hawaiian youth that they will carry through to adulthood. The curriculum is infused with traditional Native Hawaiian values of the *'ohana* (family) that are still passed on to younger generations through *kupunas* (Native Hawaiian elders). Kupunas, who currently teach in Hawaiian schools, will act as a resource for teachers and students using storytelling as a way to recount the healthier, traditional way of Native Hawaiian life.

NHLBI Healthy Weight Community Outreach Initiative: The NHLBI is developing the Healthy Weight Community Outreach Initiative that will include communication products and resources to help communities implement outreach activities. The effort will build upon the Hearts N' Parks program conducted by the NHLBI in collaboration with the National Recreation and Park Association. It will involve entire communities in activities to achieve a healthy weight and explore the potential role of environmental change in a community setting to encourage healthy weight. A strategy development workshop was held in early 2004 in preparation for a launch of the initiative in 2005.

(2) Timeline for Objective

Current Major Programs

Expected end date of FY2004:
- Cardiovascular Disease Enhanced Dissemination and Utilization Centers (EDUCs Phase I)
- Native Hawaiian Heart Healthy Curriculum

Expected end date of FY2005:
- Cardiovascular Disease Enhanced Dissemination and Utilization Centers (EDUCs Phase II)
- NHLBI Women's Heart Health Education Initiative

Expected end date of FY2006:
- Cardiovascular Disease Enhanced Dissemination and Utilization Centers (EDUCs Phase III)

Expected end date of FY2008 and beyond:
- Salud para su Corazón
- Honoring the Gift of Heart Health
- Treasure Your Heart for a Healthy Asian American and Pacific Islander (AAPI) Family Project
- Public Health in Public Housing–Community-based Outreach Initiative for CVD and Asthma
- NHLBI Healthy Weight Community Outreach Initiative

(3) The objective to improve and expand NHLBI outreach and education efforts directed toward eliminating racial/ethnic and gender disparities in cardiovascular and respiratory health is an ongoing effort.

3.1.1.2 Performance Measures

The NHLBI consistently seeks to develop new ways to reach and educate the general public and to find appropriate ways to reach out to minority populations and underserved populations. The Institute frequently reviews the progress of its current outreach programs and works closely with the

National Heart, Lung, and Blood Advisory Council to develop and implement new programs. This process of evaluation, development, and review led to development of the new EDUCs program.

The goal of the NHLBI Women's Heart Health Education Initiative is to reduce death and disability in women by increasing awareness and dispelling misinformation about heart disease risk in women, improving the way health professionals detect and treat CVD risk factors in women, reaching minority women who are at increased risk of developing CVD, and motivating communities to make greater use of resources already available at the local level.

3.1.1.3 Outcome Measures

The NHLBI points to the enhanced dissemination and utilization of science-based information by health care professionals, patients, and the public as an indicator of the effectiveness of its outreach programs. Outreach programs are designed to increase awareness of CVD risk factors, such as high blood pressure, high blood cholesterol, and obesity. The objective is to implement both patient-based and community-based activities to increase blood pressure control rates and physical activity and improve healthy behaviors. These efforts are working, but the Institute understands that much more needs to be done. For some of the programs, favorable results may not be fully realized for years to come, because they are ongoing efforts to modify public behavior and attitudes related to health. The Institute remains committed to seek out new opportunities to get its message out to the public, and to develop new programs to meet the special needs of minorities and underserved populations.

The National Human Genome Research Institute

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

MISSION STATEMENT

The National Human Genome Research Institute (NHGRI) led the National Institutes of Health's (NIH) contribution to the International Human Genome Project, whose primary goal was the sequencing of the human genome. This project was successfully completed in April 2003. Now, the NHGRI's mission is focused on a broad range of studies aimed at understanding the structure and function of the human genome and its role in health, disease, and society.

To that end, NHGRI supports the development of resources and technology that will accelerate genome research and its application to human health. A critical part of NHGRI's mission continues to be the study of the ethical, legal, and social implications (ELSIs) of genomic research. NHGRI also supports the training of scientists and clinicians, as well as the dissemination of genomic information to both the general public and health professionals.

STRATEGY FOR ADDRESSING HEALTH DISPARITITES

The NHGRI Health Disparities Strategic Plan describes the Institute's strategies to investigate the genetic and genomic component of diseases in "health disparity populations" as defined by P.L. 106-525, the Minority Health and Health Disparities Research and Education Act of 2000. The NHGRI Plan further addresses strategies to enhance research capacity and education and outreach. NHGRI is reviewing and updating existing programs to ensure that its goals to support research and develop research capacity, education, and outreach to address health disparities are in full compliance with Department of Health and Human Services (HHS) policy and current law.

NHGRI Research Goal

The NHGRI recognizes that any role that genetics and genomics may play in causing health disparities is limited. It is understood that many of the causes of health disparities have both environmental and genetic contributions. It is not the intent of NHGRI to "overemphasize genetics as a major explanatory factor in all health disparities" (Sankar P., et al., Genetic research and health disparities, *JAMA* Vol. 291, No. 24, p. 2985-2989, June 23, 2004). Rather, the contributions that the NHGRI can make in addressing and eliminating health disparities in populations affected by health disparities will derive from an integrated approach to the Institute's overall mission to understand further the structure and function of the human genome and its role in health, disease, and society.

The NHGRI Health Disparities Research Plan reflects the overall goals of the NIH. NHGRI's specific research goals in this area are to:

1. Advance our understanding of the development and progression of diseases that contribute to health disparities.
2. Develop a detailed understanding of the heritable variation in the human genome.
3. Develop robust strategies for identifying the genetic contributions to disease and drug response.

4. Use newly acquired knowledge regarding genes and pathways as a basis for the development of new, targeted therapeutic approaches to diseases that contribute to health disparities.
5. Investigate how genetic risk information is conveyed in clinical settings and how that information influences health strategies and behaviors.
6. Advance our understanding of the relationships between genomics, race, and ethnicity, and the consequences of uncovering these relationships.
7. Develop new or improved approaches for detecting and diagnosing the onset of diseases that contribute to health disparities.
8. Advance our understanding of the ELSIs of genome research and their role in understanding the causes of health disparities.

NHGRI Research Capacity Goal

The very nature of genomic and ELSI research requires the involvement of a large cadre of investigators with diverse perspectives and varying scientific interests. Since its inception, NHGRI has made a significant effort to include individuals with a variety of perspectives in all of its activities. As the Institute has grown in size and complexity, the need for inclusion and collaboration has become even more imperative. A number of initiatives have been undertaken on this front, and they continue to evolve. This Strategic Plan is intended to provide a coherent framework for all of NHGRI's activities related to health disparities and allow the Institute to further refine its programs and develop new programs in the most effective way possible. NHGRI's research capacity goals are to:

1. Increase the diversity of those engaged in (including as subjects of) genome research.
2. Expand opportunities in research training and career development for research investigators from populations affected by health disparities, including racial and ethnic minority populations; individuals with disabilities; and individuals from socially, culturally, or educationally disadvantaged backgrounds.
3. Increase the number of researchers conducting research focused on genomics and health disparities.
4. Increase representation in peer review of scientists and others from populations affected by health disparities.
5. Promote the development of inter-institutional partnerships between historically research-intensive and Historically Black Colleges and Universities (HBCUs) that seek to build the latter's research infrastructure.

NHGRI Community Outreach, Information, and Dissemination: Public Health Education Goal

"Marked health improvements from integrating genomics into individual and public health care depend on the effective education of the public and health professionals about [the] interplay of genetic and environmental factors in health and disease" (Collins F.S., et al. A vision for the future of genomics research, *Nature*, Vol. 422, No. 6934, April 24, 2003, p. 835-847). The NHGRI will expand its current activities and create new programs to:

1. Provide current information to health care providers, enabling them to enhance the quality of care provided to individuals within populations affected by health disparities.
2. Facilitate the incorporation of relevant health care information into the curricula of medical and allied health professions schools and public health schools, and the continuing education activities of health professionals.
3. Maintain ongoing communication linkages and partnerships with community-based and faith-based organizations, health care associations, foundations, and academic institutions; and foster dialogues with populations affected by health disparities in areas where NHGRI is actively conducting research.
4. Collaborate with public health and health-oriented policy centers to translate research findings into policy documents that can be used by policy groups and other stakeholders to explain new, important discoveries to decision-makers.

Application of Public Comments

In developing this plan, NHGRI has taken into consideration the public comments on the Trans-NIH Strategic Plan for FY2002-2006 and the input of the academic and research communities published in scientific commentaries. NHGRI's revised plan incorporates these public comments in the following manner:

1. NHGRI seeks to not overemphasize the role of genetics and genomics as the "major explanatory factor in health disparities" (See *JAMA* June 23, 2004, Vol. 291, No. 24, at 2985-2989).
2. The International Haplotype Map ("HapMap") project includes populations from across the world, initially including populations from Japan, China, and Nigeria (Yoruba). These groups were carefully selected as part of an inclusive process involving many members of the HapMap Consortium. Community Advisory Groups were established in Nigeria, Japan, and China to obtain specific inputs from public members of the involved communities about the design of the work. The HapMap project also is testing the expectation that information gathered from these populations will be broadly applicable to all populations in the world.
3. NHGRI will continue to sponsor and enhance programs aimed at mentoring, educating, and providing grant support to enhance the diversity of scientists in the field, including racial and ethnic minority populations; individuals with disabilities; and individuals from socially, culturally, or educationally disadvantaged backgrounds.
4. NHGRI is in the process of reviewing and updating existing programs to meet this goal.
5. NHGRI is promoting partnerships between HBCUs and institutions with significant numbers of students from educationally disadvantaged backgrounds and research-intensive institutions.
6. NHGRI education and outreach efforts are increasing the information that is provided for individuals whose native language is not English. For example, NHGRI, in collaboration with the

Genetic and Rare Disease Information Center, is developing new programs to specifically reach Spanish-speaking members of the United States population.

7. In 2003, NHGRI developed a new Branch focusing on Public Education and Community Involvement, whose goal is to promote and direct NHGRI's public information and community outreach activities.
8. In 2003, NHGRI developed a new Intramural Research Branch focusing on social and behavioral research. This new Branch investigates the social and behavioral factors that facilitate translation of genomic discoveries for health promotion, disease prevention, and health care improvements.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Genomic Research—To Study the Genetic Factors Contributing to Diseases that Disproportionately Affect Populations Affected by Health Disparities

All people share the vast majority of the human genetic information. Indeed, any two individuals share 99.9 percent of their DNA sequence. Similarly, all populations share most genetic variation. However, the small differences that do exist include variations that have important medical consequences. Thus, while most of human genetics research will apply broadly to all groups of people, it is also important to study whether specific genetic factors may underlie disparate rates of incidence or patterns of progression of disease when they are observed among different groups. Risk factors for common complex diseases such as prostate cancer and diabetes include both genetic and environmental/behavioral/social factors, but in most cases, the relative contribution of these factors is not known. NHGRI is working with the Office of Behavioral and Social Science Research (OBSSR) to investigate strategies for studying the interplay among social, behavioral, and genetic factors with respect to human health. As mentioned above, NHGRI also has established an Intramural Research Branch specifically focused on these types of questions.

Scientific opportunities to identify associations between sequence variations and incidence of disease have increased in extraordinary ways in the past several years, and they are being actively pursued by laboratories worldwide. An important aspect of these efforts will be the continued development of the research capacity in institutions to conduct research that exploits the tools and information derived from the Human Genome Project, the HapMap project, and similar large-scale studies.

1.1.1 Objective One: Continue and Further Expand Research Collaborations Between NHGRI and HBCUs

1.1.1.1 Action Plan

Investigators at NHGRI and Howard University have established a collaborative research partnership to identify the genetic and epidemiologic factors that contribute to the disproportionate increase in complex diseases such as cancer and diabetes in African-Americans. The identification of genes underlying susceptibility to common diseases and, more importantly, a thorough understanding of the function of these genes and their interaction with environmental factors will lead to improved management and treatment of these diseases. This project aims to collect family- and population-based information in a way that maximizes the participation of minority physicians, research scientists, and underrepresented communities.

During the past several years, the National Center for Minority Health and Health Disparities (NCMHD) (formerly the Office of Research on Minority Health) and NHGRI have supported an innovative research collaboration between investigators from Howard University and scientists in NHGRI's Intramural Research Program. The collaboration involves support for projects involving African Americans affected with diabetes. In FY1997, NHGRI added hereditary prostate cancer to this set of collaborative projects. In addition, Howard University and NHGRI are serving jointly as research training sites for scientists from this institution involved in these projects. Among the specific goals of this collaboration was the establishment of a Center at Howard University for collaborative research on genomic analyses of diseases that disproportionately affect African Americans. This goal was realized on May 1, 2001, when The National Human Genome Center at Howard University was formally dedicated. NHGRI will continue to develop similar collaborations with HBCUs other institutions in order to promote genomics-based research.

NHGRI took into consideration the public comments, as described above. This Emphasis Area addresses one of the six major themes: "Improve research infrastructure at minority academic institutions."

1.1.1.2 Performance Measures

- Number of collaborations started with investigators and/or scientists from diverse backgrounds underrepresented in genomic science.
- Inclusion of individuals from populations disproportionately affected by diseases as research participants.
- Number of research publications authored by investigators from HBCUs on diseases with a health disparity.

1.1.1.3 Outcome Measures

- Increased participation of HBCUs and investigators from diverse backgrounds in research collaborations with NHGRI intramural scientists.
- Increased understanding of factors underlying racial and ethnic minority participation (or refusal to participate) in genetic studies.
- Increased participation of research subjects from populations disproportionately affected by diseases.

1.1.2 Objective Two: Research on Diseases that Disproportionately Affect Some Populations

1.1.2.1 Africa-America Diabetes Mellitus Study (AADM)

Because of the high frequency of environmental risk factors for type 2 diabetes in the African-American population, it is particularly productive to study genetic risk factors in West Africans, since they are thought by many anthropologists to be the founding population of modern African Americans and have fewer dietary and nutritional confounding variables. To establish recruitment sites for the Africa-America Diabetes Mellitus Study (AADM), five sites in West Africa were selected through a peer review process from a total of 24 applications; three of these sites are in Nigeria and two are in Ghana. Because of the logistical challenges involved in doing a study of this type in West Africa, the study was planned in stages to allow assessment of the sites' ability to recruit appropriate patients, collect blood, urine, and other clinical data; and successfully send the samples and data to the Coordinating Center at Howard University. The 1-year pilot project successfully met its goal of recruiting 15 affected sibling pairs ("sib-pairs") per site. Based on this experience, a full-scale study was implemented in September 1998; this study successfully met its goal of recruiting 400 affected sib-pairs and 200 spouse controls from West Africa by the end of the study period. Genetic analysis of the blood samples was performed at The Center for Inherited Disease Research (CIDR). The services for the AADM study were awarded through a competitive application process. The study has not only yielded high-quality data, but has led to the recruitment of several top-flight scientists to the National Human Genome Center at Howard University. A number of phenotypic measurements were made on the research participants, who have stayed in touch with clinical personnel. Analysis of the genotype and phenotype data has led to the identification of several chromosomal regions that appear to harbor susceptibility genes for diabetes and related traits in this West African population. This work recently has been published (Rotimi CN et al., *Diabetes* 53:838-841, 2004).

NHGRI took into consideration public comments, as described above. This Emphasis Area addresses one of the representatives' comments: "NIH must include in its research objectives an investigation of the impact of multiple determinants of health on minority health status."

1.1.2.2 Performance Measures

Fine mapping of regions with evidence for linkage from the genome-wide scan, follow-up measurements, and ascertainment of the status (alive/dead and any clinical complications) of subjects.

1.1.2.3 Outcome Measures

- A better understanding of the etiology of type 2 diabetes mellitus in African Americans, meeting NHGRI research goals of: (1) advancing our understanding of the development and progression of type 2 diabetes in individuals of African descent; and (2) the development of new or improved approaches for detecting and diagnosing the onset of type 2 diabetes in these individuals.

1.1.3 African-American Hereditary Prostate Cancer Study Network (AAHPC)

1.1.3.1 Action Plan

The National Human Genome Center at Howard University is also coordinating the African-American Hereditary Prostate Cancer Study Network (AAHPC). The study has enrolled 100 families with hereditary prostate cancer in which at least four men, diagnosed at or before 65 years of age, are affected in each family; four other (unaffected) relatives also must be available for study. African-American prostate cancer families fitting this description are almost completely missing from other pedigree collections, despite the higher incidence and lethality of prostate cancer in African-American men. DNA from these families is being studied to see if linkage can be found to a known hereditary prostate cancer location on chromosome 1, as well as whether linkage to other chromosomal locations (or specific genes) exists.

As the first large-scale genetic study of African-Americans conducted almost entirely by African-American clinical investigators, the AAHPC study has provided a foundation and productive environment for the exploration of all aspects of the involvement of African-Americans in genetic research.

NHGRI took into consideration public comments, as described above. This Objective addresses two of the six major themes: (1) “Improve research infrastructure at HBCUs”; and (2) “Expand the scope of research to include cultural, psychological, behavioral, social, gender, environmental, and biological factors appearing unique to race.”

1.1.3.2 Performance Measures

- Scientific publications reporting the progress and results of the research
- Number of faculty, postdoctoral fellows, and graduate students trained while conducting this research

1.1.3.3 Outcome Measures

A better understanding of genetic risk factors underlying hereditary prostate cancer in African-Americans, meeting NHGRI’s research goals of: (1) advancing our understanding of the development and progression of hereditary prostate cancer in individuals of African descent; and (2) the development of new or improved approaches for detecting and diagnosing the onset of Increased participation by African-Americans in future research studies (NHGRI research capacity goal to increase the number of participants of diverse ancestry and populations in genome research).

1.2 Area of Emphasis Two: Genomic Research—To Include Racial and Ethnic Minority Populations and Other Disparity Populations in Research on Detecting and Diagnosing the Onset of Rare and Genetic Diseases

1.2.1 Objective One: Advance Our Understanding of the Natural History, Underlying Causes, and Onset of Genetic and Rare Diseases

1.2.1.1 Action Plan

Racial and ethnic minority populations are significantly underrepresented in research on rare genetic conditions. NHGRI's Intramural Research Program is developing ways in which to bolster the recruitment of individuals from racial and ethnic minority and other disparity populations so that they can participate in basic research efforts aimed at detecting and diagnosing genetic and rare diseases. Intramural research studies that are aggressively seeking to increase the diversity of racial, ethnic, and other disparity populations are:

1. The Attention Deficit Hyperactivity Disorder in Hispanics Study
2. The Severe Immunodeficiencies Study
3. The Genetic Study of Inherited Parkinson's Disease
4. The Identification of Genes Associated With Hermansky-Pudlak Syndrome (HPS) in Hispanic Population Study

1.2.1.2 Performance Measures

- Develop procedures to encourage carrier screening, beginning with affected relatives
- Recruitment of at-risk family members for screening
- Detection of at-risk couples
- Genotyping, phenotyping, clinical follow-up with participants

1.2.2.3 Outcome Measures

- Development of new or improved approaches for detecting and diagnosing the onset of genetic disorders in these individuals
- Better understanding of the natural history, causes, and treatment of genetic disorders in diverse racial and ethnic populations
- The investigation of how genetic risk information is conveyed in clinical settings and how that information influences health strategies and behaviors

1.3 Area of Emphasis Three: Ethical, Legal, and Social Implications (ELSI) Research Exploring the Ethical, Legal, and Social Issues Related to Genetics and Health Disparities

Human genetic variation research, especially as it relates to risk factors for common, complex disorders, is leading to increased knowledge regarding how this variation may contribute to the health status of individuals. It is also leading to more knowledge about variation within and among populations, and how this variation may contribute to the aggregate health status of different racial and ethnic groups. The International HapMap Project is an international effort spearheaded by the NHGRI to create a haplotype map of the human genome, a resource that will make it possible to conduct disease gene association studies much more quickly and efficiently than ever before.

Although the ultimate goal of studies aimed at relating human genetic variation to disease susceptibility is the improvement of human health, concerns have been raised that the findings of some genetic variation research may be misunderstood. Concerns also have been raised that such findings, if interpreted incorrectly and misused, will exacerbate, rather than ameliorate, already-existing health disparities among racial, ethnic, and socioeconomic groups. NHGRI, through its ELSI Research Program, has implemented two separate initiatives to encourage additional research on the ELSI of genetic variation research for both individuals and diverse population groups.

This objective addresses one of the representative public comments: “Increase numbers of health disparities populations studied by the NIH.” We have developed studies not only to include but also to increase the numbers of participants from health disparities populations.

1.3.1 Objective One: Study the Ethical, Legal, and Social Implications of Genetic Variation Research for Individuals and Diverse Racial and Ethnic Groups (FY2002-FY2005)

1.3.1.1 Action Plan

In FY2002, the ELSI Research Program released a second RFA for studies of the ethical, legal, and social implications of genetic variation research for individuals and diverse racial and ethnic groups. This RFA was designed to solicit proposals for research that further addresses the issues outlined above, building on research funded from 1999-2002. Five new studies were funded under this RFA in FY2003, most of which are relevant to the issue of health disparities. These new studies are part of a growing consortium of projects sponsored by the ELSI Research Program that directly address these issues. Currently, 26 projects are included in the consortium.

This Objective addresses one of the six major themes in the public comments: “Expand the scope of research to include cultural, psychological, behavioral, social, gender, environmental, and biological factors appearing unique to race.”

1.3.1.2 Performance Measures

- Increased number and quality of applications received in response to the 2002 initiative over those received in response to the FY1999 initiative
- Continue to support a consortium of investigators from supported studies that will meet once a year to compare findings on issues common to all projects, reduce duplication of effort, and promote sharing of information
- Assessment on an annual basis of the quantity and quality of published research resulting from this initiative, the number of grantees from diverse backgrounds underrepresented in genomic science, and the number of individuals from diverse racial and ethnic groups included as research participants
- Increased number of relevant publications

1.3.1.3 Outcome Measures

- Establishment of a body of scholarship that informs researchers on the ELSI implications of genetic variation research
- Establishment of a body of scholarship on how minority communities can be involved in genetic research

1.3.2 Objective Two: Study Hereditary Hemochromatosis and Iron Overload Disease in Diverse Populations

1.3.2.1 Action Plan

Iron overload is a common disorder affecting between one in 200 and one in 400 individuals. One of the major causes of iron overload is a genetic disorder known as hereditary hemochromatosis (hh). It has been estimated that one in every 400 White or Caucasian individuals has hh due to mutations in the HFE gene. The genetic contributions to hh in non-White populations are not entirely clear. In 1997, a panel of experts concluded that it would be premature to consider widespread genetic screening for hh until some important questions about prevalence, penetrance, genotype/phenotype correlations, and the psychosocial impact of widespread or population-based screening were addressed, especially in non-Caucasian populations.

To answer these questions, NHGRI is collaborating with the National Heart, Lung, and Blood Institute (NHLBI) to fund a large multi-center study designed to study iron overload and hh in diverse populations. Five field centers (including Howard University), a coordinating center, and a central laboratory have been funded to carry out this project. A total of 101,168 adults, of whom 44 percent are Caucasian, 27 percent African American, 13 percent Asian, 13 percent Hispanic, 0.7 percent Pacific Islander, 0.6 percent Native American, and 2 percent mixed or unidentified by self-identified race/ethnicity have been recruited and screened for these disorders during the course of this 5-year study. Data are beginning to be analyzed. The results of this research will enable investigators to answer the important questions identified above, particularly for individuals from minority communities.

This Objective addresses one of the six major themes in the public comments: "Expand the scope of research to include cultural, psychological, behavioral, social, gender, environmental, and biological factors appearing unique to race."

1.3.2.2 Performance Measures

- Efforts will be made to ensure that research participants from all backgrounds are retained to participate in this study so that comprehensive clinical exams can be carried out to better understand this disorder in individuals, particularly those from minority populations
- In FY2004-2005, data from this study will be analyzed, with special emphasis on understanding the findings from non-White populations
- In FY2003-2006, scientific publications will report the progress and results of the research, particularly as they relate to iron overload disorders and minority communities

1.3.2.3 Outcome Measures

- Increased understanding of the genetic factors underlying diverse populations and the impact of this knowledge for these populations

1.3.3 Objective Three: Develop ELSI Research on Minority Participation in Genetic Research

1.3.3.1 Action Plan

The NHGRI will support the analysis of ethical, legal, and social issues affecting African American participation in genetic research. Historically, African Americans have not participated in genetic research at the same level as members of other racial or ethnic groups. The research collaborations between NHGRI and the National Human Genome Center at Howard University on diseases that disproportionately affect African Americans (see Objective 1a.1) have produced (and continue to produce) a unique set of data that will allow investigators in bioethics and the social and behavioral sciences to examine the factors causing African Americans to consent or refuse to participate in genetic research. Special emphasis will be placed on access to information, informed consent, and community attitudes toward genetic research; emphasis will also be placed on the development of methods to optimize informed decision-making regarding participation in genetic research and use of the knowledge gained through this research. It is hoped that the research supported by this initiative will increase information available to investigators that will help them to design future genetic research in a way that will more successfully involve minority communities.

This Objective addresses a representative comment to: "Ensure that all communications with the health disparities populations and their subgroups address their needs and perspectives." NHGRI is interested in supporting programs to increase understanding of factors relating to participation in genetic studies.

1.3.3.2 Performance Measures

- Number of collaborations started with minority investigators
- Inclusion of minorities or medically underserved populations as research participants
- Published research

1.3.3.3 Outcome Measures

- Increased understanding of factors underlying African-American participation or refusal to participate in genetic studies

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

Realizing the promise of genomics-based approaches to biomedical and health disparities research depends, in large part, on the ability to train a diverse cadre of scientists in both genomic and ELSI aspects of human genome research. The challenges involved in accomplishing this are formidable. Scientists from diverse populations are severely underrepresented in genetics and genomics research and genomic medicine. Ethnicity data from other genetics professional societies reflect similar levels of underrepresentation. To attract individuals from diverse communities to this field, interest and excitement in genomics and genetics need to be engendered early. Furthermore, the initiatives must aim to encompass all stages of the career ladder, from student to professional, with opportunities for training at every stage. NHGRI has developed a series of training initiatives targeted toward enhancing the diversity of the genetic and genomic workforce. NHGRI is in the process of reviewing and updating these programs.

In late 2001, NHGRI, with approval of its National Advisory Council, implemented its Minority Action Plan. This Plan established an Institute-wide process aimed at increasing the number of individuals from underrepresented groups participating in genomics and ELSI research. The goals for this area of emphasis are: to increase the diversity of investigators participating in genomic research; to increase the diversity of students trained in genomic research approaches; and to expose a greater diversity of students and faculty to genomic research approaches. NHGRI is in the process of reviewing and updating its existing programs.

This Objective, and others detailed below, addresses one of the six major themes: "Improve research infrastructure at HBCUs and other institutions." A representative public comment read, "NIH must address the scarcity of qualified minority investigators by ensuring support for underrepresented minorities at every level of the pipeline."

2.1.1 Objective One: Expand Training Opportunities at Centers of Excellence in Genomic Science (CEGS) and Genome Production Centers

The Centers of Excellence in Genomic Science (CEGS) program will be the centerpiece of NHGRI-supported research in the future. One of the essential features of the CEGS will be their emphasis on the training of new investigators. Given this, these centers have the potential to become ideal sites for the training of individuals from underrepresented minority groups. Each CEGS is required to propose a plan describing what specific training activities it will implement and how it will recruit the relevant trainees. NHGRI staff will encourage the CEGS, as a group, to generate a range of training opportunities focused on minorities or underrepresented/disadvantaged populations.

2.1.1.2 Performance Measures

- Number of programs implemented for increasing the diversity of trainees exposed to genomics research
- Percentage of trainees from diverse backgrounds participating in these programs

2.1.1.3 Outcome Measures

- Increased number of minorities trained and proceeding to their next career development stage in the sciences

This Objective addresses such public comments as: "NIH must address the scarcity of qualified minority investigators by ensuring support for underrepresented minorities at every level of the pipeline. Sponsor programs to mentor, educate, and provide grant support to minorities who pursue health careers opportunities and promote partnerships between minority-serving and research institutions."

2.1.2 Objective Two: Support Training Opportunities at Centers of Excellence in ELSI Research

2.1.2.1 Action Plan

Centers of Excellence in ELSI Research (CEERs), which will be funded in the summer of 2004, will be the centerpiece of NHGRI ELSI multidisciplinary research in the future. Each Center is required to propose a detailed plan for training new investigators.

This new program has the potential of significantly increasing the number of racial and ethnic minority researchers and researchers from other disparity populations. The CEERs also have the potential of developing a critical mass of investigators focused on the ethical, legal, and social implications of genomics research at HBCUs and other institutions.

2.1.2.2 Performance Measures

- Number, quality, and innovative nature of programs implemented for increasing the number of minorities exposed to genomics and ELSI research
- Number of minorities participating in these programs

2.1.2.3 Outcome Measures

- Increased number of individuals from diverse backgrounds trained and proceeding into careers in ELSI research

2.1.3 Objective Three: Implement a New Program Called "NHGRI Health Disparities Visiting Faculty Program"

2.1.3.1 Action Plan

Starting in FY2003-2004, NHGRI established the NHGRI Health Disparities Visiting Faculty Program. With the 2006-2007 fiscal year, the program was expanded to increase the pool of faculty eligible for the program beyond faculty at Minority-Serving Institutions, Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training (EXPORT) and Research Infrastructure in Minority Institutions (RIMI) grantees. The NHGRI Health Disparities Visiting Faculty Program provides researchers focused on genomics and health disparities from any college or university with the opportunity to apply to spend a 6- to 12-month period at NHGRI. Visiting faculty will work with senior or associate investigators in NHGRI laboratories located in Bethesda or Baltimore, Maryland. Visiting faculty will have the opportunity to learn new technologies, develop research collaborations, or conduct sabbatical research. Basic and social science researchers may access NHGRI's laboratories, core facilities, clinics, and training programs for study in any area of health disparity research related to human genetic disease including the ELSIs of such research. Researchers are expected to share their skills and experience upon return to their home institutions, and applications will be evaluated based on this criterion.

This Objective addresses several representative public comments. NHGRI has developed research partnerships allowing visiting faculty from institutions that serve underrepresented populations to train in the area of genomics and health disparities research in NHGRI intramural research laboratories.

2.1.3.2 Performance Measures

- Increased number of research projects addressing health disparities in the Division of Intramural Research, NHGRI
- Increased number of visiting minority faculty
- Increased number of publications relevant to issues of health disparities and genomics

2.1.3.3 Outcome Measures

- Increased understanding of health disparities
- Increased understanding of health disparities to meet NHGRI research capacity goals of: (1) increased numbers of research participants of diverse ancestry and populations in genome research; (2) expansion of opportunities in research training and career development for investigators from communities underrepresented in genomic science; and (3) an increase in the number of researchers conducting research on genomics and health disparities

2.1.4 Objective Four: Continue to Support and Develop the "Current Topics in Genomics Research Short Course" for Faculty and Students at Institutions With Significantly Underserved Populations

2.1.4.1 Action Plan

The annual Short Course is designed to update faculty from institutions with student populations underrepresented in science careers including minority, rural, and disadvantaged student populations. The Short Course informs the faculty of the latest developments in genetic technology, medical genetics, gene therapy, and ethics. The objective of the course is to empower the faculty and build human resources at their home institutions. The course also assists attendees in incorporating this information into classroom teaching so as to cultivate a diverse population of students' interests in genomic research. It also offers information on careers in genetics and grant-writing skills to the participants. All participants spend time visiting NHGRI laboratories to experience the latest technologies that are being applied to genetics research firsthand.

Each successful Short Course applicant is asked to select one promising student from the faculty member's institution to attend the Genome Scholars Program. This program parallels the Short Course and offers a close-up view of careers in genomic research while providing an enhanced mentoring experience. In 2004, 16 faculty members and 16 students will participate in the program.

This Objective addresses several representative public comments. NHGRI has developed partnerships enabling visiting faculty from minority institutions to train in the area of genomics and health disparities.

2.1.4.2 Performance Measures

- Number of applicants
- Feedback from evaluation forms
- New grantees who participated in the Short Course
- Number of genome scholars that participate in NIH training programs
- Development and use of curriculum

2.1.4.3 Outcome Measures

- Integration of genomics into curriculum at the Short Course participants' institutions
- Integration of genomics Short Course information into curricula
- Increase in the number of students from diverse backgrounds who pursue genomics because of their involvement in the Short Course

2.1.5 Objective Five: Through Diversity Supplement Program, Expand the Opportunities for Students and Faculty to Participate in Genomics and ELSI Research by Supporting Relevant Research Experiences and Attendance at Workshops and Conferences

2.1.5.1 Action Plan

NHGRI, using a NIH-wide mechanism intended to increase the number of individuals from groups underrepresented in biomedical science, has several short- and long-term programs to support underrepresented students and faculty who wish to know more about or pursue genomics and ELSI research. Available through the National Research Service Award (NRSA) predoctoral fellowship program and supplemented by NHGRI grants, the program provides an opportunity for individuals to conduct intensive research related to genomics and ELSI. Participants also are encouraged to attend workshops and conferences related to genomics or ELSI. Opportunities are also available for Minority Access to Research Careers Program (MARC) students interested in genomics to be supported by NHGRI under National Institute of General Medical Sciences (NIGMS) MARC initiatives.

This objective takes into consideration the public comments. NHGRI has developed an opportunity for students and faculty to gain exposure to genomic careers.

2.1.5.2 Performance Measures

- Increased number of students and faculty from diverse backgrounds being trained in genomics and ELSI research
- Fact sheets and a brochure developed for distribution at conferences attended by underrepresented minorities, such as the Society for the Advancement of Chicanos and Native Americans in Science (SACNAS) National Conference, and the Annual Biomedical Research Conference for Minority Students (ABRCMS)
- Plenary sessions or workshops sponsored at professional/scientific meetings that target underrepresented minorities; these will discuss the advances in genomics and the available research and training opportunities
- Meetings attended that are of specific interest to underrepresented minorities
- Web page developed to highlight the Institute's diversity activities

- The importance of underrepresented minorities participating in genomics and ELSI research will be emphasized with grantees during the review of their annual research progress

2.1.5.3 Outcome Measures

- Increased number of underrepresented minorities taking courses in genomics and/or pursuing genomic or ELSI research

2.1.6 Objective Six: Expand Opportunities in the T32 Training Grant Program

NHGRI currently supports 11 T32 training grants; three of these are currently in a no-cost extension.

2.1.6.1 Action Plan

To increase the diversity of individuals enrolled on T32 training grants, including racial and ethnic minority populations; individuals with disabilities; and individuals from socially, culturally, or educationally disadvantaged backgrounds.

This Objective addresses public comments. NHGRI has developed an opportunity for students and faculty to gain exposure to genomic careers.

2.1.6.2 Performance Measures

- A brochure with information about NHGRI’s supported T32 training grant programs was distributed at conferences attended by underrepresented minorities, such as SACNAS and ABRCMS.
- Training directors attend and make presentations about their research and training grant programs at scientific/professional meetings that are of specific interest to underrepresented minorities, such as SACNAS and ABRCMS, or where active minority committees exist, such as the American Society of Cell Biology, and other professional/scientific meetings.

2.1.6.3 Outcome Measures

- Increased diversity of individuals enrolled on T32 training grants

2.1.7 Objective Seven: Increase the Number of Summer Internship Opportunities for Students from Minority or Underrepresented/Disadvantaged Populations

2.1.7.1 Action Plan

NHGRI hosts summer internships in intramural laboratories. Although only a limited number of summer students can be hosted in Division of Intramural Research (DIR) laboratories, the fraction of students from minority or underrepresented/disadvantaged populations availing themselves of this opportunity has been relatively low.

NHGRI/DIR is implementing new measures in an effort to increase the level of participation by underrepresented minority students. These measures are primarily focused on outreach and recruitment efforts. These efforts include the development of printed marketing materials specifically written for students from minority and other underrepresented populations. Research investigators giving seminars at HBCUs and institutions with a diverse student population also take time at the end of their seminars to inform students in the audience about research opportunities available at both NHGRI and NIH and encourage interested students to contact the NIH Office of Education for further information. NHGRI is in the process of reviewing and updating this existing program.

This objective addresses public comments. NHGRI has developed an opportunity for students and faculty to gain exposure to research careers.

2.1.7.2 Performance Measures

- Outreach efforts to increase application submissions from students from HBCUs and diverse backgrounds
- The number of applications submitted by minority students
- The number of students from minority or underrepresented/disadvantaged populations participating in the summer student program

2.1.7.3 Outcome Measures

- Increased number of minority students in the summer internship program going on to research careers

2.1.8 Objective Eight: Increase the Number of ELSI Researchers

Very few ELSI researchers who are currently funded (or who were funded in the past) are from HBCUs or populations affected by health disparities; racial and ethnic minority populations; individuals with disabilities; or individuals from socially, culturally, or educationally disadvantaged backgrounds. The ELSI program seeks to increase the diversity of ELSI researchers.

This objective addresses public comments: “NIH must continue to promote the development of inter-institutional partnerships between research-intensive institutions and minority-serving institutions.” NHGRI has developed a program to increase the number of researchers from minority communities.

2.1.8.2 Performance Measures

- Efforts to provide information about funding opportunities to members of minority/disabled/disadvantaged communities
- Number of seminars and technical assistance workshops for minority/disabled/disadvantaged communities on grant writing
- Percent of ELSI grant applications that come from individuals from underrepresented minority communities or from researchers at underrepresented minority-serving institutions and are successful
- Number of ELSI research papers published by researchers from underrepresented minority communities or researchers from underrepresented minority-serving institutions

2.1.8.3 Outcome Measures

- Increased number of ELSI researchers from underrepresented minority communities and institutions with diverse populations of students

2.1.9 Objective Nine: Expand the Capacity of Institutions to Conduct Research on Sickle Cell Disease

2.1.9.1 Action Plan

The NIH hosted a conference entitled "New Directions for Sickle Cell Therapy in the Genome Era" in Bethesda, Maryland, in November 2003. The aim of this conference was to consider how new genomics tools and techniques might be applied both to more fully understand the biology of sickle cell disease and to develop more effective therapeutic and preventive strategies for the disease. Following the meeting, staff from eight NIH Institutes and Centers formed the Trans-NIH Sickle Cell Disease Therapies Working Group. The working group developed a number of initiatives for consideration for implementation over the course of the next several years. NHGRI took the lead in developing several of these initiatives: facilitating the discovery of small molecules that can be used in basic biological and biomedical studies of sickle cell disease and translating basic research findings into novel therapeutics in sickle cell disease; training sickle cell researchers in genomics; and establishing a listserv to apprise the research community of funding opportunities relevant to sickle cell disease.

2.1.9.2 Performance Measures

- Establish and maintain the sickle cell listserv
- Communicate its existence to the community
- Develop a Request for Applications (RFA) for training
- Develop a RFA for small molecules

2.1.9.3 Outcome Measures

- Listserv operational
- Number of interested researchers subscribed to the sickle cell listserv and number of posts made to the list
- RFAs published
- Training grant awards made in 2005
- Research grants awarded for making small molecule assays robust in 2005

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

The broader inclusion of underrepresented racial and ethnic minorities and other disparity populations in biomedical research is imperative if it is to be applied to improve the health of all citizens. Inclusion is of particular importance to NHGRI, given the far-reaching implications of genetic information and technologies for both individuals and groups. There is a sense of urgency in the recruitment of individuals to meet the monumental challenges of translating human genome sequence information into items of societal value. The initial sequence and analysis of the human genome represents a significant milestone in science, yet formidable challenges remain in translating this genetic sequence information into clinically beneficial diagnostics and therapeutics. Generating public policy positions aimed at minimizing the potential misuses of genetic information must also be addressed in a timely fashion. To be ultimately successful, the improvements in research and health care must reach everyone. This success will depend on participation of individuals from *all* communities.

We hope to take advantage of the momentum resulting from increased visibility of genomics and genetics research with the completion of the Human Genome Project in 2003. This is an opportune time to redouble our community outreach, information dissemination, and public education efforts to encourage individuals from underrepresented racial and ethnic minority populations and other disparity populations to actively participate in the genetics revolution—as scientists, clinicians, research participants, and *active contributors* in deliberations of ethics and public policy.

This objective addresses public comments: “NIH must continue to promote the development of inter-institutional partnerships between research-intensive institutions and minority-serving institutions.” NHGRI has developed a program to increase researchers from underrepresented minority communities. NHGRI has reviewed the public comments and recognizes the themes to “…use racially, culturally sensitive and appropriate communication while strengthening the capacity of minority communities.” To address this concern, we have taken significant measures in information diffusion and dissemination.

3.1.1 Objective One: Facilitate the Incorporation of Science-Based Information Into the Curricula of K-12 Schools

3.1.1.1 Action Plan

NHGRI has developed resources to facilitate the incorporation of science-based information into high school curricula, with targeted dissemination to racial and ethnic minority and other disparity communities. "The Human Genome Project - Exploring our Molecular Selves," a grade 9-12 education resource, was originally produced by NHGRI in February 2001. In 2002, NHGRI reformatted this education kit, making the materials available for download on its web site (http://www.genome.gov), thus providing expanded access to students and teachers across the country. A second, revised edition of the kit will be developed in FY2005. This kit provides unprecedented access to cutting-edge information about the Human Genome Project and genomics, geared specifically for use by life science educators. The kit has been widely distributed and enthusiastically received.

NHGRI is creating a multimedia interactive education resource to communicate the excitement and opportunities in genomic research and genomic careers to high school and college students. The goal of this DVD is to expose students across the United States to genetics and genomics careers, with a specific aim to reach students from backgrounds underrepresented in genetic and genomic careers. This DVD would fill a critical need for resources in the NHGRI public education program, which is a key component of our strategy to increase research capacity.

The genomic careers multimedia education product will be in development throughout FY2004-2005 and is targeted for distribution and promotion in FY2005-2006. Evaluation of the product will be conducted in FY2006-2007.

This objective addresses public comments: "Sponsor programs to mentor, educate, and provide grant support to minorities who pursue health careers opportunities and promote partnerships between minority-serving and research institutions." NHGRI has developed an opportunity for students and faculty to gain exposure to genetic and genomic concepts and to genomic research careers.

3.1.1.2 Performance Measures

- Development of a product that captures the excitement of genomics research and transmits that excitement it to its target audience
- Dissemination to high schools and colleges, including targeted dissemination plan to schools with significant percentages of underrepresented racial and ethnic minority populations and other disparity populations
- Dissemination to underrepresented racial and ethnic minority schools and communities
- Dissemination to low socioeconomic status and rural schools and communities
- Increased number of community interactions with the education resources

3.1.1.3 Outcome Measures

- Evaluation of the quality and effectiveness of the resource
- Increased number of students interested in genomic careers, particularly students from underrepresented racial and ethnic minority and disparity populations
- Increased utilization of the education kit by schools with student populations underrepresented in genetic and genomic careers
- Increased utilization of the education kit by low socioeconomic status and rural schools and communities
- Increased knowledge of genomics research in schools and communities with students underrepresented in the field of genomics

3.1.2 Objective Two: Establish a Vital Presence at Disparity Populations-Focused Conferences

3.1.2.1 Action Plan

NHGRI continues to enhance its presence at conferences targeted toward diverse communities by hosting a visible and inviting exhibit booth, organizing genomics symposia, compiling an attractive brochure that highlights training opportunities in genomics, and hosting roundtables or hospitality suites so that students and faculty have a chance to speak with staff from the various training programs of NHGRI. NHGRI will actively seek out opportunities to give presentations to groups such as the Society for Advancement of Chicanos and Native Americans in Science, the National Association of Hispanic Nurses, the Association of American Indian Physicians, the National Medical Association, the National Hispanic Medical Association, the National Black Nurses Association, the Intercultural Cancer Coalition, and other organizations serving the communities appropriate for ELSI research.

NHGRI developed an outreach exhibit plan in FY2004 to increase and document its outreach activities. NHGRI will continue to increase its level of participation in conferences targeted to disparity populations.

This objective addresses public comments: "…ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives." NHGRI has developed a strategy to inform and educate disparate populations.

3.1.2.2 Performance Measures

- Increased number of conferences with an active NHGRI exhibit booth
- Increased number of interactions with underrepresented racial and ethnic minority students and faculty; students and faculty at underrepresented minority-serving institutions; and students from low socioeconomic status background and rural communities

- Increased number of genomic symposia/presentations at targeted conferences
- Increased number of students and faculty that participate in NHGRI training activities because of information provided by NHGRI staff at conferences

3.1.2.3 Outcome Measures

- Increased knowledge of NHGRI training and research programs by underrepresented racial and ethnic minority students
- Increased participation in NHGRI training and research programs by underrepresented racial and ethnic minority students
- Increased knowledge of NHGRI training and research programs by low socioeconomic status and rural students
- Increased participation in NHGRI training and research programs by low socioeconomic status and rural students

3.1.3 Objective Three: Continue to Support and Develop an Annual Conference About Genomics for the Public

3.1.3.1 Action Plan

The social, ethical, and policy challenges posed by genomics can only be addressed justly and equitably by ensuring that all segments of the population are able to participate. NHGRI will make every effort to increase minority participation in the NHGRI Annual Community Genetics Forum (also known as “Consumer Day”), which was initiated in the fall of 1999. The goal of the Forum is to engage and empower the public and members of community-based organizations, providing them with an opportunity to become informed about all aspects of human genome research. Beginning in 2005, the Forum will be held in a different region of the country each year to broaden the national scope and reach of this activity.

This objective addresses public comments: “ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives.” NHGRI has developed a strategy to inform and educate disparate populations.

NHGRI, in collaboration with community-based partners, is developing models of engaging racial and ethnic minority and other disparity communities to participate in the Community Genetics Forum program. These community-based models include collaborations with faith-based and other community-based organizations.

3.1.3.2 Performance Measures

- Attendance by members of communities underrepresented in science and biomedical research, including racial and ethnic minority communities, at the Annual Conference
- Attendance by underrepresented racial and ethnic minority students from local schools at the Annual Conference
- Attendance by members of low socioeconomic status and rural communities at the Annual Conference
- Attendance by low socioeconomic status and rural students at the Annual Conference
- Conference evaluation forms from attendees to measure impact of these conferences
- Development of additional collaborations with NHGRI Centers and grantees to reach communities around the country

3.1.3.3 Outcome Measures

- Increased participation in NHGRI activities by individuals from communities underrepresented in science and biomedical research
- Increased linkages with institutions serving minorities or disadvantaged/underserved populations

3.1.4 Objective Four: Genetic and Rare Disease Information Center

3.1.4.1 Action Plan

NHGRI and the Office of Rare Diseases Research (ORDR) established the Genetic and Rare Diseases Information Center (GARD) to provide accurate, reliable, and current information on genetic and rare diseases to patients, families, health care professionals, and biomedical researchers. NHGRI and ORDR will develop an outreach plan to provide increased access to the Center by individuals within disparity populations including U.S. racial and ethnic minority populations. NHGRI and ORDR will implement the plan in FY2005-2008.

This objective addresses public comments: “ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives.” NHGRI has developed a strategy to inform and educate disparate populations. A public comment read, “…distribute NIH resources equitably across all population groups.” NHGRI has developed a partnership to all populations to help keep them informed about rare genetics issues.

3.1.4.2 Performance Measures

- Awareness by underrepresented racial and ethnic minority communities of GARD
- Awareness by low socioeconomic status and rural communities of GARD
- Promotion of GARD services at professional and public conferences

- Provision of the latest research-based information about genetic and rare diseases to health professionals serving disparity populations
- Provision of the latest research-based information about genetic and rare diseases to health professionals serving low socioeconomic status and rural communities

3.1.4.3 Outcome Measures

- Increased utilization of the Information Center by disparity population patients and families
- Increased utilization of the Information Center by low socioeconomic status and rural patients and families
- Increased utilization of the Information Center by health care professionals serving underrepresented racial and ethnic minority patients
- Increased utilization of the Information Center by health care professionals serving low socioeconomic status and rural patients and families

3.1.5 Objective Five: Family History Public Education Initiative

3.1.5.1 Action Plan

Family History Day is an initiative whose objectives are to increase the American public's awareness of the importance of family history, to provide accessible methods for easily obtaining an accurate family history, and to increase health professionals' use of family histories in disease prevention and health promotion. A Web-based tool is being designed that will enable users to chart a pedigree and to print out a copy for themselves and their physician; the tool will be made available in FY2004.

Thanksgiving Day 2004 will serve as the inaugural National Family History Day. In a phased approach, this year's initiative will focus on increasing awareness of the importance of family history and will lay a foundation to make this an effective annual national campaign. A component of the Annual National Family History Day Initiative is to reach the diverse communities of the country. Community- and faith-based organizations will be engaged in the initiative, helping to develop models for reaching racial and ethnic minority and disparity communities.

This objective addresses public comments: "Ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives." NHGRI has developed a strategy to inform and educate disparate populations.

3.1.5.2 Performance Measures

- Increased utilization by underrepresented racial and ethnic minority patients and families of Web-based or printed family history tool
- Increased utilization by low socioeconomic status and rural patients and families of Web-based or printed family history tool

- Increased utilization by health care professionals serving racial and ethnic minority populations and other disparity populations of Web-based or printed family history tool
- Increased utilization by health care professionals of the patient's family history in the care of patients within racial and ethnic minority populations and other disparity populations

3.1.5.3 Outcome Measures

- Evaluation of the utilization of the Web tool by the public
- Increased awareness of family medical history as a preventative health tool
- Increased overall preventive health

3.1.6 Objective Six: DNA Day Public Education Programs

3.1.6.1 Action Plan

NHGRI seeks to facilitate the incorporation of science-based information about genetics and genomics in a high school outreach and information dissemination program. NHGRI, with partners the American Society of Human Genetics, the Genetic Alliance, and the National Society of Genetic Counselors, embarked in 2004 on a national "DNA Day": a high school outreach program that took place on April 30, 2004. The DNA Day program began in 2003, coinciding with the completion of human genome sequencing; this was seen as an opportunity to have a "teachable moment," given the large amount of press attention given to the Human Genome Project at that time.

Faculty, staff, and postdoctoral fellows from all three NHGRI divisions visited high schools across the country to talk to students about genomic science and how it will influence the future of biology, medicine, and society. The DNA Day Ambassador program provides an opportunity for students, specifically including those from underrepresented and disadvantaged populations, to get excited about careers in science and increase their awareness of how rapid changes in the areas of genetics and genomics will affect their everyday lives. A complete list of schools visited in 2004 can be found at http://www.nhgri.nih.gov/11511624. Ambassadors have been encouraged to stay in contact with the schools they visited so that the teachers at these schools have a "personal contact" through whom they can continue to obtain up-to-date information about genomics.

The goals of this project were to: (1) excite students about careers in genetics and genomics by exposing them to genetic concepts, genomic researchers, and health professionals; (2) update and/or introduce educators to NHGRI's education resources; (3) foster interactions between NHGRI investigators, trainees, and staff and the broader public community through schools; and (4) expand NHGRI's collaborations with consumer organizations and professional associations.

3.1.6.2 Performance Measures

- Awareness by students of genetics and genomic concepts

- Number of schools with a student body from diverse backgrounds, including rural communities or predominantly racial and ethnic minority or other disparity populations, that participate in the DNA Day program

This objective addresses public comments: "Ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives." NHGRI has developed a strategy to inform and educate disparate populations.

3.1.6.3 Outcome Measures

- Evaluation by teachers, students, and the ambassadors of the benefits of the DNA Day program
- Evaluation by teachers, students, and the ambassadors of the impact of the DNA Day program on the student body
- Increased knowledge and excitement about the Human Genome Project
- Increased interaction of NHGRI investigators with the community

3.1.7 Objective Seven: Community Based Outreach and Dissemination/Demonstration Projects

3.1.7.1 Action Plan

The success of genomics-based tools in improving the health of all depends in part on communicating advances in genomic and ELSI research to all communities and on empowering them to utilize new genetic information and technologies to maximize benefits and avoid potential misuses. In essence, the goals for this area of emphasis are: (1) to foster development of policy, education, and outreach activities relevant to increasing the involvement of diverse communities in all aspects of genetic research; (2) to reduce health disparities; and (3) to integrate new genetic technologies into health care in underserved communities. NHGRI will develop models of partnership with community-based organizations to foster dialogue on genomics and biomedical research and the dissemination of the latest research-based information on genetic disease to communities.

This objective addresses public comments: "Ensure that all communications with health disparities populations and their subgroups addresses their needs and perspectives." NHGRI has developed a strategy to inform and educate disparate populations. A public comment read, "NIH must support research and promote information dissemination through partnership with academic institutions and communities so that research results will reach communities."

3.1.7.2 Performance Measures

- Develop model community engagement programs in racial and ethnic minority communities
- Develop model community engagement programs in low socioeconomic status and rural communities

3.1.7.3 Outcome Measures

- Evaluation of the programs and the communities' knowledge about genomics
- Increased involvement of diverse communities in subjects pertaining to genetic research
- Increased integration of genetic technologies into underserved communities

The National Institute of Allergy and Infectious Diseases

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

MISSION STATEMENT

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support research that strives to understand, treat, and prevent the multitude of infectious, immunologic, and allergic diseases that endanger the lives of millions of people nationally and globally.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Overview

A central feature of contemporary human societies is their increasing diversity. Differences in socioeconomic status, racial and ethnic background, education level, and occupation all intersect in complex ways to create disparities in health status. These disparities may stem from many factors, including accessibility of health care and increased risk of disease due to occupational exposure, or underlying genetic, ethnic, or familial factors.

The NIAID has long recognized the importance of differential risk for infectious and immunologic diseases among populations. It is common practice in the field of infectious disease to identify subgroups within a population that are at higher risk for infection due to identifiable factors such as advanced age, which can increase susceptibility to serious influenza virus infections.

NIAID also recognizes that racial and ethnic differences affect susceptibility to infection and disease. African American individuals chronically infected with hepatitis C do not respond as well to antiviral therapy as do other ethnic groups. Pneumococcal infections are much more serious in children who have sickle cell disease. African American women experience a higher rate of autoimmune diseases than do White women. Native American populations have higher rates of meningitis and invasive bacterial disease from *Haemophilus influenzae* type B (Hib) than do other groups.

The study of differences in disease susceptibility can have pragmatic outcomes that impact the development of research products such as drugs and vaccines. Research that addresses disease susceptibility may also reveal critical information about the disease process that could, in turn, yield novel avenues to treatment or prevention.

The NIAID *Strategic Plan for Addressing Health Disparities Fiscal Years 2004-2008* is based on over half a century of progress toward the understanding, treatment, and prevention of infectious and immunologic diseases. Many of NIAID's advances have helped to eliminate or mitigate health disparities. Development of effective glyco-conjugate vaccines to prevent Hib infections, for example, has almost eliminated Hib-related diseases in the Native American population. The development of effective therapies for hepatitis B, education and interventions to improve asthma control in inner-city populations, and the development of improved therapies for Human

Immunodeficiency Virus (HIV) infection are all NIAID-supported research advances that have reduced health disparities.

Not all citizens, however, reap full benefit of our increased knowledge. Although health disparities affect many segments of the U.S. population, some medically underserved populations bear a disproportionate share of this burden. NIAID maintains its commitment to improve minority health and to attract capable minority scientists into research related to infectious and immunologic disease. Recognizing that we can achieve our mission only through the interaction and participation of the minority scientific community throughout the United States, NIAID has sought to involve colleges and universities, medical centers, and professional organizations, in conjunction with minority communities and groups that assist underserved populations, to realize its goals.

NIAID's *Strategic Plan for Addressing Health Disparities Fiscal Years 2004-2008* focuses on diseases within the Institute's research portfolio that disproportionately impact underserved minority and socioeconomic populations. The plan includes specific objectives to provide the tools necessary to eliminate health disparities. Many NIAID research activities that fall outside the *Strategic Plan* bear indirectly on race, ethnic, and socioeconomic inequities in health status. For example, improvements in treatments for HIV/Acquired Immunodeficiency Syndrome (AIDS), particularly those treatments that are less expensive and/or involve less complex regimens, will contribute greatly to health equality.

PUBLIC COMMENTS

The NIAID reviewed the public comments obtained since publication of the 2002-2006 *Strategic Plan* and made several revisions to its *Strategic Plan* for 2004-2008. To address concerns about diversity in the populations it studies and the use of racially and culturally sensitive language, NIAID hosted a Health Disparities Symposium on October 2, 2003. An important goal of this symposium was to identify best practices for recruitment of subjects from diverse backgrounds into NIAID-sponsored clinical trials during FY2004. The symposium audience consisted of researchers, primary care physicians, nurses, health care workers, and advocacy groups, as well as the general public.

Symposium speakers and workshop leaders were drawn from the same background as the audience. Many different health care disciplines and research areas were represented. The major topic addressed at the symposium was how to conduct successful clinical trials. This included how researchers should interact with patients and what steps lead to better retention of study subjects. Participants were made aware that mistrust engendered by the scientific community may lead to reluctance on the part of primary care physicians to recommend to their patients that they participate in clinical trials. Primary care physicians were assured of their crucial role in the process and that they would not "lose" patients to the institutions conducting the clinical trial. A summary of the proceedings will be placed on the NIAID web site in the near future.

In response to inquiries regarding the partnering of research-intensive institutions with students from minority institutions, NIAID expanded the Introduction to Biomedical Research Program to include the Asofsky Scholars in Research. NIAID encourages grantees to recruit students from minority and other underrepresented populations between high school and first year postbaccalaureate to study in their laboratories. In the first year (FY2003), 19 minority students were supported.

NIAID remains committed to increasing the number of investigators from underrepresented populations in all areas of its scientific mission. Historically, the NIAID has supported a variety of biomedical research programs for underrepresented populations from high school through postdoctoral training. Although these programs have demonstrated success in specific areas, only a few investigators from underrepresented populations have become well established biomedical researchers. Therefore, NIAID issued a Request for Applications (RFA) (AI-03-45) entitled “NIAID Enhancement Awards for Underrepresented Minority Scientists,” with the twin goals of increasing the number of investigators from underrepresented populations performing independent competitive research in the areas encompassed by the NIAID’s scientific mission and enhancing the long-term research skills and potential of these individuals. Grants were funded in FY2004, and the RFA has not been reissued. If reissued in the future, its target would be broadened to include a cadre of researchers who can contribute to the diversity in the academic workforce and trainee pool.

NIAID has further addressed concerns regarding presentation of information in a culturally and language-sensitive format by publishing low-literacy English and Spanish language booklets about tuberculosis. These publications are helpful in explaining the disease, its treatment options, and the need to adhere to the treatment regimen. NIAID continues to provide quality scientific publications that are written to impart knowledge to the general public with the use of plain language.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: HIV/AIDS

The burden of HIV disease in the United States continues to increase among minority populations and women. The proportional distribution of AIDS cases among racial and ethnic groups has shifted since the beginning of the pandemic in 1981; the proportion of cases among Whites has decreased over time while it has increased among African Americans and Hispanics. Women account for a steadily increasing proportion of AIDS cases.

One of the greatest challenges facing HIV/AIDS researchers today is the recruitment and retention of racial and ethnic minority patients for clinical trials, particularly African Americans, Hispanics, Asians and Pacific Islanders, and American Indians/Alaska Natives. As the changing demographics of this pandemic continues, access to and participation in clinical research becomes critical to those populations most affected.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Racial and ethnic minority populations in the United States, primarily African Americans and Hispanics, constitute 61 percent of the more than 830,000 cases of AIDS reported to the U.S. Centers for Disease Control and Prevention (CDC) since the epidemic began in 1981. African Americans make up 41 percent of all AIDS cases reported in the United States, yet according to the U.S. Census Bureau, they comprise only 12 percent of the U.S. population. Hispanics represent 19 percent of all AIDS cases and are approximately 13 percent of the U.S. population. Injection drug use is a major factor in the spread of HIV/AIDS in minority communities; other factors contributing to the spread of HIV/AIDS in these communities include men who have sex with men (MSM) and increasingly, heterosexual transmission.

According to the CDC, as of December 2002:

- African Americans and Hispanics represented 57 percent of males and 78 percent of females living with AIDS.
- Fifty-nine percent of all women reported with AIDS were African American and 19 percent were Hispanic.
- African American children represented almost 59 percent of all pediatric AIDS cases.
- Of the 92 pediatric AIDS cases reported in 2002, 82 (89 percent) were African Americans and Hispanics.
- AIDS is the leading cause of death among African American men ages 25-44.

NIAID's Division of AIDS (DAIDS) addresses minority issues in the areas of HIV/AIDS treatment, natural history, and vaccine research; infrastructure development and training of minority researchers; and outreach activities. DAIDS continues efforts to encourage racial and ethnic minorities to enroll in its clinical trials and epidemiology cohorts. In both therapeutics and prevention research, DAIDS strives to: (1) ensure that the number of members of underserved populations participating in clinical trials is representative of the national epidemic; (2) identify the need for and/or assist in developing culturally sensitive education materials; and (3) identify real or potential barriers to recruiting and retaining these groups in clinical research and help develop mechanisms to overcome these barriers.

NIAID also continues to support research to better understand the impact and course of HIV disease in minority communities and to develop and evaluate treatment and prevention strategies that could help mitigate the disproportionate impact on these communities.

1.1.1 Objective One: Support Research to Study the Factors That Effect the Recruitment of Women and Minorities Into HIV/AIDS Clinical Trials

Public Law 103-43 requires that: (1) the National Institutes of Health (NIH) ensure that women and minorities are included in all human subject research, including Phase III clinical trials, to allow for valid analysis; (2) cost not be an acceptable reason for exclusion of these groups; and (3) NIH initiate systems and support for outreach efforts to recruit volunteer women and minorities in clinical studies. In addition, it is important for NIAID to enroll a significant proportion of people from traditionally underserved populations, including African Americans and Hispanics, into its clinical trials to ensure that the treatment and/or preventive measures being evaluated are appropriate for all communities.

To increase the enrollment of women and minorities into clinical trials, NIAID seeks to identify the factors that influence the decisions of members of these communities to enroll in HIV/AIDS clinical trials and to identify innovative solutions and strategies to increase the future enrollment of these populations in HIV/AIDS clinical trials.

1.1.1.1 Action Plan

Steps

Through a Program Announcement, *Enrolling Women and Minorities in HIV/AIDS Research Trials,* NIAID is soliciting applications to study innovative and practical approaches to access, enroll, and study minority women and young adult populations in HIV/AIDS research trials in the United States, targeting the underserved, particularly in urban areas.

Timeline

FY2003
- Program Announcement released in September 2003.

FY2004
- Receive applications by January 2, May 1, and September 1, 2004 deadlines.
- Identify Special Emphasis Panel and convene for scientific review 2-3 months after receipt of applications.
- Provide the Center for Scientific Review Panel’s summary statement to NIAID staff.
- Identify grant applicant(s) that meet the NIAID-established payline.
- Identify any grant applicant(s) that meet scientific gaps outlined in the Program Announcement that were not scored favorably and recommend these grants for funding with set-aside NIAID funds.
- Generate the funding plan for approval of requested grant application funding.
- Release NIAID funds to approved investigator institution(s) within 6 to 8 months, allowing the investigator to conduct the proposed research project. The next cycle of grant applications and resubmissions also will be received for grant review process.

FY2005-2008
- Continue to identify underserved or disenfranchised populations (e.g., women, minorities, adolescents, and young children).

- Specify barriers to participation in clinical research for these and other special populations.
- Develop initiatives to address the problems identified above and increase minority enrollment and enrollment of special populations into clinical trials.

1.1.1.2 Performance Measures

- Publication of initiative in the NIH Guide.
- Submission of grant applications.
- Funding of awards.
- Provision of technical assistance.

1.1.1.3 Outcome Measures

- Funded investigators provide an annual progress report detailing advances/status on specific goals listed in the grant application.
- Implementation of innovative solutions for increasing the enrollment of women and minorities in HIV/AIDS research trials.

1.1.2 Objective Two: Support HIV Vaccine Research to Prevent HIV Infection, Which Would Ultimately Reduce Disparities in the Incidence And Prevalence of HIV/AIDS

A vaccine that effectively prevents HIV infection is critical to controlling the HIV/AIDS pandemic and to reducing disparities in the incidence and prevalence of HIV/AIDS. The primary objective of HIV vaccine research is to identify a vaccine that provides immunity to multiple strains of HIV, and that can either prevent infection or slow the course of disease, so that the immunized person is healthier and less infectious.

In November of 2002, the Dale and Betty Bumpers Vaccine Research Center (VRC) launched a Phase I clinical study of a novel DNA vaccine directed at the three most globally important HIV subtypes, or clades. The vaccine developed by the VRC incorporates HIV genetic material from clades A, B, and C, which cause about 90 percent of all HIV infections worldwide. This is the first multigene, multiclade HIV vaccine to enter human trials and marks an important milestone in the search for a single vaccine that targets U.S. subtypes of HIV, as well as clades causing the global epidemic. The first phase of the trial, in which a total of 50 healthy, HIV-negative volunteers have been enrolled, is being conducted by the VRC at the NIH in Bethesda, Maryland, and is designed to determine the vaccine's safety at three dose levels. VRC scientists also are evaluating the vaccines to determine the strength of the immune responses at each dose level. A larger clinical trial to further evaluate safety, immune response, and schedule is being conducted through the NIAID DAIDS HIV Vaccine Trials Network (HVTN) at several domestic sites. A Phase I clinical trial with 30 healthy volunteers also will be carried out in Uganda in collaboration with the Makerere University-Walter

Reed Project (MUWRP), DAIDS, and the VRC. The DAIDS Adult AIDS Clinical Trials Group (AACTG) is also conducting a Phase I clinical trial of this vaccine in HIV-infected volunteers.

1.1.2.1 Action Plan

Steps

Identify and develop new vaccine concepts, particularly those that induce broadly neutralizing antibodies, consistent and high levels of cytotoxic T-lymphocytes, and strong mucosal immune responses.

1. Evaluate new vaccine concepts for immunogenicity, safety, and efficacy in animal models.
2. Manufacture, using Good Manufacturing Practices (GMP), those products that show promise and that may not have adequate industry backing; and move novel, improved products through the U.S. Food and Drug Administration's (FDA) Investigational New Drug (IND) approval process.
3. Define critical components of the immune response to HIV that may be associated with protection by studying immune responses in HIV-infected adults and children who are long-term non-progressors as well as in vaccinated animals and human recipients of candidate HIV vaccines.
4. Define the components of HIV-specific mucosal immunity.
5. Develop vaccine candidates that will help decipher the impact of HIV variability on AIDS vaccine efficacy.
6. Promote the evaluation in humans of a broad range of promising HIV vaccine candidates with different designs. Whenever possible, conduct studies with common protocols, reagents, and assays to make meaningful comparisons of various approaches.
7. Develop and implement mechanisms for timely review of safety data from volunteers in HIV vaccine trials. Provide the FDA with real time, periodic, and final reports evaluating vaccine safety when DAIDS holds the IND. Request similar regulatory compliance for DAIDS-funded studies when the sponsor files the IND.
8. Utilize knowledge on the mechanisms of protective immunity to improve and further develop a range of laboratory assays to evaluate protective human immune responses induced by vaccines in human trials.
9. Expand the capacity of the HVTN to carry out a comprehensive HIV vaccine research agenda, including the conduct of domestic and international clinical trials of the most promising HIV vaccine candidates.
10. Continue to promote NIAID programs for domestic and international research to ensure that the best researchers vigorously pursue the best approaches worldwide.
11. Foster early and continued collaboration with industry in the clinical development of a broad range of candidate vaccines.
12. Develop the necessary strategies, infrastructure, and collaborations with governments, communities, and non-profit organizations to conduct vaccine trials.

13. Work with other programs within DAIDS to foster research on both the natural history and immune response to early HIV infection, in particular those studies leading to the selection of appropriate endpoints to consider in vaccine trials.
14. Foster studies of the genetic variability of the virus and host at international sites that are conducting or will conduct HIV vaccine clinical trials.
15. Develop novel strategies to test HIV vaccines in efficacy trials that address the multiple challenges of assessing the impact of HIV vaccines to prevent infection, disease progression, and transmissibility of HIV to uninfected humans.

Timeline

FY2004

- Expand HIV clinical trials capacity through the HVTN.
- Expand HIV Vaccine Design and Development Teams.
- Establish HIV Vaccine Advance Development Program.
- Expand Integrated Preclinical/Clinical AIDS Vaccine Development.
- Expand the Innovation Grant Program for AIDS Research.
- Expand HIV Vaccine Research and Design Program.
- Perform extensive statistical analyses of the VaxGen Phase III U.S. study (in conjunction with VaxGen) to evaluate potential vaccine efficacy based on race, ethnicity, and/or gender.
- Continue to work cooperatively with the U.S. Army Medical Research and Materiel Command (USAMRMC) of the Department of Defense (DoD) Program to ensure the effective integration and coordination of HIV vaccine research efforts of the USAMRMC's newly transferred HIV Research and Development Program to the NIAID, established through an interagency agreement in October 2002.
- Initiate or continue a number of HIV vaccine trials.
- Perform Phase I trials of candidate HIV vaccines developed by the VRC. This will involve community education on HIV prevention, recruitment of healthy adults into clinical trials, study design and analysis, and maintenance of regulatory standards.

FY2005

- Renew/expand central laboratory to support efficacy trials.
- Renew Innovation Grant Program for AIDS Vaccine Research.
- Expand HIV Vaccine Advanced Product Development.
- Expand HIV Vaccine Design and Development Teams.
- Expand Integrated Preclinical/Clinical AIDS Vaccine Development.
- Renew HIV Vaccine Research and Design Program.
- Renew/Expand human leukocyte antigen (HLA) typing and epitope mapping for HIV vaccine design.
- Continue ongoing and initiate new activities at the VRC.

- Establish Center for HIV/AIDS Vaccine Immunology in support of Global HIV Vaccine Enterprise.

FY2006
- Expand HIV Vaccine/Microbicide Preclinical Development program.
- Renew HIV Vaccine Design and Development Teams.
- Renew HIV Vaccine Advanced Product Development program.
- Renew Integrated Preclinical/Clinical AIDS Vaccine Program.
- Renew Innovation Grant Program for AIDS Vaccine Research.
- Renew HIV Vaccine Development Resources.
- Expand Interagency Agreement for HIV Vaccine Efficacy Trials.

FY2007-2008
- Evaluate candidate vaccines in Phase II/III trials in high risk populations:
  - Identify immunologic, virologic correlates of protection; and
  - Link findings with animal model studies.
- Develop cohorts and collect epidemiological information to prepare for large trials, particularly in underserved minority communities.
- Initiate studies to decipher relevance of genetic subtypes.
- Evaluate immune responses, including validation of assays to be used in pivotal trials and development of new assays to measure the full breadth of induced immune response.
- Standardize and optimize clinical trial design to accelerate the pace of evaluation and to ensure rapid licensure in special populations, all at-risk groups, and adolescents.
- Contribute to discussions to facilitate U.S. and international licensure of HIV vaccines.
- Collaborate with other organizations targeting special populations and working in the area of vaccine research and development to further advance research efforts.

1.1.2.2 Performance Measures

- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

1.1.2.3 Outcome Measures

- Availability of new and improved vaccine candidates for testing.
- Publication of scientific advances relevant to HIV/AIDS vaccines in refereed scientific journals.
- Interest of industry and governments in the production of HIV/AIDS vaccines.

1.1.3 Objective Three: Support Research on Topical Microbicides to Reduce Health Disparities Related to AIDS and Sexually Transmitted Diseases

NIAID supports several programs that develop and evaluate topical microbicides. This research will directly benefit all women, especially minority women at high risk of HIV infection. By eliminating the need to negotiate over the use of a condom, the use of topical microbicides will allow women at high risk of HIV infection more control over the type of protection they may use, which may result in a reduced risk of sexually transmitted HIV.

1.1.3.1 Action Plan

Steps

1. Develop a topical microbicide that:
    - Prevents infection and/or viral replication by both cell-free infectious HIV particles and cell-associated infectious particles; and
    - Is safe and non-inflammatory (causes no irritation to the vaginal/cervical/urethral/rectal epithelium); and reduces infectivity of other sexually transmitted infectious (STI) agents.
2. Support fundamental research to delineate the early steps in HIV infection via mucosal surfaces.
3. Encourage the development of combination microbicides containing multiple active products that target more than one of the steps in the HIV life cycle relevant to mucosal transmission and/or have activity against other STIs, in particular those STIs that may potentiate HIV transmission.
4. Support research and development of safe and effective formulations and delivery methods.
5. Develop and utilize suitable animal models for safety and efficacy testing.
6. Support preclinical to clinical translational research for topical microbicides.
7. Conduct clinical trials to determine safety, acceptability, efficacy, and effectiveness of the most promising topical microbicides.
8. Continue to promote NIAID programs to domestic and international researchers to ensure that the best researchers vigorously pursue the most promising approaches worldwide.

Timeline

FY2004
- Establish Microbicide Design and Development Teams.
- Expand microbicide clinical trials capacity through the HIV Prevention Trials Network.
- Expand the Integrated Preclinical/Clinical Program for Topical Microbicides.
- Expand the HIV Vaccine/Microbicide Preclinical Development program.

FY2005
- Initiate a Phase II/IIb safety and effectiveness study of the vaginal microbicides BufferGel and 0.5 percent PRO200/5 Gel (P) for the prevention of HIV infection in women (HPTN 035).

- Expand Sexually Transmitted Infections and Topical Microbicides Clinical Trials Groups (STI-CTG) for Phase I/II microbicide trials.
- Expand microbicide dedicated clinical trials capacity for Phase II/III studies.
- Renew Microbicide Design and Development Teams.
- Renew Integrated Preclinical/Clinical Program for Topical Microbicides.

FY2006

- Renew/Expand Microbicide Design and Development Teams.
- Expand HIV Vaccine/Microbicide Preclinical Development program.
- Expand STI-CTG for Phase I/II microbicide trials.
- Expand Preclinical Resource: Formulations for Topical Microbicides.
- Establish Microbicide Innovation Program.

FY2007-2008

- Continue to conduct all phases of clinical research focusing on products with appropriate safety profile (daily use), multiple mechanisms of attack, and combinations.
- Evaluate the best products in Phase IIb/III trials.
- Evaluate user and partner acceptability and adherence, particularly in high risk, underserved populations and dissociated from sexual intercourse.
- Explore correlates of safety and efficacy.

1.1.3.2 Performance Measures

- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

1.1.3.3 Outcome Measures

- Availability of new and improved topical microbicide candidates for testing.
- Publication of scientific advances relevant to HIV/AIDS microbicides in referenced scientific journals.
- Interest of industry and governments in the production of topical microbicides against HIV/AIDS.

1.1.4 Objective Four: Support Research to Prevent Mother-to-Child Transmission of HIV

The prevention of mother-to-child transmission (pMTCT) of HIV is a high priority of the NIAID. Since the initial demonstration that a significant reduction of the rate of maternal to child transmission (MTCT) of HIV-1 can be achieved with antiretroviral intervention in the perinatal period, dramatic reductions in the rates of neonatally acquired HIV-1 infection have occurred in locations where perinatal transmission prevention programs have been instituted. One of the more dramatic results that emerged from the HIVNET 012 study was that a single dose of Nevirapine delivered to the mother at the time of delivery was capable of reducing transmission by as much as 70 percent. Nonetheless, in 2003, 500,000 children worldwide died as a result of HIV/AIDS.

There are opportunities to intervene successfully to prevent infection from mother to child. One of NIAID's highest priorities is to develop safe, simple, inexpensive interventions that do not impair future care or treatment of the mother or child.

1.1.4.1 Action Plan

Steps

1. Develop *in vitro* and animal models to study aspects of the pharmacokinetics and toxicity of antiretroviral, immunotherapeutic, and other therapeutic drugs related to perinatal transmission.
2. Define the mechanisms and risk factors for HIV transmission to children and adolescents as well as risks for disease progression within the framework of clinical studies and trials.
3. Continue to implement studies to identify safe, practical, and more effective approaches to further reduce MTCT, especially in resource-poor countries.
4. Continue to implement studies to define treatment options for both mother and child.
5. Continue to provide technical knowledge to ensure prolonged success of pMTCT programs.

Timeline

FY2004
- Expand international site capacity and support HIV and HIV-related complications research, appropriate to the setting.
- Initiate studies in HIV-infected women and children to determine if prior exposure to Nevirapine in pMTCT programs modifies response to treatment with combination treatment regimens containing non-nucleoside reverse transcriptase inhibitors (NNRTIs) in the future.
- Initiate studies of short-course combination regimens with Nevirapine in women during the immediate postpartum period to reduce the emergence of drug resistance.

FY2006-2008
- Continue to conduct studies to identify strategies that optimize and simplify regimens for pre-, peri- and post-partum to:
  - Further decrease transmission, especially during breastfeeding;
  - Minimize drug toxicity in women and infants;
  - Simplify delivery of regimens to increase adherence;
  - Prevent the emergence of drug resistance; and
  - Evaluate the impact of resistance on future treatment options for mothers, children, and communities.

- Continue to conduct studies to evaluate the safety and pharmacokinetics of new drugs and drug combinations for HIV-negative non-pregnant women, HIV-positive non-pregnant women, HIV-positive pregnant women, and HIV-positive very young children.
- Conduct studies to evaluate the safety and efficacy of vaccines to prevent MTCT at the time of delivery and during breastfeeding.
- Conduct studies to evaluate the safety and efficacy of passive immunization of newborns.

1.1.4.2 Performance Measures

- Initiation of clinical trials.

1.1.4.3 Outcome Measures

- Availability of new and improved regimens for prevention of MTCT.
- Further decrease in MTCT transmission with new combination regimens.
- Decrease emergence of resistance detectable by genotype analysis.
- Identification of new regimens for prevention of MTCT with fewer side effects for women.
- Publication of scientific advances relevant to MTCT in refereed scientific journals.

1.1.5 Objective Five: Support Research to Better Understand the Course of HIV Disease Among Minority Women

The number of women with HIV infection and AIDS has been increasing steadily worldwide. By the end of 2003, according to the World Health Organization (WHO), 19.2 million women were living with HIV/AIDS worldwide, accounting for approximately 50 percent of the 40 million adults living with this disease.

By the end of 2002, 159,271 adolescent and adult women in the United States were reported as having AIDS. Based on cases reported by 29 states to the CDC through December 2002, more than 57,376 women have been infected with HIV but have not progressed to AIDS. Among adolescent and adult women, the proportion of AIDS cases more than tripled from 7 percent in 1985 to 26 percent in 2002. In the past 4 years, however, AIDS cases in adolescent and adult women have declined by 17 percent, reflecting the success of antiretroviral therapies in preventing the development of AIDS.

Worldwide, more than 90 percent of all adolescent and adult HIV infections result from heterosexual intercourse. Women are particularly vulnerable to heterosexual transmission of HIV due to substantial mucosal exposure to seminal fluids. HIV disproportionately affects African American and Hispanic women. Together they represent less than 25 percent of women in the United States, yet they account for more than 82 percent of AIDS cases in women in this country.

Women suffer from the same complications of AIDS as men, but women also suffer sex-specific manifestations of HIV disease, such as recurrent vaginal yeast infections and severe pelvic inflammatory disease, which increase their risk of cervical cancer. Women also exhibit different characteristics from men for many of the same complications of antiretroviral therapy, such as metabolic abnormalities.

As part of the recommendations of an external review of the Women's Interagency HIV Study (WIHS), the Program Announcement (PA), "HIV Pathogenesis in the Women's Interagency HIV Study," was issued in August 1997. This 3-year PA was re-issued in April 2001, with other NIH Institutes co-sponsoring the WIHS, and focuses on basic science investigations in the Institutes' respective areas of interest. The PA has initiated research on a broad range of topics. This past year, a virology basic science grant was funded to evaluate hepatitis C virus (HCV) and HIV co-infection among women in the WIHS. Previously funded grants focused on research in HIV virology, HIV resistance to antiretroviral drugs, illicit drug use and HIV resistance to antiretroviral therapy, and human papillomavirus infection and associated cervical and anal cancers.

1.1.5.1 Action Plan

Steps

1. Support research on the long-term natural history of HIV infection in women; in particular, support research that evaluates the impact of antiretroviral therapy on the natural history of HIV.
2. Evaluate the introduction of antiretroviral therapy into populations with high-prevalence epidemics.
3. Monitor the development of antiretroviral-resistant virus and the effect of resistance on individual therapeutic benefit as well as population-level transmission and disease control.
4. Increase the participation of HIV-infected women in clinical trials by identifying barriers to recruitment and retention and methods to ameliorate these barriers.
5. Evaluate immune reconstitution in women after initiation of antiretroviral therapy, including research on the natural history of immune reconstitution, the quality of the recovered immune function, and impact of other covariates on immune recovery.
6. Determine the effect of sex/gender on disease progression, treatment, complications of HIV disease and its treatment, and the long-term outcome of antiretroviral therapy.
7. Examine the prevalence of high-risk behaviors (including commercial sex work and exchange of sex for drugs) and barriers to medical care among adolescents and women to design effective risk reduction interventions.
8. Develop and test a broad spectrum of HIV-preventive approaches, such as topical microbicides, control of sexually transmitted diseases, and behavior modification strategies.
9. Determine the effect of hormonal, endocrine, and local factors on viral load and sexual transmission.

10. Study the female genital tract compartment, including the microenvironment, HIV virology, and immunology of the female genital tract as compared to blood.

Timeline

FY2004

- Continue support for the WIHS.
- Continue to support and foster collaborative research between the Multicenter AIDS Cohort Study (MACS) of men who have sex with men and the WIHS to explore sex/gender differences in HIV disease. (This research is facilitated by the recent expansion of MACS to include more minority men with or at risk for HIV infection.)
- Emphasize multidisciplinary approach to investigations of HIV in women to address biologic, behavioral, and health access issues.
- Continue to facilitate the work of the clinical trials groups to enroll women into clinical trials and conduct research that focuses on gender and sex-specific issues.

FY2005-2008

- Continue support for the WIHS to 2007, through trans-NIH collaborations with the National Institute of Child Health and Human Development, National Institute on Drug Abuse, National Cancer Institute, and National Institute of Dental and Craniofacial Research.
- Continue to support other researchers to develop collaborations with the WIHS study team to enhance the areas of research conducted within this study population.
- Solicit renewal applications from the WIHS investigators for external peer review of their continued scientific research program (2007-2012).

1.1.5.2 Performance Measures

- Initiation of relevant studies within the WIHS.
- Collaborations to expand research based on the WIHS cohort database.

1.1.5.3 Outcome Measures

- Availability of data on HIV/AIDS among minority women.
- Publication of scientific advances relevant to HIV/AIDS among minority women in refereed scientific journals.

1.2 Area of Emphasis Two: Organ Transplantation

Organ or tissue replacement is the preferred treatment for end-stage organ failure when other therapies have failed or are not available, and when the person affected by organ failure is deemed likely to benefit from organ transplantation. The benefits of organ transplantation, as evidenced by prolonged survival and/or improved quality of life, are clearly demonstrated for children and adults suffering from a wide range of congenital and acquired diseases. In 2004, transplant centers in the United States performed nearly 27,037 organ transplants. This represents a 47 percent increase in solid organ transplants over 10 years, during which advances in surgical, clinical, and immunosuppressive strategies greatly improved short-term graft and patient survival. However, these advances have had little success in reversing the decline in long-term graft and patient survival that is seen in recipients of any organ transplant. Furthermore, complications of long-term pharmacologic immune suppression such as systemic hypertension, diabetes mellitus, renal insufficiency, and malignancy continue to adversely affect long-term outcomes.

Added to the challenge of immune-mediated morbidity and mortality after organ transplantation, another major obstacle is the critical shortage of available organs. In 2003, there were 86,355 candidates on the waiting list, the majority of whom (66 percent) needed kidney transplants. More than 7,000 candidates died while awaiting transplants in 2003. Although the overall percentage increase in transplanted organs for 2002 equaled the increase in the size of the waiting list (2.7 percent for both), the gap between organ supply and demand remains a substantial problem. Efforts to increase the donor pool have included the use of expanded criteria for donor selection, deceased donor organs, living donor organs, and promoting public awareness about organ donation.

Living organ donation, which has more than doubled in the last 10 years, is the leading strategy to address the great shortage of donor organs: kidney, liver, and lung. Graft and patient outcomes are superior with living donor kidneys than with those from deceased donors. Little is known, however, about the risks to and outcomes of living donors. For example, the impact of living organ donation on developing end-stage organ failure is a salient issue because most living donors are relatives of recipients and therefore may face an increased risk of genetic susceptibility to organ disease. This is particularly important for African Americans, who are at greater risk for many of the diseases leading to end-stage organ failure.

Other significant challenges in the field of organ transplantation are overcoming the racial and ethnic disparities in the prevalence of end-stage organ failure, rate of transplantation, and outcomes following transplantation. According to the 2000 U.S. Census, African Americans comprise approximately 13 percent of the U.S. population and their rate of organ donation (13.6 percent of all donors in 2002) is proportional to their representation in the population. However, African Americans are disproportionately represented on the organ transplant waiting list, comprising 26.8 percent of the total candidates and 35.2 percent of kidney transplant candidates. This is because African Americans, compared with the general U.S. population, are at an increased risk for the development of and complications from many of the diseases leading to end-stage organ failure and the need for transplant. These diseases include hypertension, diabetes, end-stage renal disease, cardiovascular disease, hepatitis C infection, and chronic liver failure.

Despite representing more than a quarter of waitlist candidates in 2002, African Americans comprised only 18 percent of transplant recipients. For kidney transplantation, this is partially explained by matching histocompatibility molecules between donors and recipients. Histocompatibility, or human leukocyte antigen (HLA) matching, is a consideration in prioritizing the distribution of kidneys. Increasing HLA differences between the donor and the recipient raise the likelihood of graft rejection. Whites are more likely to find a good match in the donor kidney pool than candidates from other racial or ethnic groups because: (1) they are more represented in the donor kidney pool; and (2) racial or ethnic differences in HLA diversity make it more likely that Whites will find a matched or nearly matched organ. These observations also apply to hematopoietic stem cell transplantation (HSCT), where HLA mismatching increases the risk of graft failure and graft versus host disease.

In contrast to African Americans, other minority groups do not have such disparities in transplant outcomes. Hispanics, comprising 12.5 percent of the U.S. population, accounted for 14.2 percent of waiting list candidates, 12 percent of transplant recipients, and 12.3 percent of organ donors in 2002. Asians, comprising 4.2 percent of the U.S. population, accounted for 5.1 percent of waiting list candidates, 3.5 percent of transplant recipients, and only 2.5 percent of organ donors in 2002. Graft and patient survival for these minority groups are comparable to those of the general population, with the tendency for Asians to have slightly better long-term outcomes.

For reasons that are not well understood, African Americans experience poorer outcomes after transplantation than other racial and ethnic groups. Adjusted graft and patient survival rates for kidney, liver, and heart transplants at 1, 3, and 5 years are lower in African Americans compared to all transplant recipients and even lower than other racial and ethnic groups. Additionally, African Americans experience a higher incidence of acute graft rejection and long-term immunosuppression-related adverse effects (e.g., post-transplant lymphoproliferative disorder, diabetes mellitus, and systemic hypertension). This disparity in outcomes following transplant may be related to: donor-recipient HLA mismatching; other immunologic factors, including greater immune responsiveness in African Americans; differences in drug pharmacokinetics; access to health care; socioeconomic factors; and medical non-compliance.

Recognizing that knowledge of HLA diversity in minority populations can be a barrier to successful transplantation, NIAID supports research to identify new HLA alleles (variants of a gene) in distinct racial and ethnic groups. NIAID-supported researchers have discovered 13 new HLA alleles in African Americans, three new alleles in Native Alaskan Yupiks, and two new alleles in Lakota Sioux. NIAID also supports research to identity well-tolerated mismatches in HSCT that may widen the scope of possible donors for transplant candidates with infrequent HLA types.

As part of its program planning activities, NIAID solicits advice from the scientific community and the public prior to developing new research initiatives. The National Advisory Allergy and Infectious Diseases Council (NAAIDC) provides advice on programmatic areas and approves new initiatives in immune-mediated disease research, including organ transplantation research. In addition, NIAID convened expert panels to evaluate the current state of the science and provided guidance on scientific opportunities in HLA genetics and transplantation genomics research. Recommendations from these panels guided the development of the Genomics of Transplantation Cooperative Research Program and the HLA Region Genetics in Immune-Mediated Diseases Program. NIAID also solicited comments from the public on the draft Request for Applications (RFA) for Clinical Trials in Organ Transplantation.

1.2.1 Objective One

Support programs to help reduce disparities by improving donor matching for organ and tissue transplantation through discovery of immune response gene variants in minority populations and develop and apply advanced technologies for rapid donor-recipient matching.

1.2.1.1 Action Plan

Steps

1. Support research to identify and catalog new HLA genes in minority populations.
2. Support research to determine the range of diversity of other immune response genes in minority populations.
3. Encourage the development and application of DNA-based technologies to rapidly and more accurately type HLA genes.

Timeline

FY2004

- Establish the Genomics of Transplantation Cooperative Research Program to identify and characterize gene polymorphisms and expression patterns that correlate with and predict differences in responses to specific immunosuppressive therapeutics, transplant graft survival and rejection, variability in graft survival among populations, and immune responses during acute and chronic graft rejection that relate to onset and severity.
- Continue to support efforts of the International Histocompatibility Working Group (IHWG) to identify new HLA alleles and their frequencies in global populations.
- Continue to support Small Business Innovation Research (SBIR) grants for the development and application of DNA-based technologies to rapidly and accurately type HLA genes.
- Continue to support ongoing investigator-initiated research related to organ transplantation.
- Continue to support meritorious new investigator-initiated research related to organ transplantation.

FY2005

- Establish the HLA Region Genetics in Immune-Mediated Diseases program to continue and build on the previously funded efforts of the IHWG to define the association between HLA region genes or genetic markers and immune-mediated diseases, including risk and severity of disease and hematopoietic cell transplantation outcomes.
- Continue to support the Genomics of Transplantation Cooperative Research Program.
- Continue to support SBIR grants for the development and application of DNA-based technologies to rapidly and accurately type HLA genes.
- Continue to support ongoing investigator-initiated research related to organ transplantation.
- Continue to support meritorious new investigator-initiated research related to organ transplantation.

FY2006-2008

- Continue to support ongoing programs.
- Continue to support ongoing investigator-initiated research related to organ transplantation.
- Continue to support meritorious new investigator-initiated research related to organ transplantation.
- Establish Genomics of Transplantation Cooperation Research Program.

1.2.1.2 Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of meritorious awards related to organ transplantation.
- Organization of scientific meetings in organ transplantation that address research topics specific to minority populations.

1.2.1.3 Outcome Measures

- Presentation of significant findings at scientific meetings.
- Deposition of new allele sequence data in GenBank, dbMHC, and the WHO database.
- Publication of new HLA alleles that appear at a high frequency in minority populations.
- Prototyping of new, high-throughput methods to type HLA genes in donors and recipients.

1.2.2 Objective Two

Support clinical research on the immunological mechanisms of graft acceptance and rejection to reduce immune-mediated morbidity and mortality after organ transplantation, and to enhance understanding of immunological differences among and ultimately reduce outcome disparities between different racial and ethnic groups.

1.2.2.1 Action Plan

Steps

1. Support clinical research on the immunological mechanisms of graft acceptance, acute and chronic graft rejection, and donor-specific tolerance.
2. Support clinical trials of therapeutic regimens to overcome immunologic barriers to graft acceptance and improve long-term graft and patient survival.
3. Support clinical and mechanistic studies to identify differences in immune response genes among different racial and ethnic groups; understand differences in their susceptibility to graft rejection as well as to adverse consequences of long-term immunosuppression; and identify differences in their response to and pharmacokinetics of therapeutic interventions.
4. Support increased recruitment of minority subjects in clinical research.

Timeline

FY2004

- Establish the Clinical Trials in Organ Transplantation (CTOT) program to support a cooperative, multi-center consortium for interventional or observational clinical and mechanistic studies on immune-mediated pathologic processes in organ transplantation. These studies will include the investigation of gene expression as a means to predict rejection and/or organ survival, and gene polymorphism distributions that may help elucidate why certain racial and ethnic groups are at increased risk for rejection and graft failure.
- Continue to support the Cooperative Clinical Trial in Pediatric Transplantation (CCTPT) program of multi-center clinical trials that focus on pediatric kidney transplant candidates and recipients. Studies include using new drug minimization protocols to limit side effects in pediatric kidney transplant recipients, and evaluating the efficacy of pre-transplant immunotherapy to reduce the risk of graft rejection in living donor kidney transplantation. Site selection and study designs have been modified to ensure adequate representation of ethnic minority subjects.
- Continue to support the Pathogenesis of Polyomavirus Associated Nephropathy (PVAN) program to increase understanding of this emerging complication in kidney transplant recipients. Research projects will focus on latent polyomavirus reactivation and virulence in immunosuppressed individuals; knowledge of immune responses to polyomavirus infection associated with nephropathy; risk assessment; and preventive, diagnostic, and treatment strategies for PVAN.
- Continue to support the Safety and Efficacy of Kidney and Liver Transplantation in Patients with HIV, a prospective cohort study of organ transplantation in patients with end-stage kidney or liver disease. The most common indication for kidney transplantation among persons infected with HIV is HIV-associated nephropathy (HIVAN), which disproportionately affects African Americans. In a pilot study that preceded this initiative, the majority of transplant recipients were African American.

- Continue to support the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials program that supports immune-based mechanistic studies associated with clinical trials of immunomodulatory agents for immune-mediated diseases, including graft rejection and graft versus host disease in transplantation clinical trials.

FY2005

- Continue to support the CCTPT program.
- Continue to support the CTOT program.
- Continue Pathogenesis of PVAN program.
- Continue to support the Safety and Efficacy of Kidney and Liver Transplantation in Patients with HIV.
- Continue to support the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials program.
- Continue to solicit, review, and fund applications for novel tolerance induction regimens in kidney and islet transplantation through the Immune Tolerance Network (ITN).

FY2006-2008

- Establish the Living Donor Registry Program to identify existing registries or cohorts of living organ donors, create a database for exploratory retrospective research, and establish a research consortium to develop and implement a scientific agenda on issues relevant to living organ donors, including health and survival outcomes, risk assessment, and medical care needs. Issues of particular relevance to racial and ethnic minorities include differences in risks to and outcomes for living donors of different racial or ethnic backgrounds; impact of living organ donation on the risk for later needing transplant; and cultural issues regarding willingness to be a living donor, especially among Asians, who have disproportionately lower rates of donation
- Renew the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials program to incorporate immune mechanistic studies in clinical trials of immunomodulatory interventions for immune-mediated diseases, including graft failure and graft versus host disease, in transplantation clinical trials.
- Renew the Collaborative Network for Clinical Research on Immune Tolerance (Immune Tolerance Network).
- Continue to support ongoing programs.
- Continue to support ongoing investigator-initiated research related to organ transplantation.
- Continue to support meritorious new investigator-initiated research related to organ transplantation.
- Establish Clinical Outcomes of Live Organ Donors program.

1.2.2.2 Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

1.2.2.3 Outcome Measures

- Publication of advances regarding the development of non-invasive methods to detect organ graft rejection.
- Publication of results from assessment of outcomes in kidney transplant recipients receiving intravenous immunoglobulin (IVIG).
- Publication of results from analysis of therapeutic interventions for organ graft rejection in African Americans.
- Publication of analysis of patient and graft survival rates in children.

1.2.3 Objective Three

Support pre-clinical studies on immune tolerance and on the immunological mechanisms of graft acceptance and rejection to address health disparities in minority populations.

1.2.3.1 Action Plan

Steps

1. Support research in pre-clinical animal models to assess the safety and efficacy of tolerance induction regimens prior to their use in clinical trials and to elucidate the mechanisms of graft rejection and acceptance.
2. Support research to develop alternatives to human organ transplantation.

Timeline

FY2004

- Continue to support the Non-Human Primate Immune Tolerance Cooperative Study Group (NHPCSG) to evaluate the safety and efficacy of existing and newly developed immune tolerance induction regimens in preclinical kidney and islet transplantation models. In addition, the group conducts research to develop new tolerogenic regimens and to elucidate the underlying mechanisms of the induction, maintenance, and/or loss of tolerance in these models. This program also provides an opportunity for critical preclinical research to complement NIAID-supported transplantation clinical trials.

- Continue to support the NIAID Specific Pathogen-Free Rhesus and Cynomolgus Macaque Breeding Colonies to provide macaques for preclinical research in solid organ and tissue transplantation conducted by the NIAID NHPCSG.
- Continue to support the National Swine Research and Resource Center, a central resource for swine reagents, rederivation of swine lines, distribution of high-quality, pathogen-free swine; development of swine models, and related services and information. This resource, established in FY2003, will facilitate xenotransplantation preclinical research.

FY2005
- Expand the NHPCSG to include non-human primate models of heart and lung transplantation. This expansion complements NIAID's growing program in clinical trials in organ transplantation. The timely expansion of the NHPCSG will help meet the scientific needs of the transplantation research community and allow capitalization on recent and future opportunities in heart and lung transplantation.
- Establish the Immunobiology of Xenotransplantation Cooperative Research Program for the development of preclinical, large animal models of xenotransplantation. The goals of this program are to: (1) delineate the cellular and molecular mechanisms of xenograft rejection and the induction of tolerance and accommodation; (2) develop effective strategies to improve xenograft survival; and (3) characterize the physiological compatibility/limitations of xenografts. The long-term goal of this program is to develop novel and effective strategies for broad application of xenotransplantation in the clinic.
- Renew the NIAID Specific Pathogen-Free Rhesus and Cynomolgus Macaque Breeding Colonies to continue the maintenance and breeding program and support the efforts of the NHPCSG by providing high-quality macaques for this valuable preclinical research program.

FY2006-2008
- Continue to support the ongoing programs.
- Continue to support the ongoing investigator-initiated research related to organ transplantation.
- Continue to support meritorious new investigator-initiated research related to organ transplantation.

1.2.3.2 Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of meritorious awards related to preclinical organ and tissue transplantation.

1.2.3.3 Outcome Measures

- Presentation of significant findings at scientific meetings.
- Publication of advances in non-human primate and xenotransplantation models, including development of new tolerance induction regimens.

- Initiation of clinical trials following non-human primate safety and efficacy studies.

1.3 Area of Emphasis Three: Autoimmune Diseases

Autoimmune diseases are those in which the immune system mistakenly attacks the body's own cells, tissues, and organs. Collectively, autoimmune diseases afflict approximately 5-8 percent of the U.S. population. Several of these diseases, such as systemic lupus erythematosus (SLE) and scleroderma, disproportionately affect minority populations, particularly African American women. Reports also indicate increased prevalences of SLE and rheumatoid arthritis among many American Indian populations.

SLE is a chronic, inflammatory, multisystem disorder of the immune system in which antibodies develop that react against a person's own tissue. SLE varies greatly in severity, from mild cases requiring minimal intervention to those in which significant and potentially fatal damage occurs to vital organs such as the lungs, heart, kidneys, and brain. SLE occurs in one out of 2,000 Americans and is more common and more severe in African American women, occurring in as many as one in 250 young African American women. SLE is four times more prevalent among African American men than among White men.

Scleroderma is an autoimmune disease that involves the abnormal growth of connective tissue, which supports the skin and internal organs. Localized scleroderma affects the skin and musculoskeletal system; systemic sclerosis may affect blood vessels and damage the heart, lungs, and kidneys. The number of Americans affected by systemic scleroderma is estimated to range from 40,000 to 165,000. Systemic scleroderma affects more African American women than women of European descent.

The NIAID supports a broad portfolio of basic, preclinical, and clinical research aimed at understanding the pathogenesis of autoimmune diseases; investigating new ways to modify the immune system; and applying this knowledge to identify and evaluate promising approaches to treat and prevent these diseases. As part of its program planning activities, NIAID solicits advice from the scientific community and the public prior to the development of new research initiatives. The NAAIDC provides advice on programmatic areas and approves new initiatives in immune-mediated disease research, including autoimmune diseases. In addition, the NIAID is the designated lead NIH Institute for the NIH Autoimmune Diseases Coordinating Committee (ADCC). The ADCC was established in FY1998 to increase collaboration and facilitate coordination of research among NIH Institutes and Centers, other federal agencies, and private groups interested in these diseases. The third ADCC Autoimmune Diseases Research Plan and was presented to Congress in 2002. The research plan and ADCC reports can be found at:
http://www.niaid.nih.gov/publications/autoimmune.htm

1.3.1 Objective One

Support research on the causes, treatment, and prevention of autoimmune diseases to help reduce disparities in the incidence and prevalence of those diseases that disproportionately affect minorities.

Basic and clinical research to advance understanding of the underlying immune mechanisms of autoimmune diseases is important to reduce disparities in the incidence and prevalence of these diseases. This research may provide insight into the mechanisms of tolerance induction, which may lead to the development and evaluation of new immune modulation interventions to treat and prevent autoimmune diseases. Central to the success of translating basic research findings to clinical applications are the close, cross-disciplinary interactions between basic and clinical researchers.

1.3.1.1 Action Plan

Steps

1. Establish and support a collaborative approach to basic research and clinical trials among multiple institutions in various geographic areas, and enhance the exchange of information between basic scientists and clinicians involved in the study and treatment of autoimmune diseases.
2. Support the design, conduct, and analysis of clinical trials to determine the safety and efficacy of HSCT as a treatment for multiple autoimmune diseases, including SLE, systemic scleroderma, and multiple sclerosis.
3. Support a broad range of investigator-initiated research to elucidate and understand the factors relevant to initiation, maintenance, diagnosis, prevention, and treatment of systemic autoimmune diseases.

Timeline

FY2004

- Support clinical trials and clinical studies of new immunomodulatory and tolerogenic approaches to prevent or treat autoimmune diseases, including integrated basic research studies to understand disease mechanisms that can be applied to the development of therapeutic and preventive approaches.
- Continue to support the Autoimmunity Centers of Excellence (ACE), which supports integrated basic, preclinical, and clinical studies, as well as clinical trials focused on tolerance induction and immune modulation to treat and prevent autoimmune diseases. The ACE were renewed and expanded in FY2003 to include nine separate institutions.
- Continue to support the ITN, which conducts clinical trials of tolerogenic approaches for autoimmune diseases, including those that disproportionately affect minority populations. The ITN is an international consortium of scientists and clinicians dedicated to the clinical evaluation

of novel, tolerance-inducing therapies in autoimmune diseases and asthma and allergic diseases, and the prevention of graft rejection in transplantation of kidneys and pancreatic islet cells.
- Continue to support the Stem Cell Transplantation for Autoimmune Diseases Consortium, which conducts clinical trials to assess the efficacy of HSCT to treat several severe autoimmune diseases, and studies to understand the underlying mechanisms of this therapeutic approach and the disease.
- Continue to support the Sex Based Differences in the Immune Response program, which investigates differences in the immune response in female reproductive mucosa. Increased understanding of the mechanisms underlying differences in the immune response in males and females should allow more targeted approaches to prevent and treat immune-mediated disease.
- Continue to support the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials program, which supports mechanistic studies of immunomodulatory interventions conducted in conjunction with ongoing or planned clinical trials funded by private or public sources.
- Continue to support the Multiple Autoimmune Diseases Genetics Consortium (MADGC) program, which provides clinical data and tissue materials to facilitate research on the identification and characterization of genes that confer susceptibility and/or resistance to the development of autoimmune diseases.
- Continue to support the Cooperative Study Group for Autoimmune Disease Prevention program to advance knowledge for the prevention and regulation of autoimmune disease. Areas of research include understanding the immune mechanisms that underlie autoimmunity and autoimmune diseases, the mechanisms and consequences of manipulation of immune responses in autoimmunity, and application of this information to the prevention of autoimmune diseases in humans.
- Continue to support the Statistical and Clinical Coordinating Center to support the ACEs and the Stem Cell Transplantation for Autoimmune Diseases Consortium.
- Continue to support ongoing investigator-initiated research on all aspects of autoimmune diseases.
- Continue to support meritorious new investigator-initiated research on all aspects of autoimmune diseases.

FY2005
- Renew the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials.
- Continue to support the ACEs.
- Continue to support the Stem Cell Transplantation for Autoimmune Diseases Consortium.
- Continue to support the Sex Based Differences in the Immune Response program.
- Continue to support the Cooperative Study Group for Autoimmune Disease Prevention program.
- Continue to support the Statistical and Clinical Coordinating Center to support the ACEs and the Stem Cell Transplantation for Autoimmune Diseases Consortium.
- Continue to support ongoing investigator-initiated research on all aspects of autoimmune diseases.

- Continue to fund meritorious new investigator-initiated research in all aspects of autoimmune diseases.

FY2006-2008

- Renew the ITN.
- Renew the ACE.
- Renew the Hyperaccelerated Award/Mechanisms in Immunomodulation Trials program.
- Renew the Cooperative Study Group for Autoimmune Disease Prevention.
- Renew the Stem Cell Transplantation for the Treatment of Autoimmune Diseases Consortium.
- Fund new and renewal initiatives, as appropriate.
- Continue to support ongoing clinical trials.
- Continue to support ongoing investigator-initiated research on all aspects of autoimmune diseases.
- Continue to fund meritorious new investigator-initiated research in all aspects of autoimmune diseases.

1.3.1.2 Performance Measures

- Presentation of significant findings and report on progress at biennial meeting of the ACE and at national scientific meetings.
- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Initiation of clinical studies and trials.

1.3.1.3 Outcome Measures

- Publication of scientific advances (in peer-reviewed scientific journals) relevant to understanding mechanisms of induction, maintenance, prevention, and treatment of autoimmune diseases.
- Publication of the identification and evaluation of new approaches for the treatment and prevention of autoimmune diseases.
- Availability of applications of clinical trial results to the diagnosis, treatment, and prevention of autoimmune diseases.

1.4 Area of Emphasis Four: Asthma

Asthma accounted for 13.9 million outpatient visits and 1.9 million emergency department visits in 2002. Children aged birth to17 years had more than 700,000 emergency department visits, a rate of 100 per 10,000, and this visit rate was highest among children aged birth to 4 years at 162 per 10,000. CDC reported in a March 29, 2002, publication that an estimated 14.7 million school days were missed among 5- to 17-year-olds because of asthma. There remains a major health disparity in asthma: the rate of asthma-related emergency department visits for African Americans was 380 percent higher than that for Whites. In 2002, 4,261 people died from asthma, or 1.5 per 100,000. Non-Hispanic Blacks were the most likely to die from asthma and had an asthma death rate over 200 percent higher than non-Hispanic Whites and 160 percent higher than Hispanics. Females had an asthma death rate about 40 percent higher than males. The cost of asthma in 2004 is estimated to be $16.1 billion, with direct costs amounting to $11.5 billion and lost earnings due to illness and death totaling $4.6 billion.

For more than a decade, improving the management of asthma in children has remained a high priority for NIAID. The Inner City Asthma Study (ICAS) (1996-2001), cosponsored by the National Institute of Environmental Health Sciences, had both an environmental intervention approach and a physician education component. Results indicated that physician education and an extensive environmental intervention can successfully reduce asthma symptoms among inner-city children and can continue to reduce symptoms 1 year after intervention. The environmental intervention involved home-based education to reduce exposure to environmental triggers, including environmental tobacco smoke, cockroaches, house dust mites, mold, furry pets, and rodents. Data showed that the environmental intervention resulted in 2 to 4 weeks of additional symptom-free days, a reduction in unscheduled medical visits, and improvements in asthma symptoms. The physician feedback intervention provided physicians with up-to-date information on patients' asthma symptoms, medication, and health care utilization. This information included a computer-generated algorithm, based on National Asthma Education and Prevention Program (NAEPP) guidelines, for adjusting medications based on asthma severity. Data show that the physician feedback intervention resulted in a 24 percent reduction in emergency room visits. The final results of the Inner City Asthma Study revealed interventions that significantly improved health for inner-city children with asthma as well as an overall reduction of the high medical, economic, and social costs associated with this disease. In addition, the reduction in symptoms persisted for at least 1 year after the intervention was stopped. The Inner-City Asthma Consortium (ICAC), established by NIAID in 2002, is evaluating the safety and efficacy of promising immune-based asthma treatments developed to reduce asthma severity and prevent disease onset in inner-city children. ICAC conducts research to determine the mechanisms of action of immune-based therapies; develops and validates biomarkers to measure disease stage, progression, and therapeutic effect; and conducts research to understand the immunopathogenesis of asthma in inner-city children. The affect of air pollution on asthmatic children was also studied by ICAS with co-funding from the U.S. Environmental Protection Agency. The study found that short-term exposure to outdoor air pollutants resulted in symptoms, reduced pulmonary function, and days missed from school.

As part of its program planning activities, NIAID solicits advice from the scientific community and the public prior to the development of new research initiatives. The NAAIDC provides advice on programmatic areas and approves new initiatives in immune-mediated disease research, including asthma and allergic diseases research. The NIAID inner-city asthma programs resulted, in part, from a series of outreach activities held in 1990, including: "Asthma Day at Howard University," "NIAID-NMA Asthma Awareness Workshops," and similar meetings that elicited public comment and highlighted the disproportional effects of asthma on minority populations.

1.4.1 Objective One

Support research on the causes, treatment, and prevention of asthma to help reduce disparities in the incidence and prevalence of this disease.

Over the past 2 decades, our understanding of the pathophysiology and management of asthma has improved significantly, yet the prevalence of this disease has increased by more than 70 percent in all age and ethnic groups. The increasing prevalence and high morbidity from asthma among inner-city children demonstrate the importance of developing new therapies that both reduce asthma severity and prevent disease onset. Recent studies suggest that the stage is set for the development of asthma during the first several months of gestation. These and other findings offer promising new opportunities to initiate basic and clinical research aimed at clearly defining the early-life perturbations of the immune system that lead to asthma development. NIAID programs in asthma feature outreach programs to increase community participation, guide clinical study development, and enhance awareness toward impacting the rise in asthma severity and mortality.

1.4.1.1 Action Plan

Steps

1. Design and conduct clinical trials of immune-based therapies in inner-city children with asthma, carry out research to study and understand the mechanisms of action of these therapies and their effect on disease, and conduct basic research studies on the immunopathogenesis of asthma in inner-city children.
2. Support basic and clinical research on the pathobiology of asthma that will lead to a better understanding of the role that immune dysfunction plays in the early life origins of asthma in humans.
3. Support research that will explore the potential benefits of tolerogenic approaches to asthma prevention and treatment.
4. Continue to support investigator-initiated research projects that address important scientific questions relevant to the pathogenesis, diagnosis, treatment, and prevention of asthma in inner-city children.

Timeline

FY2004

- Establish the Immune System Development and the Genesis of Asthma program to understand early life changes in immune function that lead to the development of asthma. Identification of the cellular and molecular processes involved in the onset of asthma will provide the basis for devising novel and effective immune-based strategies for asthma treatment and prevention that do not compromise the integrity of the immune system and are not hampered by the limitations of current therapies.

- Continue to support the Inner-City Asthma Consortium and the Statistical and Clinical Coordinating Center.
- Continue to support the Asthma and Allergic Diseases Cooperative Research Centers (AADRCs) program on clinical research and developmental immunobiology as it pertains to the early life origins of asthma in humans. The AADRCs were expanded in FY2003 to include 13 centers.
- Continue to support the ITN clinical trials of tolerance induction approaches in asthma and allergic diseases.
- Continue to support ongoing investigator-initiated research related to asthma.
- Continue to support meritorious new investigator-initiated research related to asthma.

FY2005

- Fund the Asthma Exacerbations: Biology and Disease Progression program to increase understanding of the mechanisms involved in acute exacerbations of asthma, including the cellular and molecular processes that cause some viral infections to trigger asthma attacks.
- Fund proposals for Phase I and II trials of tolerance induction to allergens relevant to asthma.
- Renew the AADRCs.
- Open a pediatric asthma/allergy clinic at the NIH Clinical Center to provide a focal point for NIAID intramural translational research, natural history and pathogenesis studies and clinical trials of novel therapies.
- Continue to support the Immune System Development and the Genesis of Asthma program.
- Continue to support the Inner-City Asthma Consortium and the Statistical and Clinical Coordinating Center.
- Continue to support the ITN.
- Continue to support ongoing investigator-initiated research related to asthma.
- Continue to support meritorious new investigator-initiated research related to asthma.

FY2006-2008

- Continue to support ongoing programs.
- Continue to support ongoing investigator-initiated research related to asthma.
- Continue to support meritorious new investigator-initiated research related to asthma.
- Continue clinical research in the NIAID pediatric asthma/allergy clinic.

1.4.1.2 Performance Measures

- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Funding of awards.

- Initiation of clinical studies and trials.
- Full enrollment in NIAID pediatric asthma/allergy clinic studies.

1.4.1.3 Outcome Measures

- Presentation of significant findings at scientific meetings.
- Presentation and publication of results of clinical trials.
- Presentation and publication of scientific advances in basic and clinical research studies.
- Identification and evaluation of new approaches for the treatment and prevention of asthma.
- Application of clinical trial results to the diagnosis, treatment, and prevention of asthma in underserved populations.

1.5 Area of Emphasis Five: Tuberculosis (TB)

Tuberculosis (TB) disproportionately affects foreign-born, minority, and low socioeconomic populations in the United States. Individuals who have emigrated from TB endemic countries often may harbor asymptomatic infection with *Mycobacterium tuberculosis* (*Mtb*), the causative agent of TB. During 2004, of the 14,517 U.S. cases of TB reported to the CDC, 54 percent were found in racial and ethnic minority populations, primarily from Mexico, the Philippines, Vietnam, India, and China. Clusters of high TB rates are typically seen in economically impoverished regions in the United States, urban homeless shelters, and other areas where crowed and substandard living conditions expose vulnerable populations to TB aerosols transmitted by infected persons. In the United States, relatively few patients die from this disease, but worldwide TB kills approximately 2 million persons each year and is the leading cause of death for people infected with HIV.

NIAID supports an extensive TB research portfolio designed to integrate basic, translational, and clinical research to better understand TB as a disease and facilitate development of improved diagnostic, preventive, and treatment measures for this disease. In addition, NIAID provides critical resources to the research community worldwide, such as research reagents; evaluation of promising drug, vaccine, and diagnostic candidates; and the infrastructure and expertise to conduct human clinical trials.

1.5.1 Objective One

Support research on vaccines to help reduce disparities in the incidence and prevalence of tuberculosis.

The development of a new TB vaccine for worldwide use is a critical control strategy to reduce the burden of TB in minority populations and limit the health disparities associated with the disease. The vaccine should effectively prevent adult pulmonary TB or be an effective immunotherapeutic agent that either prevents the progression of latent, asymptomatic infection to active disease or shortens the duration of chemotherapy for drug sensitive and multi-drug resistant (MDR) TB. The currently available neonatal vaccine, Bacille Calmette-Guerin (BCG), offers only limited protection against adult pulmonary TB, but protects well against complications of TB in children.

1.5.1.1 Action Plan

Steps

1. Support discovery, preclinical, and clinical research for new TB vaccine candidates.
2. Support studies to refine relevant animal models of infection and disease that can be used to select the most promising new vaccine candidates.
3. Conduct studies to define the immune responses in animals and humans for promising new vaccine candidates to allow development of improved vaccination approaches.
4. Support studies to understand the human immune response after neonatal vaccination with BCG.
5. Support molecular epidemiology studies to characterize *Mtb* strains that produce disease in susceptible populations.
6. Conduct clinical trials to evaluate safety, immunogenicity, and efficacy of new TB vaccines; and to improve vaccination strategies with BCG.

Timeline

FY2004

- Continue to support clinical immunology studies conducted by the NIAID Tuberculosis Research Unit (TBRU).
- Renew and optimize the TB Research Materials and Vaccine Testing contract to increase our knowledge of vaccine performance in animal models, use post-genomic approaches to define immune responses to vaccine candidates, and develop advanced vaccine candidates and vaccination strategies.
- Expand NIAID resources to determine the biological function of target genes in animal models to facilitate selection of vaccine candidates and vaccination approaches.
- Continue to support development of new delivery and adjuvant systems under the Millennium Vaccine Initiative.
- Continue to support public-private partnerships for the translation of fundamental science into new vaccination strategies.
- Continue to encourage and support grant applications that:
  - Characterize host immune responses to *Mtb* infection and progression to disease;
  - Define pediatric immune responses to *Mtb* infection and BCG vaccination; and
  - Utilize post-genomic resources to identify new vaccine candidates.

FY2005

- Support clinical studies to better characterize the immune response to BCG vaccination.

- Conduct Phase I safety studies with new TB vaccine candidates in individuals who previously have been exposed to *Mtb.*
- Continue to support NIAID's contract resources that augment the development of new vaccines or vaccination strategies.
- Conduct workshops to coordinate the characterization of new vaccine candidates.
- Continue to encourage and support translational approaches to identify vaccination strategies against adult pulmonary TB in HIV-infected and non-infected individuals.

FY2006–FY2008

- Conduct Phase I/II studies with new vaccine candidates in healthy individuals and TB patients.
- Renew the TBRU, a contract that supports multidisciplinary approaches to answering critical questions regarding the human response to *Mtb* infection and TB disease.
- Expand resources to facilitate preclinical development and production of new vaccine candidates for human clinical trials.

1.5.1.2 Performance Measures

- Number of grants that are focused on translating basic research findings to vaccine products or approaches.
- Increased network of public-private partnerships to facilitate product development.
- Clinical trials and studies with new vaccines and/or vaccination strategies.

1.5.1.3 Outcome Measures

- Availability of expertise to conduct Phase I/II trials for new TB vaccines.
- Publication of scientific advances related to TB vaccines.
- Number of clinical trials and/or clinical studies conducted with new vaccine candidates/approaches.

1.5.2 Objective Two

Support research on improved therapeutic strategies that would reduce disparities in the incidence and prevalence of tuberculosis.

TB is essentially a treatable disease; however, to effectively clear the bacterial pathogen, drug therapy for TB requires patients to take multiple antibiotics for 6-9 months. The long duration and side effects of the drug therapy coupled with the fact that patients on drug treatment usually start feeling better after only a few weeks of therapy result in a significant number of individuals not completing the treatment. As a result, TB is not effectively treated and drug-resistant strains of *Mtb* develop. TB that is caused by MDR bacteria is difficult to treat and requires therapy for up to 2 years with more expensive and even less well-tolerated drugs. Therefore, one of the primary goals in translational research for TB is to develop either shorter or better tolerated drug regimens that facilitate treatment completion and prevent the development of MDR-TB, and/or to develop novel drugs and combinations that are well tolerated and effectively combat already existing MDR-TB. Since TB patients may also be infected with HIV, a complication that is especially prevalent in developing countries, and may be taking antiretroviral therapy, novel TB drugs also have to be evaluated in the context of HIV infection and care. Furthermore, an important component of TB control strategies is to offer effective, well-tolerated chemotherapy to treat asymptomatic infection with *Mtb* to prevent progression to active disease. The latter approach requires reliable identification of asymptomatic carriers who do not have active TB and would benefit from a different and less complex drug regimen than the therapy typically used for active TB. Development of suitable diagnostics that can complement these approaches is the focus of Objective Three.

1.5.2.1 Action Plan

Steps

1. Support discovery, preclinical, and clinical research for new TB drug candidates.
2. Support studies to define the critical biochemical pathways in *Mtb* that may serve as points of intervention with chemotherapeutic strategies.
3. Conduct studies to characterize the pharmacological action of existing TB drugs to better understand their individual contributions in a multi-drug regimen and during different phases of drug treatment.
4. Support studies to refine relevant animal models of infection and disease that can be used to select the most promising new drug candidates.
5. Expand resources to support preclinical characterization and production of materials for clinical trials.
6. Support trials to define the optimal timing and combination of TB and anti-HIV treatment.
7. Conduct clinical trials to evaluate safety and efficacy of new TB drugs and improved chemotherapeutic strategies, including existing drugs as well as combinations of drugs and immunotherapeutic strategies.

Timeline

FY2004

- Continue to support clinical drug studies conducted by the NIAID TBRU.
- Continue to support the comprehensive, multi-component Tuberculosis Antimicrobial Acquisition and Coordination Facility (TAACF) that provides support for identification and characterization of promising new anti-TB drugs.
- Renew and optimize the TB Research Materials and Vaccine Testing contracts to provide high-quality research reagents for investigators identifying potential new drug targets.

- Expand NIAID resources with contract support to determine, in animal models, the requirements of new drug candidates to optimally inhibit or eliminate *Mtb* bacteria from TB patients (pharmacology of drug action).
- Expand NIAID resources with contract support to determine the biological function of target genes in animal models to facilitate selection of appropriate molecular targets against which new drugs can be directed.
- Continue to support public/private partnerships for the translation of fundamental science into new drug targets and chemotherapeutic strategies.
- Continue to encourage and support grant submissions to:
  - Identify essential pathways in *Mtb* physiology for survival with the host;
  - Better understand the mechanism of action of existing and promising new TB drugs; and
  - Utilize post-genomic approaches to develop tools and characterize the physiological state of latent *Mtb* in the host.

FY2005
- Support clinical studies to better define early efficacy studies with new drug candidates in human patients (EBA studies).
- Conduct Phase I safety studies with new TB drug candidates in individuals who have previously been exposed to *Mtb.*
- Continue to support contract resources that augment the development of new drugs or chemotherapeutic strategies.
- Conduct workshops to coordinate between academic and industrial interests for the development of new TB drugs.
- Continue to encourage and support translational and clinical approaches to better characterize and optimize the existing multi-drug treatment regimen for TB.
- Encourage and support studies to define appropriate treatment strategies against TB in HIV-infected individuals or AIDS patients.

FY2006–2008
- Conduct Phase I/II studies with new drug candidates.
- Renew and optimize NIAID’s drug development resources to continue identification and characterization of promising new drug candidates.
- Expand resources to facilitate preclinical development, formulation, and production of new drug candidates for human clinical trials.

1.5.2.2 Performance Measures

- Number of grants including translation of basic research findings into drug candidates and chemotherapeutic strategies.
- Increased network of public-private partnerships to facilitate product development.

- Clinical trials and studies with new or existing drugs and/or chemotherapeutic strategies, including integration with antiretroviral treatment in HIV-infected individuals.

1.5.2.3 Outcome Measures

- Availability of expertise to conduct Phase II/III trials for new TB drugs or chemotherapeutic approaches in HIV-infected and non-infected populations.
- Publication of scientific advances related to TB drugs and drug target development.
- Number of clinical trials and/or clinical studies conducted with new drug candidates and/or chemotherapeutic approaches.

1.5.3 Objective Three

Support translational and epidemiologic research studies to develop specific and sensitive diagnostics for the identification of persons with asymptomatic infection at high risk of developing TB disease, and to develop rapid tests to detect MDR tuberculosis.

The development of more sensitive and specific diagnostics that can reliably detect adult pulmonary TB, especially in HIV-infected persons, identify asymptomatic infection and persons at highest risk for developing active disease, and detect TB in pediatric populations is a basic requirement for ensuring that effective TB control can be maintained. Furthermore, simple and sensitive diagnostics that can quickly identify MDR-TB are desperately needed because drug-resistant cases are steadily increasing, and proper as well as timely treatment of patients needs to be assured. Development of improved diagnostics relies on thorough epidemiological and transmission studies within the United States and across U.S. borders to identify bacterial strains with the potential to create disease outbreaks and to characterize populations that would benefit most from targeted diagnostic testing.

1.5.3.1 Action Plan

Steps

1. Support development of rapid, reproducible diagnostic strategies for identification of active TB in HIV-infected and non-infected persons and asymptomatic infection.
2. Support inclusion of diagnostic test evaluation as part of relevant ongoing or planned TB drug and/or vaccine studies.
3. Support studies to develop and/or validate rapid methods to identify drug-resistant TB.
4. Expand resources to support preclinical characterization and production of diagnostic prototypes for clinical trials.
5. Support trials to define sensitivity and specificity of promising diagnostic strategies.
6. Support molecular epidemiology studies to characterize properties of drug-resistant strains that can be exploited in microbiological diagnostics.

7. Support molecular epidemiology studies to characterize properties and transmission patterns of drug-sensitive and MDR-strains of *Mtb* that produce disease in susceptible populations.

Timeline

FY2004

- Continue to support clinical studies conducted by the NIAID TBRU that are identifying surrogate markers of infection and disease and that provide clinical specimens for diagnostic validation.
- Continue to support epidemiologic studies conducted by the NIAID TBRU and through grants that characterize disease transmission patterns and bacterial strain characteristics.
- Renew and optimize the TB Research Materials and Vaccine Testing contract to provide high-quality, standardized research reagents that will serve as components of novel diagnostic tests. Furthermore, the contract will provide post-genomic resources to facilitate the discovery of molecular markers that may help identify MDR-TB or presence of mycobacterial infection.
- Continue to support through public-private partnerships and small business grants the development and characterization of new diagnostic candidates.
- Continue to encourage and support grant submissions to:
  - Characterize immune parameters at various stages of the host/pathogen interaction that may be utilized in diagnostic tests;
  - Characterize and define the potential of antibody tests to identify *Mtb* infection;
  - Define molecular markers of *Mtb* that may be utilized in microbiologic diagnostics;
  - Characterize disease transmission patterns of drug-resistant and drug-sensitive TB; and
  - Develop diagnostic platforms that can be utilized in low-resource settings.

FY2005

- Support clinical studies to validate surrogate markers of infection and disease.
- Support feasibility studies of new microbiologic and/or immunologic diagnostics.
- Support feasibility studies for rapid identification of MDR-TB.
- Support epidemiologic studies to better characterize populations who benefit most from targeted diagnostic testing.
- Provide well-characterized clinical samples for the validation of novel diagnostic approaches.
- Encourage increased public-private partnerships and collaborations of small business entities with clinical researchers to facilitate development of commercializable diagnostics.
- Encourage and support studies to define appropriate diagnostic strategies for TB in HIV-infected individuals or AIDS patients.

FY2006–FY2008

- Conduct clinical trials to validate promising diagnostic candidates in field settings.
- Renew and optimize NIAID’s TBRU to continue development of surrogate markers of infection and disease as well as to conduct epidemiology and transmission studies.

1.5.3.2 Performance Measures

- Number of grants including translation of basic research findings and epidemiologic studies into diagnostic tests and strategies.
- Increased network of public-private partnerships to facilitate product development.
- Clinical trials and studies with new or existing diagnostic products/candidates, including studies in pediatric and HIV-infected individuals.

1.5.3.3 Outcome Measures

- Availability of expertise to conduct specificity/sensitivity evaluation under field conditions for advanced diagnostic candidates.
- Publication of scientific advances related to TB diagnostics.
- Number of clinical trials and/or clinical studies conducted with new diagnostic candidates/strategies.

1.5.4 Objective Four

Conduct tuberculosis epidemiology studies in an area with a high concentration of racial and ethnic minorities.

The NIAID will support a program to study all aspects of the genetic and social epidemiology of TB in Harris County, Texas, a metropolitan area with more than 500 new TB cases per year, more than 75 percent of which occur among African Americans and Hispanics. This study will identify traditional risk factors among patients with TB such as HIV infection, injection drug use, homelessness, and history of incarceration. In addition, the analysis of genetic polymorphisms among TB strains will allow investigators to more exactly characterize TB transmission in this defined geographic area. Molecular subtyping of the TB organism can uncover previously unrecognized outbreaks and may lead to greater understanding of transmission dynamics among this population.

1.5.4.1 Action Plan

Steps

1. Maintain facility to enroll 500 TB patients, including at least 25 pediatric patients and 250 control patients per year for a longitudinal, population-based, active surveillance and molecular epidemiologic study of TB cases.
2. Interview patients using a standardized questionnaire designed to gather basic demographic and socioeconomic data and to identify TB risk factors.
3. Acquire *Mtb* isolates from all available culture-positive patients for genetic characterization by molecular subtyping methods.

4. Use information from questionnaires and data from molecular analysis of TB isolates to characterize the epidemiology of TB in this area.

Timeline

This program began in FY2000. Sample collection will end in September 2004.

FY2004

- Maintain appropriate community liaisons to facilitate patient ability to participate in NIAID intramural research programs related to *Mtb*. Facilitate patient participation by providing transportation of patients from their homes or workplaces to the study facility, and identify incentives for study participation such as meals and/or reimbursement for time.
- Collect clinical material from a minimum of 500 TB patients and 250 control subjects. Interview patients using a standardized questionnaire designed to gather basic demographic and socioeconomic data and to identify tuberculosis risk factors.

FY2005

- Finish conducting molecular characterization of *Mtb* strains collected during 2004.
- Compile results and delineate molecular epidemiology and risk factors associated with TB transmission in this geographic area.
- Publish results in peer-reviewed journal.

1.5.4.2 Performance Measures

- Number of subjects enrolled in the trial.
- Percentage of subjects that remains enrolled through trial completion.
- Completion of the trial.

1.5.4.3 Outcome Measures

- Publication of scientific advances regarding risk factors and transmission dynamics associated with TB in the population.

1.6 Area of Emphasis Six: Hepatitis C

At least 2 percent of the world’s population is chronically infected with the blood-borne pathogen, hepatitis C virus (HCV). In the United States, there are approximately 40,000 new infections every year, adding to a large pool of 2.7 million chronic carriers. Chronic HCV infection leads to serious liver diseases, such as cirrhosis and primary liver cancer, in as many as 25 percent of carriers. Almost 40 percent of all liver transplants in the United States are due to HCV-related liver failure. The rates of chronic liver disease are highest among minority populations such as African Americans, American Indians, and people of Hispanic origin. Also, the rate of response to treatment with IFN-alpha and ribavirin is significantly lower in African Americans. These data suggest that unknown factors, including genetic predisposition, play key roles in determining the course of HCV infection and related liver disease in these populations.

At present, in the United States, populations at highest risk for HCV disease are injection and recreational drug users and individuals who received blood or blood products before 1992. Most new infections result from intravenous drug abuse and are likely to occur among relatively young people, within socioeconomically depressed communities, and in minority populations. NIAID has calculated that over 40 percent of HCV-infected individuals are minorities. In addition, African Americans have a greater propensity for infection to become chronic as well as a poorer response to therapy. HCV infection resulting from intravenous drug abuse is frequently complicated by co-infection with HIV, and the rate of development of chronic HCV infection is higher in the presence of HIV.

1.6.1 Objective One

Support research on vaccines and related areas that would help reduce the disparities in the incidence and prevalence of hepatitis C.

NIAID has two distinct, but coordinated, ongoing efforts in hepatitis C vaccine development: the first is *extramural* and the second is *intramural*. They are presented separately in the following objectives.

Extramural Program in Hepatitis C Vaccine Development

The primary objective of the NIAID extramural program remains the development of vaccines against HCV. The research efforts of the last 5 years have led to the realization that a vaccine to prevent infection is particularly challenging. In that respect, HCV shares features of HIV. Like HIV, HCV has an RNA genome, the replication of which is intrinsically error-prone, leading to virus quasi-species, which are genetically heterogeneous. This contributes to continual immune evasion and the concomitant generation of mutant viruses. In addition, HCV encodes functions that block, or suppress, adaptive host immune responses.

On the other hand, more recent research suggests that a level of immunity can be induced against HCV. The level of exposure (i.e., the frequency of exposure and the dose of virus) may influence the acquisition of a degree of protection. Prospective studies in a cohort of intravenous drug users suggest that a subset of people may be resistant to infection or re-infection, or to the development of chronic infection. It is now widely considered that protection depends greatly on vigorous and broad cellular immunity as well as high levels of antibody. These observations raise the hopes for successful immunization, at least against low-dose infection. Other observations suggest that even following chronic infection, the progression of liver disease can be slowed or arrested or even reversed if the right immune responses can be elicited. These important observations imply that specific host responses may sometimes be induced, which can lead to protection. Identifying such responses will point the direction for vaccine development. Another important observation is that a small proportion (10-20 percent) of infected individuals is able to recover spontaneously from acute infection. This suggests that the innate immunity (interferon), which is the early, non-specific response, is sometimes active enough to clear infection.

The biological resources for these studies continually are being developed. In the last few years, a number of extremely valuable tools have been generated that will significantly advance the effort. These include a robust *in vitro* system for HCV replication and HCV pseudoviruses, which can infect cultured hepatocytes, and drugs that might prevent infection. Recently, a fully permissive cell culture system for the production of infectious HCV has been developed that will help bridge a huge gap in the development of new classes of antiviral drugs. A convenient small animal model for HCV infection remains an urgent goal, although several models are being developed.

The identification of special populations and the recruitment and maintenance of patient cohorts are a cornerstone of NIAID's program to enable important clinical discoveries; evaluate the relevance of laboratory-based paradigms; and generate new hypotheses for experimental investigations. NIAID supports research in HCV-infected cohorts, particularly in Alaska Native Americans and a predominantly African American population in Baltimore.

1.6.1.1 Action Plan

The extramural action plan is guided by the Hepatitis C Framework for Progress and by recently updated objectives described in a statement issued following a Consensus Development Conference titled Management of Hepatitis C: 2002, which was organized by NIH.

Steps

- Support development of animal models and other systems.
- Support preclinical and clinical research to develop HCV vaccine candidates.
- Support studies to elucidate host and pathogen genetic contributions to HCV infection and disease progression outcomes.
- Support both prophylactic and therapeutic clinical trials of safety, immunogenicity, and efficacy of HCV vaccine candidates.

Timeline

FY2004

- Support basic research on HCV and human host genetic factors in infection and disease progression.
- Support research to identify immune responses required for virus clearance that are elicited in a small proportion of infected individuals.
- Support research to identify immune responses that reduce the severity of chronic HCV-related liver diseases.
- Support research to develop and refine new and existing infection and disease preclinical models including cell culture, mouse, tamarin, and chimpanzee systems to study infection and pathogenesis.
- Conduct Phase I clinical trial of HCV vaccine candidate through NIAID’s Vaccine and Treatment Evaluation Unit at St. Louis University.
- Fund related investigator-initiated research.

FY2005

- Continue above research activities.
- Fund related investigator-initiated research.
- Renew Hepatitis Cooperative Research Centers, which are multi-disciplinary collaborative research centers that focus on developing tools to prevent and cure HCV infection and disease.
- Support research to design promising HCV candidate vaccines based on growing understanding of immunovirology.
- Support clinical trials of safety, immunogenicity, and efficacy of prophylactic and therapeutic HCV vaccines.

FY2006-2008

- Continue above.
- Fund related investigator-initiated research.
- Release and fund new, expansion, and renewal initiatives as appropriate.

1.6.1.2 Performance Measures

- Development of initiatives as announced in the NIH Guide and Commerce Business Daily.
- Continuation of support of HCV genomic resources.
- Continuation of public-private partnerships.
- Conduct of existing and new clinical trials of candidate hepatitis C vaccines.

1.6.1.3 Outcome Measures

- Publication of scientific advances.
- Wide application of new technologies within the research community.
- Availability of new candidate vaccines.

1.6.2 Objective Two

Support research on improved therapeutic strategies for hepatitis C virus and related areas that would reduce disparities in treatment outcomes.

NIAID's "bench-to-bedside" mission places special emphasis on the following: (a) the discovery of new therapeutic targets; (b) understanding the immune mechanisms of viral clearance and protection from severe liver disease; (c) the rational development of candidate vaccines; and (d) the development of both preclinical and clinical resources to evaluate the safety and effectiveness of candidate drugs and vaccines. In addition to individual research awards, the NIAID has supported multidisciplinary and integrated research by some of the most outstanding biologists, virologists, immunologists, and molecular biologists at nine Hepatitis C Cooperative Research Centers. Two of these Centers specifically focused on disease progression and therapy in minority populations. One center studied the long-term natural history of HCV and associated disease progression in a well-defined Alaska Native cohort. A second center compared the response to pegylated interferon and ribavirin therapy in African Americans and Whites to provide more definitive evidence related to response rate differences. In addition to clinical outcome, virological and host differences (e.g., immunological and genetic) between the two groups also were investigated. These studies will pave the way for other, more effective strategies to treat HCV-infected patients, particularly minorities in the United States, who are both disproportionately at risk for HCV-related liver disease and refractory to currently available therapy. Three of these centers have been renewed for a further 5 years and five new ones have been established. Their efforts have been refocused to identify and define immune responses that mediate recovery from acute HCV infection so that they can be recapitulated in new vaccine strategies.

1.6.2.1 Action Plan

Steps

- Support research focused on host and pathogen genetic contributions to and mechanisms involved in sustained elimination of HCV in response to therapy.
- Support research on early predictors of both disease progression and sustained response to therapy.
- Support model system development.
- Support development of new therapeutic modalities.

- Support clinical trials of new antivirals, immunomodulators, and therapeutic vaccines.

Timeline

FY2004
- Support basic research on HCV and human host genetic factors in infection and disease progression.
- Support research to identify immune responses required for virus clearance that are elicited in a small proportion of infected individuals.
- Support research to identify immune responses that reduce the severity of chronic HCV-related liver diseases.
- Support research to develop and refine new and existing infection and preclinical disease models, including cell culture, mouse, tamarin, and chimpanzee systems, to study infection and pathogenesis.
- Support evaluation of candidate therapies in preclinical models.
- Fund related investigator-initiated research.

FY2005
- Continue above research activities.
- Renew Hepatitis Cooperative Research Centers, which are multi-disciplinary collaborative research centers that focus on developing tools to prevent and cure HCV infection and disease.
- Renew Animal Models for the Prevention and Treatment of Hepatitis B and C, a network of animal models for hepatitis drug screening.
- Support research to design promising HCV candidate vaccines based on growing understanding of immunovirology.
- Support clinical trials of safety, immunogenicity, and efficacy of prophylactic and therapeutic HCV vaccines.
- Fund related investigator-initiated research.

FY2006-2008
- Continue above.
- Release and fund new, expansion, and renewal initiatives as appropriate.
- Fund related investigator-initiated research.

1.6.2.2 Performance Measures

- Development of initiatives as announced in the *NIH Guide* and *Commerce Business Daily*.
- Funding of awards.
- Active program participation in Cooperative Hepatitis C Research Centers.
- Continued utilization of contracts devoted to screening candidate HCV therapies.

1.6.2.3 Outcome Measures

- Publication of scientific advances.
- Availability of new technologies for application.
- Availability of new candidate therapies for testing.

1.6.3 Objective Three: Intramural Program in Hepatitis C Vaccine Development

A better understanding of the molecular biology of HCV and the immune response to hepatitis C infection are critical to the development of a safe and effective hepatitis C vaccine. The action plan for hepatitis C vaccine development is based on the NIAID's "Hepatitis C Framework for Progress," developed by a panel of expert scientists, including representatives who are implementing this plan in the NIAID's intramural laboratories.

1.6.3.1 Action Plan

Steps

1. Define mechanisms of protective immunity to hepatitis C.
2. Define neutralizing antibodies to hepatitis C antigens.
3. Define natural mechanisms and correlates of recovery and persistence.
4. Distinguish protective from injury-invoking role of cell-mediated immunity responses.
5. Define immunological mechanisms associated with, and identify alterations in response to, repeated infections and co-infections.
6. Use basic and preclinical research results to devise rational vaccination strategies.
7. Conduct clinical trials of promising HCV candidate vaccines.

Timeline

FY2004-2008
- Continue to develop and share research reagents, such as polyclonal HCV pools for challenge experiments.
- Continue in-depth analysis of humoral versus cellular immune responses to HCV infection and their association with virus evolution.
- Continue to study the natural history of HCV infection in chimpanzees transfected with infectious cDNA clones of HCV.
- Continue to use the GBV-B tamarin system to study characteristics of the virus that it shares with HCV. Attempt to construct HCV-GBV-B chimeras that can infect tamarins.
- Study the replication of HCV genomes with or without adaptive mutations in cell culture to identify cells that will permit the production of HCV virions.

- Continue efforts to identify antigens/epitopes that stimulate broadly protective HCV neutralizing antibodies.

1.6.3.2 Performance Measures

- Distribution and availability of reagents necessary to conduct hepatitis C vaccine research.
- Initiation of trials in animals.
- Initiation of clinical trials of candidate hepatitis C vaccines.

1.6.3.3 Outcome Measures

- Publication of scientific advances.
- Application of new technologies.
- Availability of new candidate vaccines for testing.
- FDA licensure of effective hepatitis vaccine.

1.7 Area of Emphasis Seven: Sexually Transmitted Infections (STIs)

The current epidemic of STIs in the United States disproportionately affects minority populations. Recent studies indicate that the more prevalent non-ulcerative STIs (such as chlamydia, gonorrhea, and trichomoniasis), as well as ulcerative diseases (genital herpes, syphilis, and chancroid), increase the risk of HIV transmission by at least three- to fivefold. Although STIs like chlamydia, human papillomavirus (HPV), and herpes are widespread across racial and ethnic groups, STI rates tend to be higher among African Americans than Whites. For herpes, one study determined that African Americans accounted for 60 percent of herpes cases in STI clinics. Reported rates for gonorrhea and syphilis in 2002 were shown to be as much as 24 times higher for African Americans than for Whites. Based on data for 1999, when all reportable STIs are combined, African Americans and Hispanics account for 45 percent of all STIs.

The long-term consequences as well as the incidence of STIs are higher among non-Whites than among Whites. For example, although African American and Hispanic women comprise only 17 percent of the total female population of the United States, they make up a disproportionate share (33 percent) of reported clinic visits for pelvic inflammatory disease (PID). PID is a disease of the upper reproductive tract that is primarily caused by sexually transmitted bacterial infections. Moreover, women in these populations suffer more often from cervical cancer, a sequela of HPV.

1.7.1 Objective One

Support research on therapeutics and diagnostics to help reduce disparities in the incidence and prevalence of gonorrhea, syphilis, and trichomoniasis.

Syphilis, a genital ulcerative disease, facilitates the transmission of HIV and may be important in contributing to HIV transmission in those parts of the country where rates of both infections are high. Untreated early syphilis in pregnant women results in perinatal death in up to 40 percent of cases and, if acquired during the 4 years preceding pregnancy, may lead to infection of the fetus in more than 70 percent of cases. Despite national progress toward syphilis elimination, particularly among African Americans and among women, syphilis remains an important problem in the South and in some urban areas in other regions of the country. In 2002, although the rate of primary and secondary (P&S) syphilis among African Americans declined from 11.0 to 9.8 cases per 100,000 between 2001 and 2002, the rate of P&S syphilis reported in African Americans was still eight times greater than the rate reported in Whites (1.2 cases per 100,000). This differential was substantially less than that in 1997, when the rate of P&S syphilis among African Americans was 44 times greater than the rate reported among Whites. Declining differential rates between African Americans and Whites between 1997 and 2001 are due to consistent decreases in rates in African Americans during this period in conjunction with an increase in rates in Whites in 2001.

In 2002, gonorrhea was the second most frequently reported communicable disease in the United States, with 125.0 cases per 100,000 persons. Although gonorrhea rates have been decreasing since the mid-1970s, rates remain high in the southeastern states among minorities and among adolescents of all racial and ethnic groups. From 2001 to 2002, gonorrhea rates among African Americans declined by 5.1 percent (782.3 and 742.3 cases per 100,000 population, respectively). In 2002, rates decreased among Asians/Pacific Islanders by 9.7 percent. During the same period, gonorrhea rates increased by 10.8 percent among American Indians/Alaska Natives, 2.4 percent among Hispanics, and 5.4 percent among Whites. The health impact of gonorrhea is largely related to its role as a major cause of PID, which frequently leads to infertility or ectopic pregnancy. In addition, data suggest that gonorrhea facilitates HIV transmission.

Trichomonas vaginalis is caused by protozoan parasites, trophozoites, which are transmitted principally through vaginal intercourse. Infection with the organism, while frequently asymptomatic, can cause vaginitis in women and urethritis in men; additionally, this parasite may play a critical and underrecognized role in amplifying HIV transmission. Studies suggest that *T. vaginalis* is one of the most common STIs in the United States, with an estimated 5 million new cases occurring annually. Studies of this disease in minority and ethnic populations have shown the prevalence of trichomoniasis to be highest in African Americans (23-51 percent), ranging from approximately 1.5 to nearly 4 times greater than in other racial and ethnic groups.

1.7.1.1 Action Plan

Steps

1. Assess new, easy-to-administer treatments for syphilis such as single-dose oral therapy that might increase treatment compliance among affected populations.

2. Collaborate with CDC on research activities related to understanding syphilis as a reemerging infection.
3. Interact with WHO on their activities within the STI Diagnostic Initiative to develop new diagnostic tests for syphilis.
4. Discuss with Pan American Health Organization (PAHO) their project to eliminate congenital syphilis in South America.

Timeline

FY2004
- Continue a large efficacy study examining azithromycin for the treatment of syphilis.
- Award the Sexually Transmitted Infections Clinical Trials Group.
- Support relevant investigator-initiated research.

FY2005
- Continue efficacy study for treatment of syphilis.
- Support additional relevant investigator-initiated research.

FY2006-FY2008
- Completion of azithromycin efficacy trial for syphilis and analysis of data.
- Continue support of relevant investigator-initiated research.

1.7.1.2 Performance Measures

- Identification and testing of new treatment modalities for syphilis.
- Additional awards for research and clinical programs in gonorrhea, syphilis, and trichomoniasis.

1.7.1.3 Outcome Measures

- Identification of new diagnostic and treatment modalities for syphilis.
- Publication of scientific advances relevant to gonorrhea, syphilis, and trichomoniasis.
- Continuation of clinical trials.

1.7.2 Objective Two

- Support research on vaccines to help reduce disparities in the incidence and prevalence of STIs.

- A widely delivered vaccine that effectively prevents an STI would dramatically reduce the burden of these diseases in minority populations and the health disparities associated with them.

1.7.2.1 Action Plan

Steps

1. Stimulate vaccine development for STIs caused by bacteria with newly sequenced genomes: *T. vaginalis*, *Chlamydia trachomatis*, *Treponema palidum*, and *Neisseria gonorrheae.*
2. Stimulate development of vaccines against herpes simplex virus.

Timeline

FY2004
- Award the Sexually Transmitted Infections and Topical Microbicide Cooperative Research Centers.
- Continue to support an efficacy trial of a herpes vaccine.
- Support additional relevant additional investigator-initiated research.

FY2005
- Continue support of grants on development of vaccines for STIs.
- Continue efficacy trial of herpes vaccine.
- Continue to support relevant investigator-initiated research.

FY2006-FY2008
- Complete enrollment in an efficacy trial of a herpes vaccine.
- Continue to support relevant investigator-initiated research.

1.7.2.2 Performance Measures

- Funding of awards for vaccine research in STIs.
- Initiation of clinical trials in the STI Clinical Trials Group.

1.7.2.3 Outcome Measures

- Availability for testing of new vaccine candidates for prevention of STIs.
- Publication of scientific advances relevant to STIs.

1.7.3 Objective Three

Support research on prevention strategies and product acceptability studies to help reduce disparities in the incidence and prevalence of STIs.

Development of prevention strategies to reduce the incidence and prevalence of STIs is a high priority for NIAID. The spiraling acute and chronic morbidity of STIs, particularly among minority populations, provides a clear rationale for the development of better, more effective strategies to diagnose, treat, and prevent these diseases.

1.7.3.1 Action Plan

Steps

1. Develop studies to examine strategies for diagnosing and preventing STIs.
2. Evaluate the acceptability of products such as topical microbicides as approaches to STI prevention and control.
3. Collaborate with CDC and/or other agencies to identify factors and strategies for implementation of vaccines or other interventional studies in minority populations and adolescents.

Timeline

FY2004
- Award the Sexually Transmitted Infections and Topical Microbicide Cooperative Research Centers.
- Award the Sexually Transmitted Infections Clinical Trials Group.
- Collaborate with CDC's Advisory Committee on Immunization Practices to develop recommendations for the introduction of vaccines to prevent STIs such as HPV.
- Continue to support additional relevant investigator-initiated research.

FY2005
- Develop an initiative to promote topical microbicide development.
- Work with the STI and Topical Microbicide Cooperative Research Centers to initiate research focused on development of prevention strategies for STIs.
- Continue to support additional relevant investigator-initiated research.

FY2006-FY2008
- Continue to support STI and Topical Microbicide Cooperative Research Centers.
- Continue to support topical microbicide development.
- Continue to support relevant investigator-initiated research.

1.7.3.2 Performance Measures

- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Funding of awards.
- Initiation and conduct of clinical trials to evaluate prevention strategies.

1.7.3.3 Outcome Measures

- Publication of scientific advances related to diagnostics, vaccines, and topical microbicides to prevent STIs.
- Availability of candidate products for testing.
- Interest of private and public sector partners in development of diagnostics, vaccines, and topical microbicides to prevent STIs.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

The NIAID supports a comprehensive portfolio of biomedical and behavioral research aimed at addressing health disparities through capacity building. These activities include fostering the development of research infrastructure at Historical Black Colleges and Universities (HBCUs) and resource-limited institutions, while promoting the training and career development of investigators from minority and other underrepresented populations and stimulating interest in the biomedical sciences among a diverse cadre of students.

2.1 Area of Emphasis One: Research Infrastructure of HBCUs and Other Resource-Limited Institutions and Research Careers for Investigators From Underrepresented Populations

NIH funds various training award programs to create diversity in the biomedical and behavioral research workforce. NIAID is committed to increasing the pool of researchers from underrepresented populations conducting research in its scientific mission. Diseases and conditions that fall under NIAID's scientific area that impact health disparities and underserved populations include HIV/AIDS, infectious diseases, type 1 diabetes, and autoimmune and allergic diseases.

2.1.1 Objective One

The Research Centers in Minority Institutions Program (RCMI) is an initiative administered by the NIH National Center for Research Resources (NCRR). The RCMI Program began at the NCRR in 1985 in response to Congressional report language (House Report 98-911, on the Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill for FY1985 (July 26, 1984, pages 78-79)) directing funds to "establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health." RCMI support includes funds to recruit established and promising researchers, acquire advanced instrumentation, modify laboratories for competitive research, and to fund core research facilities and other research support.

Many of the RCMIs funded through NIAID conduct research on HIV/AIDS, which disproportionately impact minority institutions, as stated in Section 1.1 of this document.

2.1.1.1 Action Plan

Step

1. Support funding of research infrastructure capacity building in an effort to increase the diversity at institutions that conduct biomedical and behavioral research.

Timeline

FY2004

- Participate in the RCMI Ninth International Symposium on Health Disparities on November 2004. NIAID will disseminate information on its funding opportunities through workshops at the RCMI Symposium.
- Continue to fund six RCMIs with HIV/AIDS studies, three of which are HBCUs.

FY2005-2008

- Continue to co-fund, with the RCMI.
- Continue to provide ongoing support to six RCMIs with HIV/AIDS studies.

2.1.1.2 Performance Measures

- Number of RCMIs supported.
- Number of researchers supported under this mechanism.

2.1.1.3 Outcome Measures

- Mentoring of junior researchers from underrepresented populations by NIAID-supported researchers.

2.1.2 Objective Two

Support career development of researchers from underrepresented populations through the Enhancement Awards for Underrepresented Populations (EAUM). The program is under review, and if reissued in the future, consideration would be given to broadening the eligibility criteria.

2.1.2.1 Action Plan

Steps

1. Initiate and fund a new Enhancement Award for Underrepresented Minority Scientists.
2. Broadly advertise and generate enough applications to ensure the success of the initiative.
3. Target advertising to researchers from underrepresented populations to encourage their participation in the NIAID research agenda.

Timeline

FY2004

- Received 58 applications, 10 of which addressed HIV/AIDS related issues. Held scientific review in June 2004. Expected to be make four to six awards by August 2004.

FY2005-2008

- Continue to support activities related to increasing and/or retaining participation of researchers from underrepresented populations in conducting basic and clinical research.

2.1.2.2 Performance Measures

- Funding four to six awards.

2.1.2.3 Outcome Measures

- Progress of grantees using established methods such as quarterly performance reports.
- Award recipients successfully secure NIH research grant support in FY2007.

2.1.3 Objective Three

Support career development of scientists from underrepresented populations from high school to independent scientist status by means of Research Supplements to Promote Diversity In Health-Related Research. The RSUM (Research Supplements for Underrepresented Minorities) program is now known as the Research Supplements to Promote Diversity in Health-Related Research (PA 05-015), and NIAID has participated in this initiative since 2005.

This initiative supports a diverse cadre of students and scientists from underrepresented populations, students with disabilities, and students from disadvantaged backgrounds.

2.1.3.1 Action Plan

Steps

1. Continue advertising this mechanism through the NIAID web site and at scientific conferences attended by students and professionals from underrepresented populations.
2. Establish a database to record and track the success of the awardees funded by NIAID in receiving the NIH Independent Researchers Award (R01).

Timeline

FY2004
- Continue to fund and support 80 percent of applications received for this mechanism.

FY2005-2008
- Continue to fund and support 80 percent of applications received for this mechanism.

2.1.3.2 Performance Measures

- Number of supplements supported under this mechanism in FY2004.
- Number of researchers supported under this mechanism.

2.1.3.3 Outcome Measures

- Progress of grantees using established methods such as quarterly performance reports.
- Success of award recipients in securing NIH research grant support at the conclusion of their supplemental award; a 30 percent goal is set.

2.1.4 Objective Four

Through the Bridging the Career Gap program, foster the career development of graduate students and postdoctoral trainees from minority and other underrepresented populations. This program is currently being reviewed and updated to consider broader eligibility criteria.

In 1993, NIAID launched the Bridging the Career Gap program to provide junior researchers from minority and other underrepresented populations with the tools and information needed to pursue successful careers in biomedical and behavioral research. This biennial program brings junior researchers supported by NIAID to NIH for a 2-day program. The Bridging the Career Gap program addresses career choices, networking, mentor selection, and an overview of the NIH grant process. NIAID is proud of this model, and Institute staff work very closely with many of these students throughout the various phases of their careers. The Bridging the Career Gap program celebrated its fifth anniversary in FY2002 and will be repeated in FYs 2006 and 2008. Beginning in 2005, NIAID incorporated all applicants from the Diversity Supplement program into its Bridging the Career Gap workshop and continues to obtain full inclusion of all participants from diverse backgrounds.

2.1.4.1 Action Plan

Steps

1. Actively encourage junior researchers from underrepresented populations receiving NIAID support to attend the Bridging the Career Gap workshop.
2. Provide travel funds to workshop participants.

Timeline

FY2004
- Bridging the Career Gap workshop held in November 2003. Feedback from workshop sessions validates NIAID's continuance of this initiative in FY2006.

FY2005-2008
- Encourage junior researchers from underrepresented populations to apply for NIAID Diversity Supplements for support to attend the Bridge Programs in FY2006 and FY2008.

2.1.4.2 Performance Measures

- Number of Bridging the Career Gap workshop participants.

2.1.4.3 Outcome Measures

- Survey Bridging the Career Gap workshop participants at the conclusion of proceedings.
- Monitor the success rate of attendees in securing NIH research grants.

2.1.5 Objective Five

Through the use of regular research award mechanisms, ensure the development of junior researchers from underrepresented populations.

NIAID will increase funding of junior researchers from underrepresented populations applying for research grants by utilizing grant mechanisms currently in place. The amount of funding dedicated specifically to this purpose varies according to the scientific merit of projects submitted.

2.1.5.1 Action Plan

Steps

1. Advertise requests for grant proposals and contracts through various media and conferences to ensure circulation to a broad audience of researchers from underrepresented populations.
2. Utilize new and innovative mechanisms to support research in health disparities (i.e., Research Scholar Development Award (K22)). The K22 program supports postdoctoral trainees as they make the transition to assistant professor positions in an academic institution. This mechanism's eligibility criteria have been expanded to include postdoctoral trainees from underrepresented populations supported on RSUMs that are now known as Diversity Supplements.

Timeline

FY2004
- Number of awards to researchers from underrepresented populations.

FY2005-2008
- Continue the funding of K22 grants.
- Expand the applicant pool through increased advertising of the program via the NIH/NIAID web sites, by attendance at scientific meetings, and in professional journals.

2.1.5.2 Performance Measures

- Number of awards to researchers from underrepresented populations.

2.1.5.3 Outcome Measures

- Number of awards to researchers from underrepresented populations.

2.2 Area of Emphasis Two: Training Scientists from Underrepresented Populations in Biomedical Research

A well-trained cadre of researchers from underrepresented populations who bring a special blend of cultural knowledge and intellectual interest is required to address and resolve health disparities issues. NIAID hopes that bolstering the number of investigators from underrepresented populations participating in our scientific agenda will provide the level of cultural competency in disadvantaged communities to ensure that the Institute's research mission appropriately targets minority and other underrepresented populations' concerns, and that clinical research is designed to be responsive to the needs and concerns of the minority and other underrepresented communities, which, in turn, would increase the benefits of our research efforts to that community. Training efforts focus on NIAID's Introduction to Biomedical Research Program (IBRP) intramural and extramural program initiatives.

2.2.1 Objective One

Provide training opportunities through the Office of Training and Special Emphasis Programs (OTSEP) for researchers from underrepresented populations in NIAID intramural programs.

NIAID, through the Office of Training and Special Emphasis Programs, will continue to expand its highly successful mechanisms for recruiting pre- and postdoctoral researchers from underrepresented populations into its intramural research laboratories. Special seminars and events are planned for trainees in our diversity programs to enrich their research experience and their professional development.

2.2.1.1 Action Plan

Steps

1. Develop OSTEP infrastructure to support outreach, recruitment, and program management.
2. Expand national contacts for recruiting.
3. Enrich NIAID training experience for researchers from underrepresented populations.
4. Increase the number of postbaccalaureate and postdoctoral researchers from underrepresented populations receiving Intramural Research Training Awards (IRTAs).
5. Track graduates from training programs from minority and other underrepresented populations for program evaluation, networking, and recruitment contact.
6. Inform scientists about NIAID diversity issues and progress.
7. Develop resources for assisting mentors in meeting the mentoring needs of underrepresented populations in biomedical science.
8. Expand outreach efforts through the NIAID's annual IBRP Intramural NIAID Research Opportunities (INRO).

Timeline

FY2004

- Expand OTSEP staff to include a Scientific Recruitment/Training Specialist and a Scientific Recruitment/Training Administrator.
- Develop an online application system for INRO, NIAID's major outreach program for underrepresented populations.
- Develop electronic capability to export data from the INRO online application system into the online application systems for all the training programs run by the NIH Office of Intramural Training and Education, and into OTSEP's Data Management System.

- Expand OTSEP's web site and key links from relevant web sites.
- Expand the national database of recruitment contacts.
- Expand the number of predominantly ethnic minority and resource-limited colleges and universities with minimal research infrastructure that have established relationships with OTSEP.
- Visit select universities to meet students from underrepresented populations and science faculty to inform them about NIAID programs for underrepresented populations.
- Increase the number of sponsored trainees from underrepresented populations from 10 to 12.
- Increase the number of sponsored graduate students from underrepresented populations from zero to one.
- Increase the number of sponsored postdoctoral candidates from underrepresented populations from one to two.
- Plan four to six seminars for trainees.
- Plan, conduct, and evaluate the annual NIAID INRO program for 2004 (i.e., advertise, develop program, schedule interviews, plan logistics, decide on trainee placements, and write up summary).

FY2005

- Expand OTSEP staff to include a Program Analyst.
- Expand OTSEP's web site and key web links from relevant web sites.
- Expand the national database of recruitment contacts.
- Expand the number of established partnerships with underrepresented predominantly ethnic minority and resource-limited colleges and universities that serve a diverse population base.
- Focus recruitment activities on increasing diversity at Rocky Mountain Laboratories (RML) in Hamilton, Montana.
- Increase the number of sponsored postbaccalaureate trainees from underrepresented populations from 12 to15.
- Support an inclusive/diverse population of graduate students.
- Increase the number of sponsored postdoctoral trainees from underrepresented populations from two to three.
- Plan four to six seminars for trainees.
- Plan, conduct, and evaluate the annual Intramural NIAID Research Opportunities program, INRO 2005 (advertise, develop program, schedule interviews, plan logistics, decide on trainee placements, and write up summary).
- Conduct a follow-up tracking study of trainees sponsored by OTSEP and those participating in the Intramural NIAID Research Opportunities program, INRO, from 2003 to 2005.
- Develop a newsletter for current and past NIAID minority trainees.
- Prepare a report to the NIAID's intramural research laboratory chiefs about the Institute's diversity issues and progress.
- Communicate to the broader community the unique mentoring needs of minority trainees in biomedical research.

FY2006

- Expand OTSEP's web site and key links from relevant web sites.
- Expand the national database of recruitment contacts.
- Expand the number of predominantly ethnic minority and resource-limited colleges and universities that have established relationships with OTSEP.
- Maintain the number of sponsored postbaccalaureate trainees from underrepresented populations at 15.
- Continue support for graduate students from underrepresented populations.
- Increase the number of sponsored minority postdoctoral trainees from three to four.
- Plan four to six seminars for minority trainees.
- Plan, conduct, and evaluate the annual NIAID INRO program for 2006.

FY2007-2008

- Expand OTSEP's web site and key links from relevant web sites.
- Expand the national database of recruitment contacts.
- Expand the number of predominantly underrepresented ethnic minority and resource-limited colleges and universities that have established relationships with OTSEP.
- Maintain the number of sponsored postbaccalaureate trainees from underrepresented populations at 15.
- Continue support for graduate students until graduation, and then recruit a new cadre of diverse graduate student applicants.
- Increase the number of sponsored postdoctoral trainees from underrepresented populations from four to five.
- Plan four to six seminars for trainees.
- Plan, conduct, and evaluate the annual NIAID INRO program for 2007-2008.

2.2.1.2 Performance Measures

- Number of qualified applicants submitted to the INRO program.
- Number of INRO participants selected for subsequent NIAID training programs (e.g., the Postbaccalaureate IRTA, the Summer Internship Program in Biomedical Research, the Postdoctoral IRTA).
- Number of applications submitted for NIAID training programs as a result of outreach efforts to colleges, universities, and national minority student meetings.
- Number of trainees who participate in seminars, workshops, and retreats.
- Number of OTSEP-sponsored trainees entering graduate or medical school upon completion of the Postbaccalaureate IRTA.
- Tracking report to assist OTSEP in program planning for trainees.

- OTSEP's visibility increased among NIAID's intramural research scientists, the NIH community, and secondary educational institutes nationwide.

2.2.1.3 Outcome Measures

- Postbaccalaureate and postdoctoral diversity programs expand significantly.
- Postbaccalaureate trainees begin graduate studies at the end of their training program.
- Network of NIAID trainees established.
- INRO program expands in terms of qualified applications submitted and in the number of participants selected for additional NIAID training experiences (including the RML).

2.2.2 Objective Two

Support creative mentoring and summer laboratory experiences by creating the Richard M. Asofsky Scholars in Research Award. This program has been subsumed under the Diversity Supplement Program.

The Richard M. Asofsky Scholars in Research Award (ASIR) summer program supports students from underrepresented populations who work with independent researchers supported by NIAID-funded research project grants. This program has proven to be an important, viable alternative for students who cannot afford to travel to the Washington, DC, metropolitan area for the summer as well as for the NIAID intramural research program, which has a limited number of positions available for summer students.

Summer programs developed by NIAID grantees for students from underrepresented populations from high school through the first of year graduate school will include mentoring as well as an introduction to scientific processes. Grantees may be allowed to support up to five students on this supplement, focusing on attracting students from local schools and institutions to their laboratories. NIAID will closely monitor this cadre of budding investigators to ensure that they continue to progress in their chosen areas of research.

2.2.2.1 Action Plan

Steps

1. ASIR Program Announcement launched in FY2003; 19 students supported. NIAID will continue to advertise the ASIR mechanism at scientific conferences attended by minority students and professionals from underrepresented populations, as well as on the NIAID web site.
2. Use the NIAID RSUM database to record and track the ASIR students for success in future NIAID awards.

Timeline

FY2004
- Continue to support all fundable applications received for this mechanism.

FY2005-2008
- Continue to support all fundable applications received for this mechanism.

2.2.2.2 Performance Measures

- Increase in the number of ASIRs supported in FY2004.
- Increase in the number of students supported under this mechanism.
- Diversity Supplement tracking database operational by end of FY2004.

2.2.2.3 Outcome Measures

- Monitor progress of grantees by established methods such as quarterly performance reports.
- Measure success of program by the number of students trained by extramural scientists over the summer.

2.2.3 Objective Three

Support the development of novel educational materials to stimulate middle school student interest in science and research careers in NIAID's scientific agenda.

2.2.3.1 Action Plan

Steps

1. Consider funding unsolicited R25 applications that employ innovative materials to teach middle school children about infectious diseases and the microbes that cause them.
2. Selected applications will disseminate instructional materials that meet National Science Education Content Standards free of charge via an established web site and a link from the NIAID web site.

Timeline

FY2004
- Review R25 applications and fund best application(s).

FY2005-2008

- Monitor success of program(s) via quarterly progress reports. Initial goal is to expand the program beyond the initial three states to other states via presentations at professional meetings, publishing research data, linking with other like web sites, making the program available in Spanish, and adding new programs as new information becomes available.

2.2.3.2 Performance Measures

- Three-state distribution of materials via web site.
- Translation of program materials into Spanish.

2.2.3.3 Outcome Measures

- Establishment of a web site.
- Number of students reached and impact on classroom studies.
- Published findings in national journals.

2.2.4 Objective Five

Support the development of novel approaches to providing rural, inner-city, or lower socioeconomic middle and high school students with an opportunity to perform laboratory experiments related to their current science curricula. The purpose is to afford these students the ability to consider a research career in NIAID's scientific agenda.

2.2.4.1 Action Plan

Steps

1. Consider funding unsolicited R25 applications that employ innovative materials to teach middle school children about infectious diseases and the microbes that cause them.

2. Selected application(s) will enable students to use a wet laboratory to conduct experiments related to exercises currently developed by NIAID. Grantee will ensure that students from rural as well as inner-city schools are afforded the opportunity to use these facilities.

Timeline

FY2004
- Review R25 applications and fund best application(s).

FY2005-2008
- Monitor success of program(s) via quarterly progress reports.

- Initial goal is to engage rural counties and inner-city schools in the State of Maryland with an eye toward promoting this program to other states.

2.2.4.2 Performance Measures

- Ability to provide materials and experiment support to the teachers of these students.
- Ability to provide the facilities needed for the conduct of the experiments.

2.2.4.3 Outcome Measures

- Number of schools and students participating in the project.
- Feedback from teachers participating in the project.
- Published articles on the success of the project.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

To reduce the incidence, prevalence, and severity of health problems that are particularly critical for some populations, NIAID must continue to reach out to the affected communities, seeking input from diverse groups to guide priority setting. Through such outreach, NIAID learns about the extent and impact of disparities, has a window on health issues that may be addressed by further research, and determines the features that clinical trial protocols must include to facilitate participation by the affected community.

Reducing health disparities also requires that the affected communities and their health care providers understand and be aware of health-related information to reduce or eliminate risks for immunologic and infectious diseases and improve their options to treat those diseases when they do occur. This is a complex activity that requires the development and dissemination of consistent and credible messages on health risks and health care, as well as information about ongoing research activities and developments. Often, these messages must be tailored to the communities at highest risk for the adverse consequences of the health disparity in question.

NIAID’s efforts to date have been strong and include pioneering the concept of community advisory boards for clinical trial networks, producing and disseminating print and audiovisual materials, exhibiting at professional and community meetings, sponsoring workshops and conferences for community health care providers and the public, and supporting demonstration and education research projects. Also, the NIAID web site is heavily utilized as a reliable source of health information. However, strengthening and expanding NIAID efforts is important to produce health information that is culturally appropriate and to ensure that the information is disseminated to the appropriate communities. Developing methods to assess the effectiveness of these outreach and communication efforts also is critical.

3.1 Area of Emphasis One: Support the National HIV Vaccine Trial and Outreach as Part of Our Interactions With Minority Populations

NIAID continues to implement the National HIV Vaccine Trials Communication Campaign by: (1) creating a sustainable environment in which HIV-affected communities and individuals at higher risk of HIV infection are more aware, educated, and supportive of HIV vaccine research;[2] (2) improving knowledge, perceptions, and attitudes toward HIV vaccine research among target populations (e.g., African Americans, Hispanics, men who have sex with men); (3) improving attitudes among the general population and target populations toward both HIV vaccine trial volunteerism and those who volunteer; (4) improving the general public's knowledge, perceptions, and attitudes toward HIV vaccine research; and (5) enhancing the national dialogue concerning HIV preventive vaccines, vaccine research, and the promise of HIV vaccines to control the AIDS pandemic.

3.1.1 Objective One

Support HIV vaccine communications and outreach to educate target communities, primarily African Americans, Hispanics, and men who have sex with men, as well as the general public, about the importance of HIV vaccine research and trial participation.

3.1.1.1 Action Plan

Steps

1. Maintain a community-focused, research-driven campaign with a national communications firm in cities where NIAID-sponsored HIV vaccine clinical trials are taking place.
2. Increase market penetration of the Campaign's six key messages and monitor audiences' understanding of these key messages.
3. Continue building national community partnerships, especially among target populations

---

[2] *There are six key messages for the National HIV Vaccine Communications Campaign. The first four were developed as a result of a national quantitative survey conducted in 2002; the last two were the result of dialogue with prevention, treatment, and care providers as well as community activists and vaccine researchers. They are as follows: First, there is no HIV vaccine currently available. Second, HIV vaccines being tested in humans do not contain HIV; therefore, they cannot cause HIV infection. Third, individuals who volunteer for an HIV preventive vaccine trial must be HIV-negative. Fourth, the best long-term hope for controlling the AIDS epidemic is the development of safe, effective, and affordable preventive HIV vaccines. Fifth, a comprehensive approach to vaccine research includes partnerships between prevention, care, and treatment providers. Sixth, in order for an HIV vaccine to work for all individuals, diverse populations must participate in clinical trials.*

4. Continue collaborations with the HVTN, NIAID's VRC, and the NIAID National HIV Vaccine Communications Steering Group to produce culturally diverse education materials.
5. Provide assistance and expertise when necessary and appropriate to the Community Education and Outreach Program Partnership subcontractors.
6. Provide issues management support.

Timeline

FY2004

- Implement Community and Education Outreach Partnership Program (CEOPP)—a program that awards funding to nonprofit community-based and national organizations to conduct HIV vaccine awareness and education activities in target communities (African Americans, Hispanics, men who have sex with men). The aims of CEOPP are to increase awareness, knowledge, and positive attitudes about HIV vaccine research so that communities are more supportive of and receptive to HIV vaccine trial volunteerism.
- Develop and disseminate HIV vaccine research materials, including fact sheets, posters, and talking points.
- Conduct activities in support of HIV Vaccine Awareness Day (HVAD), including providing materials to nearly 700 organizations across the United States, to commemorate HVAD and educate communities about HIV vaccine research.

FY2005-2008

- Develop and disseminate, in conjunction with the HVTN and VRC, an HIV Vaccines 101 video.
- Publish findings from the "Understanding Attitudes to HIV Vaccine Research" quantitative survey in a peer-reviewed journal.
- Conduct activities in support of HVAD, including providing materials to nearly 700 organizations across the United States, to commemorate HVAD and educate communities about HIV vaccine research.
- Research, develop, and disseminate HIV vaccine research materials, including fact sheets, posters, and talking points.
- Re-compete HIV vaccine Communications Campaign contract.
- Continue development and cultivation of HIV vaccine awareness through partnerships with community-based organizations and AIDS service organizations.
- Release new or expand HIV vaccine outreach initiatives, as appropriate.

3.1.1.2 Performance Measures

- Number of HIV vaccine-related educational presentations and forums.
- Amount of earned and paid media.
- Increase in knowledge and awareness about HIV vaccine research in cities where NIAID-sponsored research is taking place, as evidenced by a pre- and post-test measure.

3.1.1.3 Outcome Measures

- Increased support for HIV vaccine research and volunteers in general and target populations.
- Effectively informed public regarding HIV vaccine research and volunteer opportunities.
- Increased understanding of the Campaign's key messages.

3.1.2 Objective Two

Improve access of racial and ethnic minorities to TB clinical trials.

The objective of this program is to establish relationships with community-based, public health, and hospital-based clinics in the Washington, DC, metropolitan area that are treating patients with TB and HIV to facilitate participation of these clinics in NIAID's intramural research basic studies and clinical trials.

3.1.2.1 Action Plan

Steps

1. Maintain liaison with community-based, public health, and hospital-based clinics.
2. Collect prospective data from these facilities on a yearly basis from available records to better characterize the ongoing epidemic of TB in the locality of these facilities and the greater metropolitan area.
3. Assess the needs of these clinics and hospitals to determine what resources are needed to enable these facilities to participate in this project and provide a plan to overcome any barriers to participation.
4. Develop informational materials to assist in recruitment.

Timeline

This program began in 1994 and is slated to run through 2005.

FY2004

- Maintain liaisons in 1-6 hospital or public health department-based clinics that are diagnosing and treating at least three new cases of TB per month and 1-3 community based clinics that are diagnosing and treating at least one new case of TB per month. These facilities must be willing to participate in NIAID's intramural research investigation of TB.
- Collect prospective data from these facilities on a yearly basis from available records to better characterize the ongoing epidemic of TB in the locality of these facilities and the greater metropolitan area. Include reporting of TB incidence in the catchment area; factors associated with successful and unsuccessful TB treatment in these facilities; and factors associated with the development and diagnosis of MDR TB in these facilities.

- Develop informational brochures appropriate for patient and physician populations at the participating facilities.

FY2005

- Maintain liaisons in hospitals, public health department-based clinics, and community-based clinics.
- Continue collecting prospective data from these facilities on a yearly basis.
- Facilitate patient recruitment for clinical studies conducted by NIAID's intramural research program and provide clinical material, clinical data, and epidemiologic data for both basic and clinical research studies.
- Arrange periodic meetings (approximately one every 3 months) with key staff at participating facilities to discuss program progress and any specific areas requiring direction or attention.
- Maintain social work and community outreach programs to facilitate patients' ability to participate in NIAID intramural research programs. Programs may include transportation of patients from their homes to NIH and identification of incentives to increase study participation, such as daycare and provision of meals.
- Provide laboratory and diagnostic tools to identify *Mtb* from clinical specimens.
- Convene an annual one-day meeting of program contractor, participating clinics and hospitals, participating NIH intramural scientists, and other key personnel for discussion and sharing of the program's progress and intended direction.

3.1.2.2 Performance Measures

- Number of sites participating in the program.
- Establishment of patient services to promote patient participation.
- Number of brochures distributed.

3.1.2.3 Outcome Measures

- Increased enrollment of ethnic and racial minorities in NIAID's intramural research TB clinical trials using 1999 as the base year.

3.1.3 Objective Three

Support new and maintain established partnerships with agencies, organizations, and advocacy groups that have minority health agendas to maximize the impact of NIAID activities to address health disparities.

NIAID frequently partners with other NIH Institutes and Centers, other Department of Health and Human Services agencies, non-governmental organizations, and industry to coordinate research and outreach activities and to amplify the potential impact of NIAID efforts. The following examples from just two disease areas, HIV and TB, illustrate NIAID's use of partnerships.

The activities of the NIAID-supported TBRU at Case Western Reserve University are coordinated with other major organizations involved in TB research, including the CDC, U.S. Agency for International Development (USAID), FDA, WHO, Global Alliance for TB Drug Development, and International Union Against Tuberculosis and Lung Disease, as well as interested industrial partners.

NIAID's VRC spearheads a variety of public education campaigns focused on informing priority populations about HIV vaccine research. Among its partners is the Washington, DC-based Community Education Group, which arranges monthly events for hard-to-reach, African American audiences. This group provides an open exchange of questions and concerns regarding HIV vaccine technology and information about current vaccine clinical trials. Those attending these meeting are especially concerned about how mandated regulatory entities oversee medical research to ensure that ethical standards are upheld. Other groups that consistently engage VRC speakers are the Congressional Black Caucus, the African American AIDS Conference, the National Black Nurses Association, the National Association for Equal Opportunity, Advocates for Youth, the Self Reliance Foundation, the Black Women's Health Imperative, the Black AIDS Institute, and a wide variety of local community-based organizations/AIDS service organizations and faith-based organizations.

3.1.3.1 Action Plan

Steps

1. Seek input from program staff to identify appropriate organizations and societies.
2. Maintain existing partnerships.

Timeline

FY2004-2008
- Continue with an Institute/Center or scientific organization guest lecturer in the seminar sessions.
- Maintain existing partnerships.

3.1.3.2 Performance Measures

- One-on-one interface sessions with other Institutes and/or scientific organizations.
- Co-sponsorship of initiatives, meetings, and workshops.

3.1.3.3 Outcome Measures

- Complement of activities across NIH, the Department of Health and Human Services, and the federal government.
- Complement of activities among the Government, non-governmental organizations, and industry.

3.1.4 Objective Four

NIAID will continue to seek input and participation from diverse groups on its NAAIDC as well as ad hoc Community Advisory Boards, Blue Ribbon Panels, and scientific workshops to maximize and improve the Institute's health disparity agenda.

3.1.4.1 Action Plan

Steps

1. Seek input from the NAAIDC regarding NIAID plans to address health disparities.
2. Seek input from NIAID standing review committees and other, ad hoc groups regarding NIAID plans to address health disparities.

Timeline

FY2004

- Present NAAIDC with NIAID's comprehensive *Strategic Plan for Addressing Health Disparities Fiscal Years 2004-2008* and seek comments.
- Present NIAID standing review committees and other, ad hoc groups with NIAID's comprehensive *Strategic Plan for Addressing Health Disparities Fiscal Years 2004-2008* and seek comments.

FY2005-2008

- Utilize input and comments from the NAAIDC, NIAID standing review committees, and ad hoc groups to improve NIAID's comprehensive *Strategic Plan for Addressing Health Disparities*.
- Continue to seek input from NAAIDC, NIAID standing review committees, and ad hoc groups on matters pertaining to health disparities.

3.1.4.2 Performance Measures

- Substantive input, comments, and recommendations from the NAAIDC, NIAID standing review committees, and ad hoc groups on NIAID's comprehensive *Strategic Plan for Addressing Health Disparities.*

3.1.4.3 Outcome Measures

- Revisions to the NIAID *Strategic Plan for Addressing Health Disparities* and implementation of initiatives based on revisions to the Plan. NIAID is committed to providing information to the public not only on recent advances, but on areas of concern for the maintenance of public health.

3.1.5 Objective Five

Support participation of NIAID scientists in the presentation of information to audiences in minority communities and continue to expand the translation and dissemination of health information materials to high-risk populations as part of NIAID's efforts to reach minority populations.

In 1998, NIAID intramural staff located at NIAID's RML in Montana began an outreach program for local public schools. In 2000, RML expanded the program to schools located in American Indian communities. The Biomedical Research After School Scholars (BRASS) is designed to communicate the nature of scientific research and to stimulate interest in science careers among students in junior high and middle schools. The typical BRASS course runs for 5 weeks and consists of lab sessions covering topics such as blood, genetics, cancer, AIDS, infectious diseases, and animal research.

For 10 years, NIAID has written and published biennial pamphlets on minority health research (A Partnership for Health) and women's health research (Women's Health in the U.S.). These pamphlets set forth the latest statistics on health disparities related to immunologic and infectious diseases, highlight recent scientific findings of particular concern to minorities and women, and articulate research plans and priorities. The documents are key tools in NIAID's effort to reach out to minority communities with information on biomedical research that is of special interest to those populations. Both are distributed to outside organizations, at scientific meetings, and to the general public.

The NIAID National Cooperative Inner City Asthma Study (NCICAS, 1991-1996) developed a highly successful asthma intervention. This educational and behavioral intervention is delivered by an asthma counselor and has been shown to reduce symptoms and hospitalizations in inner-city children with moderate to severe asthma. Recently, NIAID collaborated with the CDC to launch a program to disseminate and implement the intervention. NIAID-funded scientists translated the complex NCICAS research intervention into a form that can be efficiently utilized in a variety of health care delivery settings, including health maintenance organizations (HMOs), health departments, and community clinics. Now, NIAID is working with CDC to disseminate the Asthma Treatment Guidelines. The 4-year program targets children with moderate to severe asthma living in inner cities and is being implemented through 23 inner-city health care organizations throughout the United States. More than 6,000 inner-city children with asthma will benefit from the effort.

3.1.5.1 Action Plan

Steps

1. Expand outreach by NIAID intramural staff located in our RML in Montana to public schools located in American Indian communities.
2. Continue to publish and disseminate NIAID's minority and women's health pamphlets.

3. Collaborate with CDC to disseminate the asthma intervention guidelines developed and tested by the National Cooperative Inner City Asthma Study.

Timeline

FY2004

- NIAID personally invited Montana high school science faculty and their classes from the six area high schools to the RML West Nile Virus Symposium in March 2004; several attended.
- In April 2004, NIAID provided a hands-on scientific tour for high school and college students who are members of the American Indian Science and Engineering Society. Continued interaction with this group via its University of Montana chapter is anticipated.
- In April 2004, NIAID staff participated in a local professional day and presented a lecture to elementary students on the importance of being aware of insect vectors that could impact their lives (West Nile, Lyme Disease) and how to minimize that impact. In addition, students were informed of the various careers in science.
- NIAID conducted “Introduction to Science Sessions” in Montana public schools.
- NIAID updated and published the Partnership for Health and Women’s Health in the U.S. pamphlets.
- NIAID supported dissemination of the asthma intervention guidelines and disease fact sheets at student conferences.

FY2005-2008

- Continue outreach to Montana public schools by RML scientists.
- Continue to update pamphlets on a biennial basis (FY2006 and FY2008).
- Continue outreach efforts to Native American students in the Montana public school system.

3.1.5.2 Performance Measures

- Publication of updated versions of the pamphlets “Partnership for Health” and “Women’s Health in the U.S.” as well as provision of Section 508 compliant versions of the pamphlets on the NIAID web site.
- Outreach sessions targeted to Native Americans in Montana public schools by RML staff.
- Presentations by NIAID staff to community audiences.

3.1.5.3 Outcome Measures

- Number of copies of The Partnership and Women’s Health pamphlets distributed.
- Range of venues in which the pamphlets are distributed.
- Number of outreach sessions targeted to Native Americans in Montana Public Schools by RML staff and number of students participating.
- Number of presentations given by NIAID staff to community audiences.

3.1.6 Objective Six

NIAID will continue to support Internet-based methods of communication and audiovisual materials to disseminate health information to individuals subject to health disparities.

NIAID's web site provides a wealth of health information useful to individuals subject to health disparities. Equally important, the site includes research plans and links for people seeking to participate in clinical trials.

3.1.6.1 Action Plan

Steps

1. Continue facilitating a Web Working Group consisting of cross-divisional representation to analyze current content and to develop new information architecture for a topic-based web site.
2. Improve the usability of the NIAID web site as a whole, including public health and science information and new research findings, particularly for topics of interest to audiences subject to health disparities.
3. Establish policies and guidelines for 508 compliance and utilize technology tools to check and assess compliance of web site code.

Timeline

FY2004

- Continue the redesign and development of the NIAID web site based on new information architecture, usability testing and guidelines, web site user satisfaction survey information, and web site statistics.
- Establish Web Style Guidelines, procedures, and policies to ensure a citizen-centric, usable, and accessible web site.
- Establish content review and expiration deadlines to keep content current.
- Establish policies and guidelines for 508 compliance and utilize technology tools to check and assess compliance of web site code.
- Continue modifying existing content to comply with Section 508 guidelines.
- Perform usability testing on new site information architecture and design; include cross-audience representation (public and researchers) with a wide range of demographics.
- Develop a publication and editorial standards guide to be used in the development of Institute print and film media.
- Continue promoting special events (e.g., HIV Vaccine Awareness Day) with audience-specific content, press releases, and fact sheets.
- Continue providing online Publications Order Form where users can order copies of NIAID publications for educational purposes and for dissemination within their communities.

- Continue using the ASCII Satisfaction Index (Foresee Results Survey); provide online survey to solicit feedback on user satisfaction on the web site to help identify audiences and main content interests, allowing identification of high-priority improvements with the most impact on user satisfaction.

FY2005-2008

- Incorporate print-friendly style sheets.
- Improve search engine capabilities.
- Improve search results through appropriate metadata tagging of content.
- Training Opportunities: provide link in the new site design/architecture from the home page to Training Opportunities information, including training programs aimed to mitigate health disparities in research by attracting and retaining researchers from minority groups.
- *Información en español*: provide link on home page to index of NIAID content available in Spanish.
- Include "who is at risk" for relevant health and science topics.
- Establish links with other related government web site content.
- Provide links to and information on clinical trials/studies.
- Provide links for Special Events when and where appropriate in sections such as News & Events Section and Highlights Section on the home page, as well as from relevant Health or Research topics.
- Maintain and update Web Style Guidelines, procedures, and policies to ensure a citizen-centric, usable, and accessible web site.
- Continue setting and following content review and expiration deadlines to keep content current.
- Continue implementing Section 508 compliant code following established policies and guidelines, and utilize technology tools to check and assess compliance of web site code.
- Continue promoting special events (such as HIV Vaccine Awareness Day) with audience-specific content, press releases, and fact sheets.
- Continue providing online Publications Order Form where users can order copies of NIAID publications for educational purposes and for dissemination within their communities.
- Continue using the ASCII Satisfaction Index (Foresee Results Survey); provide online survey to solicit feedback on user satisfaction on the web site and to help identify audiences and main content interests, and identify high priority improvements with the most impact on user satisfaction.
- Maintain and update a publication and editorial standards guide to be used in the development of Institute print and film media.

3.1.6.2 Performance Measures

- Launch of NIAID web site re-design.
- Compliance with Section 508.

- Accessibility of health and research topics of interest to users affected by health disparities on web site.
- Completion of Publications and Editorial Standards Guide and Web Style Guidelines, policies and procedures.
- Dissemination of the Publications and Editorial Standards Guide and Web Style Guidelines, policies, and procedures.

3.1.6.3 Outcome Measures

- Increase in number of visits on NIAID web site to content pertinent to health disparities.
- Reduction in call center and email requests for content of importance to individuals affected by health disparities due to increased accessibility of content online.
- Compliance of web site and printed materials with Editorial and Style Guidelines.
- Increased ASCII Satisfaction Index from Foresee Survey results.
- Improved usability testing results evidenced by increased success in completion of web tasks.
- Reduction in Section 508 compliance issues.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

MISSION/VISION STATEMENT

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports basic, clinical, and epidemiologic research; research training; and information programs on diseases of the bones, muscles, joints, and skin. Most of these diseases are chronic and many cause lifelong pain, disability, or disfigurement; they afflict millions of Americans; cause tremendous human suffering; and cost the U.S. economy billions of dollars in health care and lost productivity. These diseases affect people of all ages, racial and ethnic populations, and economic groups; almost every household in America is affected in some way by one or more of these diseases. Many of these diseases within our mandate affect women and minorities disproportionately, both in increased numbers and increased severity of the diseases. We are committed to uncovering the basis of gender, racial, and ethnic disparities and devising effective strategies to treat them.

Within this report, we have highlighted several areas of research, research capacity, and community outreach aimed at addressing health disparities. Our specific areas of emphasis include systemic lupus erythematosus (SLE), scleroderma, rheumatoid arthritis (RA), and osteoarthritis (OA). The areas of emphasis presented in this plan are representative, however, of a broader health disparities research agenda at NIAMS. Advances in health disparities research have been seen across research areas in arthritis and musculoskeletal and skin diseases.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIAMS has approached the research challenges and opportunities in addressing health disparities by utilizing a broad array of strategies. We have a commitment to maintaining a diverse research portfolio; we invest in our numerous areas using many approaches. Basic research is continuing to uncover many of the most fundamental mechanisms of life and is elucidating strategies for conquering clinical challenges. We take the lessons of basic research and translate them to the clinical arena—known as "bench to bedside" research. Conversely, research also moves from "bedside to bench," and clinical research can be very useful in providing clues to basic mechanisms. These basic/clinical interactions and translations have served to lay a strong foundation for the present and provide many research opportunities for the future. Research being supported by the NIAMS provides for better diagnosis and treatment, as well as potentially for prevention, of many of the most common, disabling, costly, and chronic diseases compromising life for the American people, including diseases that often affect women and minorities disproportionately.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Systemic Lupus Erythematosus

SLE, or lupus, is a chronic and potentially fatal autoimmune disease, often occurring in women of childbearing age. It can affect many parts of the body, including the joints, skin, kidneys, heart, lungs, blood vessels, and brain. People of all races have lupus; however, African American women are three times more likely to have lupus and are more likely to die from lupus than are White women. African American women also tend to develop the disease at a younger age than White women and develop more serious complications. Lupus is also more common in women of Hispanic, Asian, and Native American descent. Women are nine times more likely to have lupus than are men. Lupus is often difficult to diagnose because of its highly varied and often serious insidious clinical manifestations.

The NIAMS has received input on health disparities in lupus from a variety of scientific, advocacy, and patient communities to formulate future research goals. For example, the NIAMS recently sponsored the meeting *SLE: Targets for New Therapeutics: A Scientific Conference*. The purposes of this conference were to facilitate the exchange and integration of scientific information between scientists working in disparate areas related to SLE, and to identify novel strategies for clinical intervention. The NIAMS also leads the newly developed Federal Working Group on Lupus, which is designed to coordinate government efforts in this research area. Additionally, the NIAMS is an active participant in the National Institutes of Health (NIH) Autoimmune Diseases Coordinating Committee (ADCC).

Although the importance of genetics in ethnic differences in SLE cannot be denied, these factors do not explain all of the differences observed. Social/behavioral factors also appear to play an important role in the observed health disparities. Therefore, the NIAMS is committed to identifying the underlying causes for health disparities in the frequency and severity of lupus in populations at increased risk, including race/ethnic factors, cultural values, beliefs, and practices that affect SLE course and outcome.

1.1.1 Objective One: Identify and Address Race/Ethnic Factors, Cultural Values, Beliefs and Practices that Affect SLE Course and Outcome

Ethnicity has been identified as a factor that may influence a patient’s experience with lupus. Ethnicity includes race as well as cultural values, beliefs, and practices, which may be associated with a certain socioeconomic status. This information comes from the study Lupus in Minorities: Nature versus Nurture (LUMINA), conducted by NIAMS-supported researchers. The study, which includes over 300 African American, Hispanic, and Caucasian lupus patients aged 20 to 50 years, is designed to identify the relative contribution of genetic and socioeconomic factors to the course and outcome of lupus among these three ethnic groups. LUMINA researchers are investigating features such as socioeconomic-demographic characteristics (e.g., age, gender, marital status, income, health insurance); clinical attributes (e.g., disease onset and duration, clinical manifestations, treatments); behavioral-psychosocial factors (e.g., social support, abnormal illness-related behaviors, feelings of helplessness, acculturation [Hispanics only]); immunologic factors (e.g., autoantibodies); and genetic factors.

To date, the LUMINA study reveals that ethnicity, more than several other factors, does have a significant impact on some aspects of the disease. Both African American and Hispanic lupus patients tend to develop lupus earlier in life, experience greater disease activity at the time of diagnosis (including kidney problems), and have more severe disease overall than Caucasian patients. Furthermore, African American patients have a higher frequency of neurological problems such as seizures, hemorrhage, and stroke, whereas Hispanic patients experience cardiac disease more frequently.

Results from this study, and other NIAMS-supported studies, will help to address the need to identify racial/ethnic factors and cultural values, beliefs, and practices that affect SLE course and outcomes.

1.1.1.1 Action Plan

- The NIAMS will encourage biomedical and biobehavioral research to identify the causes for health disparities in lupus, including genetic studies in disproportionately affected ethnic and racial groups, prospective studies to establish long-term outcomes in affected patients, and comparison of co-morbidities in affected patients.

- The NIAMS will encourage and participate in leveraging resources with other organizations to advance the understanding of the genetic basis for lupus disparities.

- The NIAMS will promote the identification of lupus biomarkers for populations at risk for more severe disease.

1.1.1.2 Performance Measures

- One or more research studies will be funded that examine the genetic susceptibility factors in health disparities in lupus.

- One or more research studies will be funded to examine co-morbidities in lupus patients.

- One or more research studies will be funded to identify and evaluate biomarkers for lupus risk and severity.

1.1.1.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of the results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs or suggest potential intervention strategies.

1.1.2 Objective Two: Determine Predictors and Outcomes of Adherence to Medical Recommendations Across Racial/Ethnic Groups

The outcome of patients with rheumatic disease, in particular systemic lupus erythematosus (SLE), as well as RA, is variable and often unpredictable, and important differences have been observed across racial groups. Patients often show poor adherence to therapy, but the determinants and outcomes of compliance-related behaviors have not been adequately documented. Some of the ethnic differences in the outcome of these diseases may be related to degree of compliance with physician recommendations. There is a need to quantify adherence to medical recommendations in patients with SLE and RA from diverse ethnic backgrounds, and to determine predictors and outcomes of adherence.

1.1.2.1 Action Plan

- The NIAMS will seek high-quality applications that examine attitudes and behaviors toward adherence to treatment in patients with SLE and RA from diverse ethnic backgrounds.

- Research also will assess the role of patient beliefs, expectations, and attitudes about their disease on their adherence to treatment; assess the role of elements of the medical interaction on patients' compliance; evaluate ethnic differences in compliance; and determine the impact of non-compliance on patient outcomes.

1.1.2.2 Performance Measures

- One or more research studies will be funded that examine the beliefs and attitudes of different ethnic groups regarding SLE and RA treatment, treatment barriers, and perceived benefits.

- One or more research studies will be funded to evaluate the determinants of adherence to SLE and RA treatment in patients from diverse ethnic backgrounds.

- One or more research studies will be funded to examine the relationship between adherence and health outcomes in ethnically diverse patients with SLE and RA.

1.1.2.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs or suggest potential intervention strategies.

1.2 Area of Emphasis Two: Scleroderma

Scleroderma is an autoimmune disorder that occurs much more frequently in women than in men. Research also indicates a higher prevalence among Native Americans. The hallmark of scleroderma is the abnormal growth of connective tissue that supports the skin and internal organs. In addition, many forms of scleroderma involve tissues in the lungs, heart, kidneys, intestinal tract, muscles, and joints. In severe cases, scleroderma can be fatal. Although the cause is unknown, researchers believe that both environmental and genetic factors play a role in scleroderma. Currently, there is no treatment that controls or stops the overproduction of collagen. Little is known about the cellular changes that cause the skin and organs to harden, and the disease may be difficult to diagnose. Understanding the early cellular and molecular changes in scleroderma will help scientists develop more effective treatments.

The field of autoimmunity currently is exploding with activity and newly launched initiatives. Many NIH Institutes, including the NIAMS; the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; and the National Institute of Dental and Craniofacial Research are active members of the NIH ADCC, which is led by the National Institute of Allergy and Infectious Diseases. The ADCC provides a forum for coordinating research efforts for autoimmune diseases and brings together various stakeholders including the NIH, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and other public and private organizations. The Committee recently developed a comprehensive research plan for autoimmune diseases, including scleroderma. This is just one example of how the NIAMS receives public input on developing the Institute's research portfolio in scleroderma.

1.2.1 Objective One: Define the Biologic Mechanisms That Underlie Increased Susceptibility to and Severity of Scleroderma in Minority Populations

To investigate the prevalence of scleroderma in Native American people, NIAMS-supported investigators have blended modern-day genetic marker research and century-old tribal records, using census and historical records dating back to the 1800s. Researchers have identified a chromosomal site associated with scleroderma in Oklahoma Choctaw Native Americans. This study suggests that the gene for the protein fibrillin-1 is a possible susceptibility gene for scleroderma. Fibrillin-1 also is known to be responsible for a scleroderma-like condition in a mouse model of the human disease. This work represents the results of an effective public/private partnership, as the NIAMS was joined by other Institutes and Offices of the NIH and several private organizations.

Building on these findings, as well as other research in the broader field of autoimmunity, the NIAMS will continue to explore the biologic mechanisms that underlie increased susceptibility to and severity of scleroderma in minority populations.

1.2.1.1 Action Plan

- The NIAMS will continue to support research studies in all priority areas in scleroderma. These could include scientific meetings to explore the current state of research in scleroderma and Requests for Applications in targeted areas of research on scleroderma.

- The NIAMS will continue to emphasize the importance of discerning the health disparity dimensions of scleroderma in all affected populations and will give special priority to high-quality research applications that address health disparities, including identification of the risk factors involved.

1.2.1.2 Performance Measures

- One or more research studies will be funded that examine the genetic basis of scleroderma.

- One or more research studies will be funded to evaluate the non-immunologic contributors to disease progression in scleroderma.

1.2.1.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs or suggest potential intervention strategies.

1.3 Area of Emphasis Three: Rheumatoid Arthritis

RA is an inflammatory disease of the synovium, or lining of the joint, that results in pain, stiffness, swelling, joint damage, and loss of function of the joints. Inflammation most often affects joints of the hands and feet and tends to be symmetrical (occurring equally on both sides of the body). This symmetry helps distinguish RA from other forms of arthritis.

1.3.1 Objective One: Identify Factors Affecting Disease Severity and Progression in African Americans with Rheumatoid Arthritis

The long-term outcome of African American patients with rheumatoid arthritis has not been established. There is a need to identify risk factors for disease progression and early markers of treatment efficacy.

1.3.1.1 Action Plan

1. The NIAMS will continue to seek high-quality applications that examine the longitudinal evaluation of African Americans with early rheumatoid arthritis to identify both the genetic and non-genetic prognostic factors of disease outcome using radiographic presence of bony erosions as the primary outcome measure.

2. The NIAMS will use current and future research advances to provide the basis for prospective analyses of factors that are predictive of the clinical phenotype and outcomes in rheumatoid arthritis.

1.3.1.2 Performance Measures

- One or more research studies will be funded that examine factors affecting disease progression in African American patients with rheumatoid arthritis.

- The NIAMS research portfolio will be expanded to include research investigating cardiovascular complications of rheumatoid arthritis in African American patients.

1.3.1.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs or suggest potential intervention strategies.

1.4 Area of Emphasis Four: Osteoarthritis

OA or degenerative joint disease is the most common form of arthritis. It is painful and disabling and is characterized by the progressive loss of joint cartilage. As the U.S. population swells with graying baby boomers, vast numbers of people will suffer from degenerative joint diseases. Today, 35 million people —13 percent of the U.S. population—are 65 years of age or older, and more than half of them have evidence of OA in at least one joint. By 2030, 20 percent of Americans—about 70 million—will have passed their 65th birthday and will be at risk for OA.

Ethnic differences have been noted: African Americans have higher risks of both bilateral radiographic (x-ray defined) knee OA and hip OA than Caucasians. Obesity is associated with bilateral knee and hip OA and is a more important risk factor for bilateral knee OA in African Americans than in Caucasians. In addition, studies have shown that African Americans have much lower rates of total knee replacement than Whites, even when adjusted for age, sex, and insurance coverage.

The NIAMS is supporting a broad spectrum of studies in OA, from the most fundamental that are seeking to learn more about the normal function and survival of cells lining the joints, to clinical studies in which new drugs are being developed, to new prevention strategies. The NIAMS is encouraging research studies to evaluate risk factors for the development and progression of OA in vulnerable populations. Furthermore, the Institute recently sponsored a workshop on the prevention of onset, progression, and disability of OA, with sessions aimed at researchers and clinicians, as well as health educators and patients with OA. Information and insights from these efforts may lead to the identification and development of potential interventions to treat or prevent OA.

1.4.1 Objective One: The Osteoarthritis Initiative

Scientific and clinical experts in the field of OA currently perceive that the lack of discrete indicators of disease progression that are acceptable to the U.S. Food and Drug Administration as clinical endpoints is a major obstacle to the ability to diagnose, monitor, and treat this degenerative joint disease. The objective of the Osteoarthritis Initiative (OAI) is to coordinate public and private scientific expertise and funding to collect, analyze, and make widely available the largest research resource to date of clinical data, radiologic information, and biospecimens from individuals with early and progressing OA. The goal is to create a public resource to validate imaging and biochemical biomarkers and ensure that validated biomarkers are made widely available to further drug development and improve public health.

One of the most exciting aspects of the OAI is the coordination of private and public funds to create a publicly available scientific and drug discovery resource that would not have been possible by either sector alone. No intellectual property rights in the research resource will accrue to any consortium members. The NIH and other consortium members have determined that widespread availability of validated biomarkers and other research tools arising from use of the OAI resource by third parties is necessary to maximize the public health benefit of the Initiative. Thus, renewable resources arising from the OAI, such as clinical data, x-rays, and magnetic resonance images, will be made freely available to qualified scientists everywhere. For OAI resources that are limited, such as biospecimens, priority will be given to validation of biomarkers that, in addition to demonstrating scientific merit, will be made widely available by their owners for internal research and commercial use in accordance with the NIH Principles and Guidelines on Obtaining and Disseminating Biomedical Research Resources.

The OAI was developed with input from academic, government, and private industry scientists and health advocacy groups. The plan developed from these discussions was posted on the NIAMS web site for public comment for 4 months. The final document was modified to accommodate recommendations included in the public comments that were submitted.

1.4.1.1 Action Plan

The NIAMS joined with five other NIH Institutes and Centers and four pharmaceutical companies to fund the OAI in 2002. To address the ethnic differences in knee OA, the cohort will be enriched by at least 20 percent African American participants. The data collected over the 7-year study should define disease standards for individuals at high risk of developing OA and those at high risk of disease progression. Four clinical centers and a coordinating center were funded in summer 2002. Recruitment of the cohort began in January and enrollment in March 2004. The data collected will become a public resource for investigators worldwide to help quicken the pace of scientific studies and identification of unique biomarkers of disease. The first installation of this database is expected in fall 2005 with updates quarterly for the next 5 years. Enrollment of the cohort should be completed by June 2005 with follow-up visits continuing on a yearly basis until June 2009. Although data gathering from the cohort will be completed by 2009, the database will be a resource for many years to come. In addition, the OAI has developed a public information web site (http://www.niams.nih.gov/ne/oi/index.htm) that presently includes information for interested parties about the study as well as links to information about OA and, later, will include results that have come from the study.

1.4.1.2 Performance Measures

- Performance is demonstrated based on numbers of individuals from diverse populations recruited and enrolled into the cohort in the short term and use of the database in the long term.

- Use of the OAI resource will be noted in publications in scientific journals and abstracts presented at scientific and lay meetings.

1.4.1.3 Outcome Measures

Impact will be determined by assessing progress in development of OA biomarkers and improvements in treatment and evaluation of patients with OA. The assessment of health disparities in African Americans will be highlighted throughout these studies.

1.4.2 Objective Two: Increase Research Studies on the Origins of Health Disparities in Osteoarthritis

Although investigators have made significant contributions to the field of OA research, additional research is needed to address the origins of health disparities in OA.

1.4.2.1 Action Plan

The NIAMS will encourage research studies to evaluate risk factors for the development and progression of OA in vulnerable populations. This will be carried out through workshops and meetings related to prevention of onset, progression, and disability of OA, with a component of the meeting focusing on minority populations, with sessions aimed at researchers and clinicians as well as health educators and patients with OA. Information and insights from these efforts may lead to the identification and development of potential interventions to treat or prevent OA. In addition, Program Announcements and Requests for Applications may be developed if areas of need are identified through these discussions or through analysis of existing research efforts.

1.4.2.2 Performance Measures

- The number of high-quality applications received in this area will be tracked with specific emphasis on grants to new investigators and to established investigators choosing to change focus to health disparities research.

1.4.2.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs or suggest improvements in prevention, diagnosis, and treatment of minority patients with OA.

1.4.3 Objective Three: Strengthen and Improve Research Efforts With Regard to Health Disparities Related to Total Joint Replacement

Total joint replacement has been shown to be a safe and cost-effective treatment for alleviating pain and restoring function in patients who do not respond to non-surgical therapies for degenerative conditions affecting the knee. NIAMS-supported researchers recently have reported that African Americans are less likely than Whites to report that surgery had helped someone they knew with hip or knee pain, and they appeared less likely to perceive that this form of treatment is beneficial. Hispanics aged 65 and older were less than one-third as likely as non-Hispanic Whites of the same age to undergo total hip replacement—an operation that can alleviate pain and improve physical function and quality of life in patients with severe OA.

In December, 2003 the NIAMS and the Office of Medical Applications of Research joined the National Institute of Child Health and Human Development, the Food and Drug Administration, the National Institute of Standards and Technology, and the Office of Research on Women's Health to sponsor the NIH Consensus Development Conference on Total Knee Replacement. The final report from this meeting is available at: http://consensus.nih.gov/cons/117/117cdc_statementFINAL.html. In addressing what factors explain disparities in the utilization of total knee replacement in different populations, the panel found that there was clear evidence of racial/ethnic and gender disparities in the provision of total knee replacement in the United States. Women not only have been found to have worse pain and functional limitation at the time of surgery, they are less likely to undergo total knee replacement than men. Previous reviews of the Medicare databases reveal that Hispanic and African American men and women are less likely to undergo this procedure. This disparity is not limited to total knee replacement but has been found for other procedures as well. The following have been recognized as possible factors in explaining these disparities: equity and access, physician recommendations, patient perceptions and preferences, and interactions between health care providers and patients. In the final analysis, however, the full explanation for these differences is not known.

1.4.3.1 Action Plan

- Identify the extent to which disparities in the use of total knee replacement are the result of subjective differences across groups in perception of pain or disability and orientation to surgery;

- Identify patient-level factors affecting outcomes after surgery, including medical and socio-demographic characteristics, participation in rehabilitation services, the extent of social support, and the level of patient's physical activity after surgery.

1.4.3.2 Performance Measures

- Development of Program Announcements/Requests for Applications in the area of total joint replacement that have a special emphasis on investigating health disparities associated with these procedures.

- Tracking the number of high-quality applications received in this area.

1.4.3.3 Outcome Measures

Presentations by NIAMS-supported researchers at professional meetings and publications in peer-reviewed journals of results of NIAMS-funded research addressing this objective will be used as outcome measures. It is expected that such presentations and publications will both enhance knowledge in this area and highlight future research needs. A long-term outcome measure includes monitoring the Medicare databases for changes in demographic data related to total joint replacement.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Research Supplements to Promote Diversity in Health-Related Research (PA 05-015)

The advancement of research in health disparities and minority health is facilitated by the recruitment of a diversified workforce. The NIAMS is committed to promoting opportunities in biomedical research for underrepresented populations, including racial and ethnic minorities, by providing

Research Supplements to Promote Diversity in Health-Related Research. In addition, the Institute is committed to enhancing the research capacity of institutions serving minority and other underrepresented populations that include Historically Black Colleges and Universities (HBCUs) and other institutions that serve students from underrepresented populations in arthritis, muscle, bone, and skin disease research areas. The Institute is currently in the process of reviewing and updating existing programs, as appropriate, to ensure that a broad range of diversity goals are served by them.

2.1.1 Objective One: Research Training and Career Development for Investigators From Minority and Other Underrepresented Populations

As part of the NIH-wide effort to promote research training and careers among underrepresented minority investigators, the NIAMS continues to support the expansion of a diversified workforce in arthritis, muscle, bone, and skin diseases research areas. To facilitate this process, principal investigators currently holding a grant from NIAMS have the opportunity to apply for administrative supplements to facilitate the recruitment of individuals from groups with low representation in the biomedical and behavioral sciences. The NIAMS will provide research training and career development support in health disparities research by participating in the administrative supplements program.

2.1.1.1 Action Plan

Areas of emphasis will include targeting the hiring of scientists from underrepresented groups to our research programs, including people at all stages of their careers, and working to promote the training of clinical investigators in academic health centers that serve individuals from minority and other underrepresented populations.

2.1.1.2 Performance Measures

Participation in NIH Program Announcements and Requests for Applications related to the promotion of research training and career development opportunities for underrepresented minority investigators.

2.1.1.3 Outcome Measures

The number of highly qualified applications received in key health disparity research areas will be examined on an annual basis.

2.1.2 Objective Two: Enhance the Research Capacity in Institutions Serving Individuals From Minority and Other Underrepresented Populations

To enhance the research capacity in underrepresented minority-serving institutions, the NIAMS utilizes the Collaborative Arthritis and Musculoskeletal and Skin Diseases Sciences Award

(CAMSSA) program. The objective of the CAMSSA program is to develop and promote competitive scientific research programs in areas within the mission of the NIAMS at institutions serving individuals from minority and other underrepresented populations. The CAMSSA program is designed to encourage collaborative investigations among scientists at institutions with substantial underrepresented minority enrollment with grantees from research-intensive institutions who have grant support to conduct research in arthritis and musculoskeletal and skin diseases. The nature of the collaborations will include joint research efforts, specialized training in research techniques, and participation in research seminars. The CAMSSA program develops and expands scientific opportunities among the participating institutions for research in arthritis and musculoskeletal and skin diseases.

2.1.2.1 Action Plan

The NIAMS will continue to support the CAMSSA program to support investigator-initiated research projects in which the applicant and a collaborating scientist work in a clearly defined area of mutual research interest. Because the intent of the award is to develop competitive research programs at institutions with substantial underrepresented minority enrollment, the applicant and collaborating investigators must document the potential for developing scientific approaches to accomplish the objectives of the proposed research project. The project must consist of a scientifically meritorious research plan that involves an efficacious collaborative effort among the participating investigators, each of whom will be conducting a portion of the total research project in his/her own laboratory. Examples of the collaborative interactions include the sharing of ideas and data and exchanging of research techniques and expertise.

2.1.2.2 Performance Measures

The NIAMS will monitor program progress via annual progress reports submitted by the principal investigators, including a summary of activities related to the specially designed research project described above. Continued support will be contingent upon successful demonstration of the award guidelines.

2.1.2.3 Outcome Measures

The number of highly qualified applications in key health disparity research areas received will be examined on an annual basis. A long-term goal is to monitor the number of successful R01/P01 applications from minority and other underrepresented populations supported by the CAMSSA program.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

NIAMS has been—and will continue to be—engaged in identifying and developing materials aimed at reducing health disparities by educating affected populations about disease treatment and prevention. The Institute already has in place a rigorous process for determining what materials should be developed, and biennially solicits input from NIAMS staff and clearinghouse, voluntary health and professional organizations, community organizations participating in the Washington, DC-based Health Partnership Program, and members of the NIAMS Advisory Council.

Bilingual materials and materials for those of other cultures, languages, and literacy levels continue to be developed and pretested before distribution. Examples of NIAMS publications addressing diseases that affect certain populations disproportionately include: *Handout on Health: Osteoarthritis, The Lupus Nurses Guide, The Many Shades of Lupus, Handout on Health: Scleroderma, and Questions and Answers About Vitiligo*. The Institute also provides information in Spanish through bilingual booklets on arthritis and lupus, as well as fact sheets on OA, Sjogren's syndrome, and Marfan syndrome. In addition, NIAMS has created a Spanish-language web site for its Spanish-speaking audiences. Outlined below are two areas of emphasis in which the Institute will engage: Health Literacy and Targeted Outreach to Underserved Minority Populations.

3.1 Area of Emphasis One: Health Literacy

Recognizing the importance of providing the general public with information that is easy to understand to promote informed decisions about health, the NIAMS publishes materials to meet the needs of various audiences, including people with limited English proficiency. To ensure health information access to these audiences, the Institute has expanded and will continue to expand its resources to include publication titles in bilingual, non-English, and easy-to-read formats that are available in print as well as electronic formats. This area of emphasis responds to the Healthy People 2010 objective of improving the health literacy of persons with inadequate or marginal literacy skills, which was developed following a number of planning meetings in which public input was obtained.

3.1.1 Objective One

To develop relevant, culturally appropriate health education materials about arthritis and musculoskeletal and skin diseases at diverse reading levels to promote informed health decision-making among people from underserved and minority populations, including easy-to-read and bilingual materials and/or materials in languages other than English.

3.1.1.1 Action Plan

- Expand the NIAMS Spanish-language web site to include newly developed and/or translated health information.

- Expand NIAMS publication titles in languages other than English in print and electronic formats.
- Produce press releases and science stories describing the work of NIAMS and NIAMS-funded researchers with implications for people from underserved and/or minority populations.
- Develop Fast Facts series in English for limited literacy audiences, which provide basic disease information including definitions, symptoms, and resources for more information.

3.1.1.2 Performance Measures

To assess performance on this action plan, NIAMS will track the development of: (1) new material posted on the English and Spanish-language web sites; (2) new publication titles that respond to the needs of diverse cultures in languages other than English; (3) press releases; and (4) the Fast Facts series.

3.1.1.3 Outcome Measures

- Update the NIAMS web site and its Spanish-language counterpart on a frequent basis, as new publications titles are produced.
- Produce at minimum five Spanish-language publications per year.
- Produce at minimum one bilingual brochure per year.
- Produce up to three press releases or science stories describing research funded by NIAMS with implications for people from underserved and/or minority populations.
- Develop a minimum of three new English publications per year, including the Fast Facts series for limited literacy audiences.

3.2 Area of Emphasis Two: Targeted Outreach to Underserved Minority Populations

We are committed to a comprehensive program of information dissemination to patients and their health care providers. Research advances are of limited value if they never reach the arena of health care and miss the goal of improving public health for all Americans. The NIAMS supports information dissemination through three primary means: the Institute's Office of Communications and Public Liaison, the NIAMS Information Clearinghouse, and the NIH Osteoporosis and Related Bone Diseases ~ National Resource Center.

In addition, we work closely with many voluntary and professional societies and community-based organizations to both learn their needs and views and disseminate our research findings. We have also targeted our information to particular areas of need and to diverse populations (including printed information and our toll-free information line in English and in Spanish). We will continue to build and strengthen these relationships with the community and will strive to make our information accessible to the vast and diverse populations affected by the diseases within our mandate.

3.2.1 Objective One

To enhance information dissemination efforts for the underserved and minority populations through existing and newly identified communication venues.

3.2.1.1 Action Plan

- Seek collaborations with non-NIH government agencies to disseminate NIAMS public health information to underserved and/or minority populations.
- Collaborate with the Federal Consumer Information Center to distribute health information to the public, with targeted efforts to underserved and minority populations.
- Enhance the NIAMS Exhibit Program, coordinated through the NIAMS Information Clearinghouse and the NIH Osteoporosis and Related Bone Diseases ~ National Resource Center for distribution of materials to organizations at the community and national levels, as well as to health professionals who serve minority, ethnic, and other special populations.
  - Expand dissemination efforts to minority health professionals through annual meetings, job fairs, and other gatherings such as the National Medical Association, National Hispanic Medical Association, American Indian Science and Engineering Society, National Black Nurses Association, and National Hispanic Nurses Association, among others.
  - Increase dissemination of health materials through community events, such as health fairs, seminars, and local adult literacy programs through the Institute's Washington, DC-based Health Partnership Program and through individual requests to the clearinghouse and resource center.
  - Distribute information on NIAMS-funded clinical studies with special emphasis on studies related to diseases and disorders that disproportionately affect people from underserved and/or minority populations.
- Disseminate the newly developed NIAMS curriculum, "Looking Good, Feeling Good: From the Inside Out," to middle schools.

3.2.1.2 Performance Measures

To assess performance on this action plan, NIAMS will track dissemination of materials through the Health Resources and Services Administration (HRSA), the Federal Consumer Information Center, the NIAMS Exhibit Program, and organizations distributing the middle school curriculum.

3.2.1.3 Outcome Measures

Success of the information dissemination plan will be judged in terms of: (1) the number and types of materials distributed through HRSA and the Federal Consumer Information Center; (2) the number of local and national exhibits, requests for materials, the amount and types of material distributed, and the number of contacts made through the NIAMS Exhibit Program; and (3) the number of schools using the middle school curriculum.

3.2.2 Objective Two

To obtain perspectives from the public on health information needs for the disease areas within the Institute's mission, with emphasis on the information needs of people from underserved and minority populations.

3.2.2.1 Action Plan

- Track the number and type of requests to the NIAMS Information Clearinghouse to help determine the topics of strong public interest.
- Analyze and respond to the inquiries obtained from the NIAMS web site, which includes a "Contact NIAMS" button to encourage inquiries.
- Conduct meetings with the NIAMS Patient Representatives Group to obtain input on information needs from current and former patients in NIAMS clinical trials.
- Conduct meetings with community partners, Washington, DC-area organizations participating in the NIAMS Health Partnership Program, to obtain input on the program's research projects and information dissemination efforts.
- Obtain input on the NIAMS publications plan from voluntary and professional groups, with special emphasis on the needs of underserved and minority populations.
- Obtain input on publications and dissemination plans for bone diseases through the NIH Osteoporosis and Related Bone Diseases ~ National Resource Center Osteoporosis Coordinating Council.

3.2.2.2 Performance Measures

To assess performance on this action plan, NIAMS will track and analyze the types of input received on health information needs.

3.2.2.3 Outcome Measures

The success of the Institute's efforts to obtain input from the public about health information will be measured by the number and types of revised or new health information dissemination initiatives developed based on feedback provided by the public through scheduled meetings and web site submissions.

The National Institute of Biomedical Imaging and Bioengineering

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL **I**NSTITUTE OF **B**IOMEDICAL **I**MAGING AND **B**IOENGINEERING

MISSION/VISION STATEMENT

Public Law 106-580 authorized the establishment of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to provide a research home for the development and application of new technologies and techniques for the delivery of health care. NIBIB brings the research communities of biomedical imaging, bioengineering, and the physical sciences together with the life sciences community to advance human health and quality of life and reduce the burden of disease. It is the mission of the NIBIB to improve human health by leading the development of and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. The vision of the NIBIB is to profoundly change health care. NIBIB will push the frontiers of technology to make the possible a reality.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Since the establishment of the NIBIB, the Institute has focused on building a portfolio and identifying key principles to guide its growth. The Institute does not concentrate on specific health conditions associated with life span, disease, or anatomical site. It is, however, positioned to identify challenges in medical research that can benefit from bioengineering and bioimaging approaches. NIBIB provides leadership in developing cross-cutting research and training in biomedical imaging and bioengineering, to reduce health disparities, with the ultimate goal of improving the health and well-being of all Americans.

The NIBIB has developed a strategic plan that outlines priorities for research, training, dissemination of research findings, and community outreach for the next 3 to 5 years. The outcome of this process includes specific program plans for addressing health disparities. One broad area of exploration is the potential of various technologies to improve access and enhance the affordability of medical technologies that improve quality in health care. NIBIB currently is supporting research from at least two initiatives that may contribute to advances in these areas. Another approach may be to investigate the potential for imaging and engineering to improve prevention, diagnosis, and treatment in the six identified areas that account for the most serious health disparities: infant mortality; cancer screening and management; cardiovascular disease; diabetes; human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS); and immunization. NIBIB will work collaboratively with other National Institutes of Health (NIH) Institutes and Centers and other federal agencies to optimize impact.

The Institute plans to build upon current efforts to increase participation of a diverse pool of applicants, including underrepresented racial and ethnic, economically and socially disadvantaged, and disabled students and new investigators in NIBIB training programs. However, selection of successful applicants will be based on scientific merits and program priority, not on racial/ethnic identities. Recognizing the success of many existing NIH/federal initiatives, the NIBIB will continue to join and support effective programs to expand opportunities for training in imaging and engineering sciences that target diverse groups or those engaged in health disparities research. The Institute will conduct a public outreach campaign to increase awareness of and participation by members of underrepresented, disadvantaged, and disabled groups in these programs and other training and research programs supported by the NIBIB.

Communicating research findings and health messages to the public is an important component of the NIBIB mission. This information must be broadly disseminated in minority communities in culturally appropriate ways. The NIBIB will expand communication efforts to convey information on the latest advances and applications in biomedical imaging and engineering.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Medical Technologies for the Detection, Diagnosis and Treatment of Human Diseases and Injury

The NIBIB is committed to the development of medical technologies that reduce health disparities. Modern medical technologies are critical for quality health care, yet remain widely unavailable to many patients in poor and underserved communities. The invention and development of low-cost medical devices may provide more widespread use and efficient application of modern medical technologies. Thus, the NIBIB is committed to supporting novel investigations for low-cost medical devices that can be broadly applied to research and treatment of disease and injury. Because many current medical devices used for detection, diagnosis, and treatment are expensive and unavailable to some segments of society, the NIBIB plans to stimulate research that will lead to lower cost medical devices. Development of inexpensive, innovative medical devices is needed, with particular emphasis on early detection and efficient treatment of disease and injury. Cost reductions in high-technology medical devices may lead to reduced health care costs and consequent reduction of health disparities.

1.1.1 Objective One: Low-Cost Medical Technologies

This objective focuses on the development of low-cost medical technologies that enable wide dissemination of medical imaging devices and engineering technologies.

1.1.1.1 Action Plan

To accomplish the objective of low-cost medical technologies NIBIB will:

- Promote research on the development of new, affordable medical technologies.
- Support cost reductions in existing medical technologies to make them more widely available.

In 2003 NIBIB released a Request for Applications (RFA) directed toward the development of low-cost medical imaging technologies. Twenty-four grants were funded, and the NIBIB continues to support these and additional investigator-initiated applications for low-cost imaging. R21 grantees, funded as part of the low-cost medical imaging initiative, will be encouraged to explore methods for additional funding (e.g., R01 support). R01 grantees will be urged to seek added support from venture capital, industry, etc., to advance their research development to commercialization.

1.1.1.2 Performance Measures

1. Funded low-cost imaging grants.
2. Meetings with industry stressing the importance of these efforts.

1.1.1.3 Outcome Measures

1. Number of funded grants.
2. Number of grants that progress to Phase II and Phase III.

1.1.2 Objective Two: Advances in Telehealth to Reduce Health Disparities

This objective focuses on the development of telehealth technologies to reduce health disparities by bringing medicine and medical expertise to environments and remote regions that have reduced access to medical diagnostic, planning, and treatment technologies and specialists.

1.1.2.1 Action Plan

The Internet is widely available and provides a vehicle for the transmission of medical information (e.g., images and electronic patient records) from underserved areas to major health care centers. NIBIB supports advances in telehealth that will broaden access by underserved populations to high-quality health care. Portable diagnostic devices are capable of recording physiological, biochemical, and diagnostic image data non-invasively in rural and non-hospital settings. Telehealth is defined by the Department of Health and Human Services as "the use of communications technologies to provide and support health care at a distance." Examples include the use of communications to provide patient treatment, often through the transmission of still images or video, and the exchange and distribution of public health information. Issues amenable to technical solutions arise in the diagnosis, treatment, and follow-up of a patient at a distance. The technical feasibility of telehealth applications has been well demonstrated for several specific applications in the past (as reported at the NIH Telemedicine Symposium, March 2001, http://www.nlm.nih.gov/research/telesymp.html). The current need is to generalize remote access technology to be adaptable to a broad range of telehealth applications, to develop mechanisms in which the technology can be integrated seamlessly into the routine of the provider and the patient, and to develop technology for standardizing and incorporating state-of-the-art security protocols for verifying user identities and preserving patient confidentiality.

The main objectives of advancing telehealth to reduce health disparities are demonstrated in the following examples:

- Image based consults involve medical diagnosis or treatment of a patient in a remote clinic, accomplished through the transmission of medical images to a specialist. To facilitate this, NIBIB supports the development of specialized hardware and software for image compression, storage, transmission, and display. NIBIB also supports the design and development of the peripheral (non-image) devices that can aid in a remote interactive examination.

- Home-based health care using physiological monitoring devices also benefits from development of low-cost, low-power physiological sensors, wireless technologies, and inexpensive interactive video for pre-operative or follow-up interactions with a health care provider. Future applications include hand-held or portable digital imaging and display devices. Wearable patient monitors, which are lightweight and non-invasive, long-life batteries, and telemetry hardware and software also may reduce health disparities.

In 2002, the NIBIB released a Request for Applications and a Small Business Innovative Research and Small Business Technology Transfer Program Announcement directed toward the development of telehealth technologies. Six grants were funded through these competitions, and the NIBIB continues to support these and additional investigator-initiated applications on telehealth technologies. NIBIB's program in telehealth technologies currently supports research in the following areas on health disparities: cancer screening, cardiovascular disease, and diabetes.

1.1.2.2 Performance Measures

1. Funded telehealth grants.

1.1.2.3 Outcome Measures

1. Number of funded grants.
2. Number of grants that progress to Phase II and Phase III.
3. Evidence of products developed as a result of this research.

1.1.3 Objective Three: Support the Development of Human Tissue Engineered Model Systems to Create and Evaluate New Vaccines

1.1.3.1 Action Plan

Support investigator-initiated applications as indicated by policy guidelines.

1.1.3.2 Performance Measures

1. Funded grants within this area of research.

1.1.3.3 Outcome Measures

1. Number of funded grants.

1.1.4 Objective Four: Support the Development of Needle-Free Delivery Systems for Childhood Vaccinations

1.1.4.1 Action Plan

Support investigator-initiated applications as indicated by policy guidelines.

1.1.4.2 Performance Measures

1. Funded grants within this area of research.

1.1.4.3 Outcome Measures

1. Number of funded grants.

1.2 Area of Emphasis Two: Support for Inclusion of Minorities in Clinical Studies

The inclusion of individuals from diverse groups in clinical studies is critical to the realization of effective interventions for improving health. NIH guidelines for inclusion of women and minorities in clinical studies are designed to achieve this outcome. NIBIB currently supports a number of studies with significant minority representation. The Institute will continue to monitor adherence to these policies by grantees in our portfolio.

1.2.1 Objective One

Ensure that clinical studies supported by the NIBIB adhere to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

1.2.1.1 Action Plan

NIBIB staff will continue to track inclusion data and provide guidance on these policies to NIBIB grantees.

1.2.1.2 Performance Measures

Appropriate representation by diverse groups in NIBIB-supported clinical studies and accurate and effective maintenance of inclusion data**.**

1.2.1.3 Outcome Measures

Maintain appropriate representation of women and minorities in NIBIB-supported clinical studies as mandated by federal law (Section 492B of the Public Health Service Act, as amended).

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Interdisciplinary Training of Individuals From Minority and Other Underrepresented Populations

Training a new cadre of interdisciplinary researchers is an important component of the Institute's mission. In an effort to draw talented researchers into the activities of the Institute, NIBIB is developing new training programs in the biomedical imaging and bioengineering fields as well as adopting existing NIH training mechanisms to meet the needs of the NIBIB extramural community. The Institute's approach is to develop opportunities that will fill critical gaps along the career continuum, while also enhancing the participation of the most talented researchers from all groups that have been shown to be underrepresented.

2.1.1 Objective One

Training programs to attract diverse groups to bioengineering and/or biomedical imaging research careers.

NIBIB will participate in NIH programs to promote training of diverse groups across the career continuum.

2.1.1.1 Action Plan

This objective will be accomplished by joining several NIH-wide Program Announcements.

1. The NIBIB is a participant in the NIH Program Announcement (PA-05-015) entitled "Research Supplement to Promote Diversity in Health-Related Research." This NIH-wide program provides supplements to existing NIH grantees to appoint individuals from minority and other underrepresented populations; individuals with disabilities; and individuals form socially, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research as trainees on research project grants. Eligibility

extends from high school students through established research investigators. The NIBIB will participate in any reissues of this announcement.

2. We currently participate in the NIH Program Announcement (PA-06-481) entitled "NIH Predoctoral Fellowship Awards to Promote Diversity in Health-Related Research (F31)." The primary objective of this funding opportunity announcement is to help ensure that diverse pools of highly trained scientists will be available in appropriate research areas to carry out the Nation's biomedical, behavioral, health services, or clinical research agenda. This initiative seeks to improve the diversity of the health-related research workforce by supporting the training of predoctoral students from groups that have been shown to be underrepresented. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds.
3. Bioengineering and Bioinformatics Summer Institute (BBSI) Program: This is a joint training program targeting late undergraduate and early graduate students. The goal is to attract individuals to pursue graduate careers in bioengineering and/or bioinformatics. An objective of this program is to promote diversity in health-related research.
4. NIH Institutional Training Programs: The NIBIB has joined the trans-NIH Program Announcement for institutional predoctoral/postdoctoral training grants. These programs address the recruitment of diverse populations into health-related research and track their participation in the training grant.
5. NIBIB supports the Hispanic Association of Colleges and Universities (HACU) summer internship program, a component of the White House Educational Initiatives and governed by Executive Order 13239: Educational Excellence for Hispanic Americans, to encourage their commitment to bioengineering or imaging careers.

2.1.1.2 Performance Measures

We will track the number of applications received and the number of applications awarded.

2.1.1.3 Outcome Measures

We are developing methods for tracking career progress of trainees supported by our different training programs, including individual and institutional awards.

2.2 Area of Emphasis Two: Research Community Outreach

2.2.1 Objective One

Develop new and expand current linkages with minority organizations and professional societies**.**

2.2.1.1 Action Plan

NIBIB will increase the number of institutions that are aware of NIBIB research and training programs to increase the diversity of the applicant pool into these programs.

2.2.1.2 Performance Measures

- Track distribution of printed materials to increase the likelihood that a diverse group of individuals receives these materials.
- Track NIBIB's involvement in meetings and outreach activities to ensure that diverse groups of individuals have the opportunity to participate in these activities.

2.1.1.3 Outcome Measures

Number of linkages with a diverse group of organizations and institutions

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Information Dissemination

NIBIB has initiated a comprehensive strategic planning process to identify and address present and future scientific research directions. One of the next steps in our strategic planning effort is to develop a formal process for outlining and conducting outreach and education activities, including the development and dissemination of print and media materials on health disparities or for underserved populations.

3.1.1 Objective One

Increase dissemination of NIBIB information and research advances and applications in ways that are meaningful to target audiences.

3.1.1.1 Action Plan

Communicating research findings and health messages to the public is an important component of the NIBIB mission. This information needs to be disseminated broadly to diverse communities in culturally appropriate ways. For example, the NIBIB will provide materials in Spanish when appropriate and host web sites that are accessible to individuals with disabilities. The NIBIB is expanding its communication efforts with the general public and the research community to enhance dissemination of the latest advances and applications in biomedical imaging and bioengineering research. Multiple media are being used to convey these messages, including print materials and fact sheets, the web, and an exhibit booth.

3.1.1.2 Performance Measures

- Develop and disseminate reliable scientific information and research accomplishments to a diverse group of institutions and organizations.
- Exhibit NIBIB-funded research activities, opportunities, and scientific advances at appropriate professional and scientific meetings.
- Develop culturally appropriate media opportunities and strategies to broaden awareness and knowledge of NIBIB's mission within diverse communities.
- Enhance and expand current print and online (web) information.
- Translate outreach and education material into Spanish.

3.1.1.3 Outcome Measures

- Amount and type of information disseminated.
- Number of documents translated into Spanish.
- Number of meetings at which NIBIB exhibited.
- Web site usage.

The National Institute of Child Health and Human Development

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

MISSION/VISION STATEMENT

Since its inception in 1962, the National Institute of Child Health and Human Development (NICHD) has dedicated its research to understanding the dynamic biological, behavioral, and social processes that dictate physical, emotional, and cognitive growth. NICHD research starts early, from before conception, and continues through the transitions of infancy, childhood, and adolescence, which set the foundation for conditions, diseases, and behaviors that last a lifetime. The Institute creates the knowledge to understand the complex interplay of processes that transform cells into healthy functioning individuals, free of disease and disabilities. When this goal is not achieved, or achieved unequally by different groups, the NICHD mission is to understand why, and to develop remedies to ensure the healthy functioning of all infants, children, youth, and families. The NICHD mandate also includes addressing the biological, physical, social, individual, and community forces affecting population dynamics and human reproduction, as well as supporting research to help persons with physical disabilities restore, replace, enhance, and prevent decline in function.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The Institute continues to follow the path charted in its strategic plan, *Health Disparities, Bridging the Gap*, published in FY2000, which is aimed at addressing health issues that disproportionately affect minority populations. As many of the goals and objectives identified in this plan have been reached, the Institute is developing a new plan to continue the journey. To that end, the Institute will maintain its long practice of investigating the complex biological and environmental interactions that drive developmental processes, with the goal of clarifying the many factors that lead to racial, ethnic, and even community-based disparities. By focusing and coordinating research on gestation, the early years of life, and the transitions into and out of adolescence and into young adulthood, the NICHD can address ways to prevent health disparities, as well as identify therapeutic strategies for early intervention.

INCLUSION OF PUBLIC COMMENTS

The Institute continues to solicit and consider public feedback and comment in planning all future research efforts. Scientific agenda setting and strategic planning meetings typically include representatives from scientific, professional and advocacy communities outside of the National Institutes of Health (NIH). For instance, the NICHD is supporting a series of meetings with American Indian (AI) and Alaska Native (AN) community and health leaders to address the disproportionate incidence of Sudden Infant Death Syndrome (SIDS) in these communities. Members of the AI and AN communities have conducted focus groups with parents, grandparents, and community leaders in Aberdeen, South Dakota; Billings, Montana; Portland, Oregon; Minneapolis, Minnesota; and Anchorage, Alaska to assess knowledge, attitudes, and beliefs concerning SIDS. Information from the meetings will be used to develop culturally sensitive outreach materials in a community-based initiative to reduce the incidence of SIDS among these populations.

The Institute also developed a highly successful collaboration with leaders and members of three African American Organizations: Alpha Kappa Sorority, Inc., the National Coalition of 100 Black Women, and the Women in the NAACP. The partners planned and hosted regionally based summits to inform members of the African American community about SIDS risk and to teach participants how to use SIDS risk reduction kits in their own communities. Since the summits, the three partners have continued to serve as catalysts for other SIDS reduction activities within their geographic areas and to provide the NICHD with feedback that will be useful when developing and executing future public health campaigns.

In addition, the NICHD collaborated with the National Black Child Development Institute and other organizations serving the African American community to develop “A Guide for African American Parents: Helping Children Cope with Crisis” and “An Activity Book for African American Families: Helping Children Cope with Crisis.” These publications were developed to provide materials for parents to help their children cope with extraordinary crises, such as a terrorist attack, as well as with everyday hardships, to provide comfort and a sense of safety for their children. These models will also help guide the Institute when developing future public health campaigns.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Infant and Maternal Mortality and Morbidity

Eliminating health disparities in infant and maternal health outcomes remains a critical research area for the Institute and a prime objective of our nation’s public health policy. This is particularly important because, despite a dramatic decline in infant and maternal mortality during the 20th century, significant disparities among various racial/ethnic groups persist. For example, the African American infant mortality rate is more than twice that of White infants, primarily because African American infants are more than twice as likely to be born at low birth weight (LBW) and more than three times as likely to be born at very LBW than Whites. Furthermore, LBW babies who do survive are at a greater risk of developing neurologic disorders, learning disabilities, and delayed development. The disparity in maternal mortality rates is equally disconcerting. Although maternal mortality rates have decreased dramatically overall, maternal death is still three times higher among African American women than among White women.

1.1.1 Objective One

Advance the field of maternal fetal medicine.

The NICHD continues to support the Maternal Fetal Medicine Units Network (MFMU), a network of academic institutions with the ability to conduct a variety of short- and long-term multi-center clinical research projects. Many of the MFMU studies target high-risk women and infants and, therefore, include a significant number of minorities. So, although the hypotheses may not be targeted per se, the conduct of the studies and the resultant findings provide the needed foundation to begin eliminating disparities in birth outcomes. For example, researchers working collaboratively within the MFMU made a significant breakthrough that holds tremendous promise for reducing preterm birth in women who have previously experienced a premature delivery. The researchers demonstrated that by treating these high-risk women with the hormone progesterone (17P) during subsequent pregnancies, they could increase the likelihood of the mothers carrying their babies to term, and thus reduce the rates of life-threatening complications in their newborns. Furthermore, administering 17P did not appear to cause birth defects or any other problems in the infants. As African American women benefited as much as White women from the treatment, this discovery should help to reduce the entrenched disparity in birth outcomes for African American infants.

1.1.1.1 Action Plan

- Issue a Request for Applications (RFA) for renewed funding of the MFMU Network in FY2005.
- Fund between 14 and 16 centers by April 2006.
- Continue publication of research findings as clinical trials are completed.

1.1.1.2 Performance Measures

Performance will be partially measured by the successful recruitment of appropriate minority subjects. The NICHD will also monitor research protocols conducted within the MFMU Network and the number of scientific papers published as a result of this ongoing research.

1.1.1.3 Outcome Measures

Intermediate outcomes measures will include research findings with significant translational and clinical applications, such as knowledge that can lead to reduced rates of preterm birth, fetal growth abnormalities, neurologic problems of the newborn, and maternal complications of pregnancy in minority populations.

1.1.2 Objective Two

Reduce preterm birth and LBW in minority infants by focusing on the interrelationship between biological factors and other factors, such as sociological and behavioral factors.

Better understand the interplay between the etiology, pathophysiology, and related social and behavioral factors leading to preterm births and LBW, with the ultimate goal of developing strategies for preventing preterm birth in minority populations.

1.1.2.1 Action Plan

Support collaborative, multidisciplinary biobehavioral research to expand our understanding of: (1) the underlying mechanisms that contribute to racial and ethnic variations in preterm delivery and LBW; and (2) how psychosocial and environmental factors affect or interact with these biologic mechanisms to influence pregnancy outcomes.

- The NICHD co-sponsored a Program Announcement (PA) issued by the National Institute of Nursing Research beginning in December 2003 and extending through December 2006.
- Begin funding meritorious research proposals starting in FY2005. The Institute anticipates that these studies will target high-risk women and infants, who should include a significant number of minority subjects. The Institute also anticipates that some applications will be for research with hypotheses targeting minority populations and/or the factors specifically leading to disparities.
- Preliminary research findings should follow within 5 years of the grant awards.

1.1.2.2 Performance Measures

The Institute will measure performance by the number of scientifically meritorious grant applications with a significant number of minority subjects that are funded, within the payline, over the next 3 years.

1.1.2.3 Outcome Measures

Outcomes will include research findings with significant translational and clinical applications, such as knowledge of the effects of social and behavioral factors on the etiology and pathophysiology of preterm birth and LBW. Significant findings will be reported in professional journals, at conferences, and through other means that can eventually be used by appropriate organizations and care providers to develop clinical guidance and prevention programs.

1.1.3 Objective Three

Develop a genomic and proteomic network for conducting premature birth research to accelerate understanding of the causes of LBW and preterm birth at the molecular level.

By creating this network, the NICHD hopes to hasten: (1) a better understanding of the causes of premature birth; (2) discovery of novel target molecules and diagnostic biomarkers, and ultimately, (3) development of more effective interventions to prevent premature birth. Specifically, the network will design and implement large-scale genomic and proteomic research studies and provide a public database for use by the research community. Understanding of the causes of LBW and preterm birth at the genetic and molecular level will help researchers address the fundamental causes of this health disparity and begin to formulate effective interventions in minority populations.

1.1.3.1 Action Plan

- The NICHD published an RFA in June 2004.
- Award up to five 5-year grants in spring 2005.
- Preliminary research findings should follow within 5 years of the grant awards.

It is anticipated that the network will consist of the following:

1. A clinical core, comprising up to three clinical sites, responsible for subject recruitment and specimen collection;
2. An analytical core responsible for genomic and proteomic analyses; and
3. A data management, statistics, and informatics core responsible for central data collection, analysis, and management; information technology; and coordination of the administrative activities of the network.

1.1.3.2 Performance Measures

Initially, the Institute will measure performance by the funding of scientifically meritorious clinical sites across the country that will be able to provide access to targeted data. Continued performance will be measured by progress toward recruitment of high-risk and minority subjects, adequate data collection, and the development of a strong database to sustain the needed level of informatics and related analyses.

1.1.3.3 Outcome Measures

Success will be measured by the use of the database to develop viable hypotheses concerning the basic physiologic mechanisms leading to LBW and premature birth.

1.1.4 Objective Four

Continue to support the NIH-D.C. Initiative to Reduce Infant Mortality in Minority Populations in the District of Columbia (D.C. Initiative).

Among minority populations, the District of Columbia has one of the worst rates of early initiation of prenatal care, one of the highest rates of LBW, one of the highest infant mortality rates, and one of the highest teen pregnancy rates (especially for young women 15 to 17 years of age). More than 20 percent of the District’s population lives in poverty, compared to 12 percent in the rest of the nation, and almost twice as many of the District’s children live in poverty compared to the rest of the nation. Studies on how to maximize good birth outcomes and ensure that children grow up healthy are extremely important. The institutions currently participating in the D.C. Initiative have developed into a close and collaborative working group.

1.1.4.1 Action Plan

- Expand the "D.C. Initiative to Reduce Infant Mortality" with new interventions targeting African American and Hispanic teens that simultaneously address psychosocial and behavioral risk factors to prevent preterm births and LBW. By building on existing efforts, the NICHD can take advantage of the successful working collaborations to begin new projects to improve birth outcomes.
- Issue a Letter Of Interest (LOI) requesting proposals for new initiatives for current collaborators in the D.C. Initiative by the end of FY2004.
- By the end of 2005, fund four new 5-year community-based projects that target African American and Hispanic teens and simultaneously address psychosocial and behavioral risk factors, such as maternal smoking, to prevent preterm births and LBW.

1.1.4.2 Performance Measures

Performance will be measured by the successful recruitment and retention of subjects into the new studies and by continued data sharing and other cooperation between the principal partners.

1.1.4.3 Outcome Measures

Outcomes will be measured by research findings identifying how to maximize healthy behaviors in minority mothers and health outcomes in the mothers and their children. These could be disseminated through publications, conferences, or other means. Long-term outcomes will include new knowledge with significant translational and clinical applications.

1.1.5 Objective Five

Reduce the incidence of SIDS and other adverse pregnancy outcomes in high-risk minority populations.

SIDS is the leading cause of infant mortality among AIs and ANs, with a rate of 1.47/1,000 live births; almost three times that of Whites. Epidemiological evidence suggests an association between SIDS and excessive alcohol intake. Although many AI communities have lower alcohol consumption rates than the general U.S. population, consumption rates vary among AI populations, and AI women who do consume alcohol tend to be of childbearing age and to drink heavily and episodically. For example, in some Northern Plains communities, 60 percent of pregnant women use or abuse alcohol, with binge drinking being the most common pattern found. These same populations experience a sixfold increased risk for SIDS among women of childbearing age who binge drink. Excessive alcohol consumption is also a factor in developing Fetal Alcohol Syndrome (FAS); the prevalence of FAS in these populations is nine per 1,000, well above the North American FAS prevalence of two to three cases per 1,000 children.

1.1.5.1 Action Plan

- In November 2002, the NICHD and the National Institute on Alcohol Abuse and Alcoholism issued an RFA to support cooperative community-linked research to investigate the role of prenatal alcohol exposure in the risk of SIDS and other adverse pregnancy outcomes such as stillbirth and FAS.
- The NICHD began funding in 2003 and 2004 four planning projects, in response to this RFA, that target Northern Plains Indians and other high-risk populations.

1.1.5.2 Performance Measures

Performance will be measured by the successful recruitment and retention of American Indian women of childbearing age into the study and by the development of viable hypotheses concerning the effects of alcohol consumption on basic physiologic mechanisms that lead to the development of SIDS, FAS, and other adverse pregnancy outcomes.

1.1.5.3 Outcome Measures

Outcomes will be measured by research findings that clarify the role played by prenatal alcohol exposure in fetal death, stillbirth, SIDS, and FAS. Long-term outcomes will include new knowledge with significant applications to community-based prevention and treatment programs.

1.2 Area of Emphasis Two: Improving the Health of Minority Women

Many of the disparities in women’s health are related to a variety of lifestyle factors and may be amenable to primary and or secondary preventive measures. For example, physical activity has been shown to be protective against high blood pressure, heart disease, type 2 diabetes, and certain types of cancer. However, a higher percentage of African American, Hispanic, and AI/AN women report no leisure-time physical activity when compared with Whites. Similarly, obesity is more prevalent among African American and Hispanic women than in White women. Between 1988 and 1994, 69.6 percent of Mexican women were considered overweight, as were 68.5 percent of African American women. This compares with 47.2 percent of White non-Hispanic women who were overweight. Although tobacco use has declined since the late 1980s among African American and White females, younger Hispanic and Asian American women have increased their use of tobacco. In a survey between 1997 and1999, the age-adjusted percentage of women age 18 and older who reported smoking included 31.7 percent of AI/AN women, followed by 24.0 percent of White women, 21.5 percent of African American women, 13.1 percent of Hispanic/Latino women, and 10.3 percent of Asian/Pacific Islander women.

1.2.1 Objective One

Reduce health disparities among racial/ethnic minority and underserved women by supporting research to better understand the lifestyle factors that promote or compromise the health of these women and to develop targeted health- promoting, risk-reducing interventions.

1.2.1.1 Action Plan

- Stimulate and support research to: (1) enhance the body of knowledge of a variety of factors (e.g., sociodemographic, community, societal, personal, cultural) influencing the health-promoting and health-compromising behaviors of racial and ethnic minority women and their subpopulations age 21 and older; and (2) design intervention studies that show promise for improving the health profile of minority and underserved women.
- By April 30, 2005, issue a PA collaboratively with the National Institute of Nursing Research.
- By 2008, fund two to three scientifically meritorious research projects related to this PA.

1.2.1.2 Performance Measures

Performance will be measured by examining the number of meritorious research projects funded, within the payline, and the subsequent success in recruiting minority research subjects.

1.2.1.3 Outcome Measures

Outcomes will be measured by research findings that identify how to maximize healthy behaviors among minority women and thus reduce/eliminate health disparities. These findings could be disseminated to others through publications, conferences, or other means, and could result in significant translational and clinical applications.

1.2.2 Objective Two

Reduce the occurrence of uterine fibroids in women

Approximately 20 to 40 percent of reproductive age women have fibroids, or uterine leiomyomata, and they occur two to three times more frequently in African American than in Caucasian women. This disorder is a significant source of abnormal uterine bleeding, anemia, and pelvic pain, and often poses a serious reproductive threat. The tumors also may press on adjacent structures, leading to difficulty with normal bowel or bladder function and frequently requiring surgical interventions. In fact, uterine leiomyomata are the leading reason for women to undergo a hysterectomy in the United States.

1.2.2.1 Action Plan

- In November 2002, the NICHD, along with other NIH Institutes and Offices, issued an RFA to support projects that build on recent advances in our understanding of the molecular basis of uterine fibroids and further our understanding of genetic, hormonal, and other influences on the metabolic pathways leading to fibroid development.
- During 2003 and 2004, the Institute began co-funding 13 grants in response to this RFA. Preliminary findings should be available within 5 years of awarding the grants. The grants, although not targeting minorities specifically, could provide valuable information that leads to identifying genetic and/or metabolic variations that explain the disparity in the occurrence of this disorder.

1.2.2.2 Performance Measures

The NICHD will continue to monitor progress toward reaching the research goals stated in each of these studies.

1.2.2.3 Outcome Measures

Significant findings could be disseminated to others through publications, conferences, or other means, and could result in translational and clinical applications. The knowledge gleaned from this research should ultimately lead to new therapies for prevention, treatment, and cure of uterine fibroids.

1.3 Area of Emphasis Three: Improving the Health of Minority Children: Early Antecedents of Child Health and Adverse Behaviors

There is a disproportionate incidence of accidental and non-accidental injuries in many minority communities. This compromises the health and well-being of our nation’s most vulnerable children. On average, nearly 3 million children are reported as suspected victims of child abuse and neglect, and nearly 1,000 die from such maltreatment. A disproportionate number are minority youth. In addition, homicide has reached epidemic proportions for African American youth: homicide rates for teens aged 10 to14 are three to four times greater than for Whites; they are eight times greater for older African American adolescent males.

Furthermore, children’s cognitive, socio-emotional, and physical development is influenced by social, economic, cultural, and community-level factors, or the ecological context in which they grow up. At present, however, there is limited knowledge as to how these broader factors impact children's development. Research examining the link between child development and these factors is critical as it could influence public policy development, including policies regarding childcare, welfare reform, early childhood education, and social services. These policies in particular have a large impact on poor families and their children, and could affect the future success of these children.

1.3.1 Objective One

Reduce children's exposure to domestic violence.

1.3.1.1 Action Plan

- The NICHD, along with other NIH Institutes and federal agencies, issued a PA with set-aside, in April 2003 (which will remain open until 2006) to support research to enhance our understanding of the effects on children of exposure to domestic violence, community violence, and war/terrorism. Specifically, the goal is to better understand the definition, identification, epidemiology, prevention, etiology, effects, early intervention, and mechanisms of violence exposure.
- In FY2004, the NICHD funded its first five research projects under this PA, which examine various aspects of domestic and community violence and its effects on children and adolescents. Although none of these study hypotheses target specific minority groups, their research designs include plans to recruit targeted minority and economically disadvantaged families.

1.3.1.2 Performance Measures

Performance will be partially measured by the successful recruitment and retention of minority subjects into these studies. The NICHD also will monitor research protocols and the number of scientific papers published as a result of this effort.

1.3.1.3 Outcome Measures

Eventually, research findings with significant translational and clinical applications will be reported in professional journals, at conferences, and through other means that eventually can be used by appropriate organizations and care providers to develop public policies, clinical guidance, and prevention programs.

1.3.2 Objective Two

Expand the knowledge needed to develop effective interventions aimed at strengthening family support systems and developing a sense of connectedness in minority and economically disadvantaged families.

To accomplish this objective, researchers need to better understand how the relationships between poverty, single-parent families, and related factors affect childhood well-being for minority children.

1.3.2.1 Action Plan

- The NICHD will extend research supported under the "Science and Ecology of Early Development" (SEED) program, which is examining the complex interactions of poverty with other factors that influence developmental outcomes and resilience in children and families.
- A PA was issued in June 2004 to encourage new research proposals, and new projects will be funded by January 2005.
- Support meetings to encourage dialogue between grantees and trans-NIH program officers.
- Use the SEED project to:
  1. Link studies to the evaluation of government intervention programs
  2. Create an ongoing dialogue among researchers, policymakers, and program officials

1.3.2.2 Performance Measures

Performance will be measured by the number of new meritorious research projects funded, within the payline, that measure viable hypotheses on how poverty, single-parent families, and related factors affect childhood well-being for minority children, and by the success at recruiting and retaining at-risk minority research subjects in these studies.

1.3.2.3 Outcome Measures

Research findings with significant translational and clinical applications will be reported in professional journals, at conferences, and through other means that eventually can be used by appropriate organizations to develop policies and programs directed at children living in poverty.

1.4 Area of Emphasis Four: Reduce the Incidence of Childhood and Adolescent Obesity

Results from the 1999-2000 National Health and Nutrition Examination Survey (NHANES) show that American children are getting fatter at an alarming rate. Furthermore, overweight occurs disproportionately in African American, Hispanic, and Native American minorities, especially those in impoverished circumstances. For example, non-Hispanic Black and Mexican American adolescents were nearly twice as likely to be overweight as non-Hispanic White adolescents. Similarly, Mexican American children ages 6-11 were more likely to be overweight (24 percent) than non-Hispanic Black children (20 percent) and non-Hispanic White children (12 percent). This trend is particularly alarming because overweight children have the potential to grow up to become obese adults and to suffer the associated medical consequences. Overweight and obesity in adults are known risk factors for a number of serious diseases, such as heart disease, stroke, high blood pressure, type 2 diabetes, osteoarthritis, some forms of cancer, breathing problems, and sleep apnea. Alarmingly, some of these adult obesity-related disorders are starting to occur in adolescence and are being seen in ever-increasing numbers. In fact, the incidence of type 2 diabetes has increased tenfold in adolescents over the past 15 years.

1.4.1 Objective One

Establish the precursors of the metabolic syndrome in children.

Better understand the biochemical and molecular factors in overweight in children and adolescents that contribute to the combination of insulin resistance, hypertension, and dyslipidemia known as the metabolic syndrome. Once these metabolic interactions are understood, the ultimate goal is to identify new targets for treatment. Applications could be for research with hypotheses specifically targeting minorities and/or the etiologies of existing disparities. Studies without such targeted hypotheses or aims should still include high-risk children, which would include a significant number of high-risk minority children.

1.4.1.1 Action Plan

- An RFA was issued in November 2003 to solicit research projects to examine these factors in different racial and ethnic groups, as well as among children within the same racial and ethnic group, and at different points in development.
- The Institute anticipates funding meritorious grants around the beginning of FY2005.

1.4.1.2 Performance Measures

Performance will be measured by the number of meritorious research projects funded under this RFA, as well as by the success at recruiting appropriate research subjects.

1.4.1.3 Outcome Measures

Outcomes will be measured by research findings that identify biochemical and molecular factors in overweight in minority children and adolescents that contribute to the metabolic syndrome. These findings could be disseminated to others through publications, conferences, or other means, and could result in significant translational and clinical applications.

1.5 Area of Emphasis Five: Learning and Cognitive and Behavioral Development

Children’s cognitive and behavioral development, combined with their educational attainment, is extremely important to later success in life. Data from 1998 show that African American, Hispanic, and American Indian students in 4th, 8th, and 12th grades were nearly twice as likely to perform below basic levels in reading. Similar disparities exist in math and science. The below grade level performance in Hispanics contributes to their higher dropout rates. For instance, 28 percent of Hispanic 16- to 24-year-old students dropped out of school, more than double the rate for African Americans (14 percent) and three times that for non-Hispanic Whites (8 percent). Ongoing health disparity research supported by the NICHD will address differences in acquiring basic cognitive, social, and behavioral skills among minority children and how these skills affect school readiness and performance.

These attempts to conduct research on minority children can be limited by the availability of culturally and linguistically appropriate research tools, however. This is particularly important considering that approximately 18 percent of the U.S. population over the age of 5 years speaks a language other than English at home (nearly 47 million persons), and 4.2 million households have no member over the age of 14 who speaks English without difficulty (2000 Census). The unavailability of culturally and linguistically appropriate research tools not only hampers our understanding of the typical and atypical development of children from these diverse backgrounds, but also limits our ability to determine the effectiveness of programs targeted at these populations to prepare them for success within the English-dominated American culture. There is a clear need to understand how non-English speakers develop within an English-dominated society, as well as a need to understand development as assessed using tools appropriate to these children's native cultural heritage and linguistic background.

Furthermore, despite years of research, it is still difficult to assess the developmental competence of young children in areas important to understanding readiness for school and typical early childhood development, especially among diverse populations of children and for specific developmental outcomes. Much of the previous measurement work was done within the context of specific studies, and the measures arising from this work have limited application. Additionally, as the knowledge base increases concerning important early childhood outcomes, the lack of measures of such outcomes becomes more apparent. For example, recently the importance of early social competence has been demonstrated as a predictor of school adjustment and success; however, there are few large-scale strategies available to measure social competence. Valid and reliable assessments of children's functioning also are important, as they may lead to designing programs to prevent developmental delays or to enhance children's growth in these areas. Also, these measures are important when developing policies and for assessing outcomes for young children being served by federally funded programs.

In a final research area, despite the significant advances in our understanding of how to teach young children to read and the conditions under which the necessary skills are most effectively taught, very little is known about how best to teach reading and writing to adolescent students who have been unsuccessful at learning to read at an earlier age. Minority and language minority youth are among the largest groups having difficulty with literacy skills in middle and high school. Educators need to know the extent to which current evidence about early reading instruction holds true for older students who fail to acquire the basic foundational skills for literacy, and how to motivate middle and high school students who have experienced failure in literacy at a younger age. Research is needed to focus on the reading process in these students, the optimal methods for teaching literacy skills to this age group, and the interactions of other factors that can influence the process.

1.5.1 Objective One

Evaluate the effectiveness of early childhood programs, curricula, and interventions in promoting school readiness.

1.5.1.1 Action Plan

- In 2003, the NICHD, along with the other Department of Health and Human Services (HHS) agencies and the Department of Education (ED), issued an RFA to support studies of the effectiveness of early childhood programs in promoting school readiness for preschool children who are at risk of later school difficulties.
- In 2003-2004, the Institute co-funded nine projects under this RFA. These research projects are examining integrative programs that target early learning and developmental skills necessary for school success, such as language and communication; early literacy; early mathematics; early science; self-regulation of behavior, emotion, and attention; social competency; and motivation to learn. Also under evaluation are programs that address teacher, caregiver, or parent behaviors to promote children's development in these areas.

1.5.1.2 Performance Measures

The NICHD will continue to monitor progress toward reaching the research goals stated in each of these studies.

1.5.1.3 Outcome Measures

Significant research findings will be reported in professional journals, at conferences, and through other means that eventually can be used by appropriate organizations to develop public policies and programs directed at preschool children who are at risk of later school difficulties, such as low socioeconomic status and minority-language children.

1.5.2 Objective Two

Design linguistically and culturally appropriate outcome measures for children from diverse backgrounds.

1.5.2.1 Action Plan

- Work collaboratively with other Institutes, agencies, and departments with a strong interest in children’s educational attainment to support the two RFAs described below.
- In FY2005, issue two RFAs to develop new or to adapt existing outcome measures to assess the developmental competence of young children in areas that are important to understanding typical early childhood development and school readiness. Special emphasis will be placed on working

with diverse populations, including children with disabilities, as well as children with non-majority cultural backgrounds and/or children for whom English is not their first language. The two RFAs will focus on essentially the same objectives but one will use the Cooperative Research Project Grant (U01) funding mechanism, while the other will fund grants using the Small Business Technology Transfer (STTR) and Small Business Innovation Research (SBIR) mechanisms.

- By 2006, fund scientifically meritorious research grants through each mechanism.

1.5.2.2 Performance Measures

Performance will be measured by issuing the RFAs, and by funding five to 10 scientifically meritorious research grants through the STTR and SBIR mechanisms and five to eight grants under the U01 mechanism.

1.5.2.3 Outcome Measures

Outcomes will be measured by the development of valid and reliable assessment tools that can be used on a large-scale basis to measure: (1) childhood outcomes that are predictors of later school adjustment and success, and (2) developmental competence of young minority children from diverse backgrounds.

1.5.3 Objective Three:

Adolescent literacy: Identify methods to prevent and remedy reading and writing disabilities in adolescents.

As an important first step, scientists need to better understand the complex interactions between the acquisition of basic reading skills and student factors (such as motivation, peer interaction, and social-emotional development) on the continuing development of reading and writing abilities during the adolescent years.

1.5.3.1 Action Plan

- To accomplish this objective, the NICHD plans to establish the Adolescent Literacy Research Network. This multidisciplinary network will bring together researchers with expertise in qualitative and quantitative analysis, and with designing experimental/quasi-experimental protocols.
- An RFA was issued in December 2002 with the intent of funding meritorious single- or multi-site projects
- Award first grants by the end of FY2004.

1.5.3.2 Performance Measures

Performance will be measured by funding one or more meritorious grants under this RFA and by successful recruitment of minority adolescent subjects into the trial network.

1.5.3.3 Outcome Measures

Research findings will help identify the best approaches to use in addressing these literacy problems. Significant findings will be reported in professional journals, at conferences, and through other means that can be translated into important remedial reading programs for adolescents with low literacy skills.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Increase the Research Capacity at Institutions Serving Women and Minority and Other Underrepresented Populations

The NICHD provides the administrative and basic support for the Extramural Associates (EAs) Research and Development Award (EARDA) program. The Extramural Associates Program (EAP) mission is to develop a cadre of scientists who will contribute to biomedical and behavioral research that will advance the nation's understanding of health challenges that significantly impact diverse populations. The EAP accomplishes its mission primarily through the EARDA, which provides support for infrastructure development and research activities at institutions offering undergraduate, graduate, or health professional degrees, with a traditionally high enrollment of minority and other underrepresented populations. The program is administered within the Division of Special Populations of the NICHD.

This may include community colleges or 4-year colleges and universities and is meant to target institutions that generally are not research intensive. The expectation is that by training a key faculty member in the basics of developing and conducting biomedical or behavioral research, these institutions can enhance their ability to access research resources and their capacity to conduct research. As research capacity develops at these institutions, it should lead to increased participation in research activities among their faculty and students. The EARDA program is unique among NIH programs to enhance participation of minority and other underrepresented populations in research. Although various elements of the program have been in place for more than 25 years, the success of this approach has never been analyzed or systematically assessed. An evaluation of the EARDA program would help to ensure that the program is being implemented as planned and that the EAs and their participating institutions have achieved their goals for increasing research capacity. It would also help to identify key factors that pose barriers to or enhance program success, as well as measure to what extent success is related to institutional, individual, or program factors.

The EARDA program currently consists of two components: (1) Sponsored Research Infrastructure Program (SRIP), a 5-month program primarily designed to increase the research capacity of master's and professional degree-granting institutions (e.g., M.D., D.D.S., D.V.M., and Pharm.D.); and (2) the Faculty Research Enhancement Support Program (FRESP), a 10-week program designed specifically for institutions that award degrees no higher than the baccalaureate and have little or no research activity. Funding for these programs is provided to a faculty representative through the EARDA.

2.1.1 Objective One

Conduct an evaluation of the EARDA program to measure its success as a mechanism for increasing the research capacity at colleges and universities serving women and minority and other underrepresented populations, and for increasing the pool of qualified women and minority and other underrepresented biomedical and social science researchers.

This will help to: (1) enhance the NICHD's understanding of EARDA's progress toward increasing the representation of women and minorities in biomedical and behavioral science research; (2) identify ways to improve the operations and management of the EARDA program; (3) provide feedback to EAs regarding their efforts to improve and expand research activities in the biomedical and behavioral sciences; and (4) encourage broader NIH-wide support for EARDA.

2.1.1.1 Action Plan

- In FY2004, an independent contractor laid the groundwork for the evaluation by preparing institution coding forms to extract data from annual progress reports, other records, and grant documents.
- In the fall of 2004, case studies of selected programs will be conducted and all program participants, their institutions' administrators, and all eligible but non-participating schools will receive a survey to measure their progress and/or identify ways to enhance broader participation.
- Data collection and analysis should be completed by the end of FY2005.
- Other revisions to the program are already planned, based on initial feedback from program participants and observations by the EA program administrators. For example, plans are underway to alter the elements and sequence of the EA program and the time commitment of the two components of the EA residency training.

2.1.1.2 Performance Measures

The evaluation will measure increases in research capacity at the participating institutions by examining: (1) whether implementation plans prepared by the EAs were carried out; (2) progress identified in the annual progress reports submitted by their institutions; and (3) grant applications and continuation award proposals submitted by the EA and other faculty and students of the EA institutions.

2.1.1.3 Outcome Measures

The NICHD will use the study results to improve ongoing EA program management and operations and to provide feedback to the EAs regarding their progress. Further modifications to the EA program may be made based on the outcome of the evaluation.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: American Indian Outreach

Since the NICHD initiated a campaign to reduce the risks of SIDS in 1994, the rate of SIDS has declined by more than 50 percent. This sharp decline in SIDS rates has occurred in all segments of the population. However, the decline has been less dramatic among African American, AI, and AN infants. Today, African American, AI, and AN infants are more than twice as likely to die of SIDS as White infants.

The NICHD has initiated two programs to address this problem. The NICHD staff has been conducting listening sessions with AI and AN community and health leaders. These sessions are providing the background to develop programs and materials that will help reduce the risk of SIDS among AI and AN infants. The NICHD Director has participated in some of these listening sessions. Members of the AI and AN communities have conducted focus groups with parents, grandparents, and community leaders in Aberdeen, Billings, Portland, Minneapolis, and Anchorage to assess knowledge, attitudes, and beliefs concerning SIDS.

3.1.1 Objective One

Develop outreach materials for American Indian and Alaska Native communities.

The NICHD will develop program activities and materials that AI and AN health care providers can use to help reduce the risks of SIDS in their communities.

3.1.1.1 Action Plan

- In developing this objective, the NICHD held extensive consultations with tribal and community health leaders who provided guidance on the approach, materials, and design of an outreach program. These regional meetings were held in Minneapolis, Sioux Falls, and Portland.
- Based on recommendations from these leaders, focus groups were held to assess attitudes and beliefs concerning the risks of SIDS in AI and AN communities.
- Based on guidance provided by the focus groups, develop outreach materials by December 2004.

3.1.1.2 Performance Measures

Beginning in January 2005, the NICHD staff, in collaboration with tribal and community health leaders ,will hold training sessions in the Aberdeen, Billings, Portland, Minneapolis, and Anchorage areas on how to use the AI and AN SIDS risk reduction outreach kit. From these five regional training sessions, health educators can further disseminate the information and conduct additional SIDS risk reduction training and outreach sessions.

3.1.1.3 Outcome Measures

The long-range objective of this initiative is to provide information to AI and AN prospective and current parents and infant caregivers about ways to reduce the risks of SIDS. The NICHD will use existing tribal and state reporting systems as well as feedback from health leaders to measure the number of people who have been reached through this program.

3.2 Area of Emphasis Two: African American Outreach

3.2.1 Objective One

Develop a partnership to reduce the risk of SIDS in African American communities.

Since the NICHD developed the *African American Outreach Kit to Reduce the Risks of SIDS*, several African American organizations with large memberships have incorporated the use of this kit into their strategic plan. As a result, the members of these organizations have reached thousands of parents, grandparents, and caregivers with important risk reduction messages. The highly personal nature of this communication, in which neighbors, friends, and family members deliver SIDS risk reduction messages, increases the likelihood that these messages will be received positively and acted upon. The NICHD now hopes to increase the number of national and regional organizations whose members become involved in SIDS risk reduction training activities and thereby reduce the disparity in back sleeping between African American infants and White infants. Several AA organizations contributed to and helped shape this objective.

3.2.1.1 Action Plan

- The NICHD is currently holding meetings with federal agencies, state agencies, and private organizations that have strong ties to African American community organizations, particularly in the Southeastern U.S. and in the Delta region.
- Through mechanisms such as Interagency Agreements and contracts, the NICHD will work with these organizations to foster a network capable of delivering SIDS risk reduction training in a variety of settings. These mechanisms will be in place by Sept 30, 2004.

3.2.1.2 Performance Measures

To execute this action plan, the NICHD will enter into an interagency agreement with the Health Resources and Services Administration (HRSA) *Healthy Start* program. The *Healthy Start* program will conduct SIDS risk reduction training throughout the Delta region and in other Southeastern U.S. areas.

3.2.1.3 Outcome Measures

The immediate impact of this objective will be to increase awareness in communities around the Delta region concerning the importance of back sleeping for infants. The larger impact will be to: (1) increase the number of infants who are actually placed on their backs to sleep in these areas; and (2) help build and strengthen an infrastructure of health educators who can provide education not only on ways to reduce the risks of SIDS but to increase the likelihood of the infant surviving and thriving tomorrow.

The National Institute of Dental and Craniofacial Research

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

> ***"There are profound and consequential disparities in the oral health of our citizens. Indeed, what amounts to a "silent epidemic" of dental and oral diseases is affecting some population groups. This burden of disease restricts activities in school, work, and home, and often significantly diminishes the quality of life"***
>
> Oral Health in America: A Report of the Surgeon General

INTRODUCTION

It would be gratifying to report that advances in biomedical and behavioral research, culminating in such achievements as the sequencing of the human genome, have been translated into better oral and general health and well-being for *all* Americans. They have not. American Indians/Alaska Natives, Blacks, and Hispanics have poor oral health compared to non-Hispanic Whites. It is likely that the health of other population groups, such as Asians and Pacific Islanders, individuals with disabilities, older Americans, and rural populations is also compromised, but information for these groups is limited or missing altogether. Similarly lacking are good data on the health status of groups within racial or ethnic categories, such as Puerto Ricans and Central Americans, and the many populations classified as Asian. To address these gaps in knowledge and raise the level of oral and general health of all underserved populations, The National Institute of Dental and Craniofacial Research (NIDCR) has developed a plan to eliminate health disparities. The plan builds on the NIDCR's Strategic Plan, which articulates initiatives for research, research capacity, and health communication (http://www.nidcr.nih.gov/AboutNIDCR/StategicPlan/default.htm). By focusing our initiatives in these areas, we will be better able to concentrate our resources and enhance our partnerships toward eliminating oral health disparities.

In so doing we are affirming the NIDCR mission:

To improve oral, dental, and craniofacial health through research, research training, and the dissemination of health information.

And our vision:

We will advance the oral health of all people and support the most rigorous level of science to meet the challenges of a changing society and promote the well-being of the Nation.

Health Disparities Defined

Consistent with National Institutes of Health (NIH) guidelines, we define minority health research as basic, clinical, and behavioral research on minority health conditions, including research to prevent, diagnose, and treat them. Minorities are defined as American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, Blacks, and Hispanics. Health disparities populations include underrepresented racial/ethnic minorities, low socioeconomic status (low-SES) populations, and rural populations.

The Determinants of Health

There are at least four interdependent and interacting variables that are key determinants of health: the unique biology of an individual, behavioral lifestyles, the environment, and the organization of health care. Genetic factors and other unique biological characteristics can influence an individual's susceptibility to disease and response to treatment. Lifestyle choices, such as diet and the use or non-use of tobacco and alcohol, are among the behaviors that affect health status. The environment, especially the communities and neighborhoods where people live, can be characterized by such factors as the average levels of income and education attained. In addition, communities and neighborhoods may be more or less well served in terms of the availability, organization, and delivery of health care services. However, none of these factors singly or in combination can explain why some people are healthy and others are not. Accordingly, the NIDCR plan emphasizes that eliminating oral health disparities requires more than an understanding of the biology and lifestyle of an individual; we also must take into account the community and neighborhood where the individual lives, works, and plays, as well as the larger social, cultural, and political environment. This approach is consonant with the health objectives for the Nation and the plans for their implementation as stated in the Department of Health and Human Services' *Healthy People 2010*. The focus in that document is on the promotion of healthy individuals *in healthy communities*. The challenge before us is to engage in the needed research and research partnerships to abolish oral health disparities for disadvantaged groups, wherever they may be living, so that they can attain optimal levels of oral health and well-being.

Oral Diseases Affect Everyone

To put oral health disparities in context, it is important to realize that craniofacial, oral, and dental diseases and disorders are among the most common health problems affecting people at all stages of life. Indeed, dental diseases such as dental caries and periodontal diseases are endemic in the U.S.—as they are in all developed nations of the world. The scope of diseases and disorders affecting the mouth and surrounding tissues is broader than diseases of teeth and gums. It includes oral and pharyngeal cancers, birth defects, oral soft tissue lesions, chronic oral-facial pain conditions, and other diseases and disorders. Oral manifestations of systemic diseases—such as Sjögren's syndrome, diabetes, and human immunodeficiency (HIV) infection—and disease treatments—such as radiation and chemotherapy for cancer—add to the burden of oral illness. In addition, hundreds of drugs in common use have the side effect of dry mouth, depriving the oral tissues of the protection of saliva. This can be a problem for many older Americans.[3]

---

[3] *Approximately 30 percent of all medications prescribed in the United States are for persons over age 65, with an average of 8.1 medications per patient in a long-term care facility.*

NATIONAL **I**NSTITUTE OF **D**ENTAL AND **C**RANIOFACIAL **R**ESEARCH

Oral, dental, and craniofacial diseases can devastate general health and well-being, lead to extensive pain and suffering, and extract excessive financial and social costs on the individual and on society. Although there have been substantial gains in the oral health of the nation over the past generation, not all Americans have experienced the same degree of improvement. The burden of craniofacial, oral, and dental disease, particularly untreated disease, falls heaviest on lower SES groups, which include disproportionately large numbers of racial and ethnic minorities. Individuals in lower SES groups also have higher incidences of HIV infection and diabetes, diseases that increase the risk for serious oral viral, bacterial, and fungal infections.

Children in low-SES families are particularly vulnerable to oral health problems. Their nutrition may be poor, their oral hygiene inadequate, and their access to oral health care lacking. Thus, they are at greater risk for experiencing more extensive, severe, and painful forms of oral disease, such as early childhood caries (ECC), as well as for the complications of untreated disease. Table 1 summarizes various aspects related to the prevalence and burden of oral, dental, and craniofacial diseases and disorders.

Table 1. The Burden of Oral Diseases and Disorders

Oral diseases are progressive and cumulative and become more complex over time. They can affect our ability to eat, the foods we choose, how we look, and the way we communicate. These diseases can affect economic productivity and compromise our ability to work at home, at school, or on the job. Health disparities exist across population groups at all ages. Over one third of the U.S. population (100 million people) has no access to community water fluoridation. Over 131 million children and adults lack dental insurance, almost 2.5 times the number who lack medical insurance. The following are highlights of oral health data for children, adults, and the elderly.

Children

- Dental caries (tooth decay) is the single most common chronic childhood disease—5 times more common than asthma and 7 times more common than hay fever.
- More than 50 percent of 5- to 9-year-old children have at least one cavity or filling, and that proportion increases to 78 percent among 17-year-olds. Nevertheless, these figures represent improvements in the oral health of children compared to a generation ago.
- There are striking disparities in dental disease by income. Poor children suffer twice as much dental caries as their more affluent peers, and their disease is more likely to be untreated. These poor/non-poor differences continue into adolescence. One of four children in America is born into poverty, and children living below the poverty line have more severe and untreated decay.
- Birth defects such as cleft lip/palate and hereditary ectodermal dysplasias (where all or most teeth are missing or misshapen) cause lifetime problems that can be devastating to children and adults.
- Professional care is important for maintaining oral health, yet 25 percent of children have not seen a dentist before entering kindergarten.
- Medical insurance is a strong predictor of access to dental care. Uninsured children are 2.5 times less likely than insured children to receive dental care. Children from families without dental insurance are three times more likely to have dental needs than children with either public or private insurance. For each child without medical insurance, there are at least 2.6 children without dental insurance.
- The social impact of oral diseases in children is substantial. More than 51 million school hours are lost each year to dental-related illness. Poor children suffer nearly 12 times more restricted-activity days than children from higher-income families. Pain and suffering due to untreated diseases can lead to problems in eating, speaking, and attending to learning.

Adults

- Most adults show signs of periodontal or gingival diseases. Severe periodontal disease (measured as 6 millimeters of periodontal attachment loss) affects about 14 percent of adults aged 45 to 54.
- Chronic disabling diseases such as temporomandibular disorders, Sjögren's syndrome, diabetes, and osteoporosis affect millions of Americans and compromise oral health and functioning.
- Pain is a common symptom of craniofacial disorders and is accompanied by interference with vital functions such as eating, swallowing, and speech. Pain is a major component of trigeminal neuralgia, facial shingles (post-herpetic neuralgia), temporomandibular disorders, fibromyalgia, and Bell's palsy.
- Immunocompromised patients, such as those with HIV infection and those undergoing organ transplantation, are at higher risk for oral problems such as candidiasis.
- For every adult 19 years or older without medical insurance, there are three without dental insurance.
- A little less than two thirds of adults report having visited a dentist in the past 12 months. Those with incomes at or above the poverty level are twice as likely to report a dental visit in the past 12 months as those below the poverty level.

Older Adults

- Twenty-three percent of 65- to 74-year-olds have severe periodontal disease. At all ages, men are more likely than women to have more severe disease; and people at the lowest socioeconomic levels have more severe periodontal disease.
- About 30 percent of adults 65 years and older are edentulous, compared to 46 percent 20 years ago. These figures are higher for those living in poverty.
- Oral and pharyngeal cancer is diagnosed in about 30,000 Americans annually, and 8,000 die from it each year. These cancers are primarily diagnosed in the elderly. The 5-year survival rate for White patients is 56 percent; for Blacks, it is only 34 percent.
- Most older Americans take both prescription and over-the-counter drugs. About 400 of these drugs have an oral side effect—usually dry mouth. Dry mouth increases the risk for oral disease because saliva contains antimicrobial components as well as minerals that protect against tooth decay.
- At any given time, 5 percent of Americans ages 65 and older (currently some 1.65 million people) are living in a long-term care facility where dental care is problematic.
- Many elderly individuals lose their dental insurance when they retire. The situation may be worse for older women, who generally have lower incomes and may never have had dental insurance. Medicaid funds dental care for the low-income and disabled elderly in some states, but reimbursements are low. Medicare is not designed to reimburse for routine dental care.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

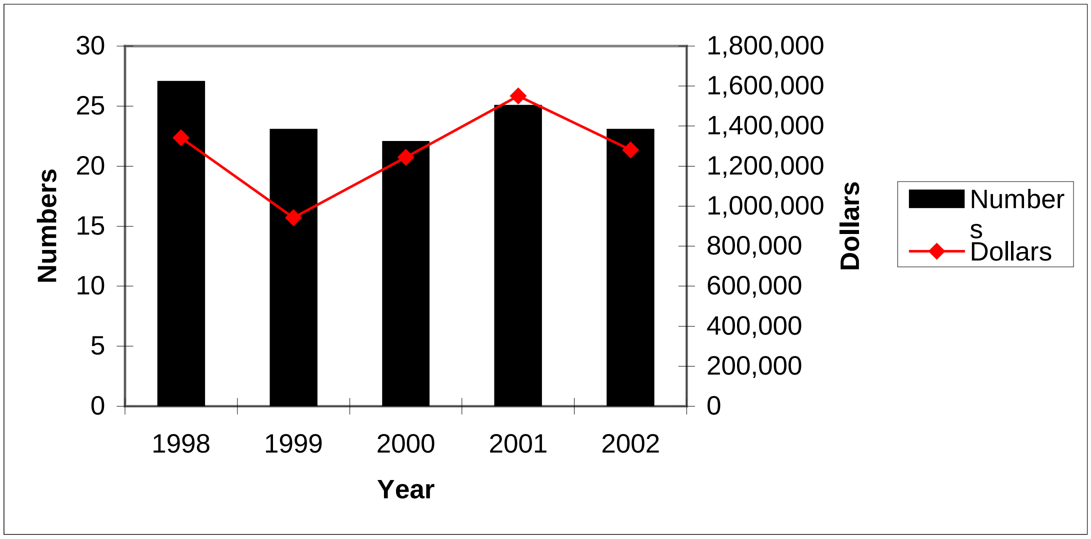
NIDCR History of Health Disparities Activities

NIDCR has long been a leader in programs aimed at reducing health disparities in minority populations. These activities have resulted in increased support of biomedical and behavioral oral health research relevant to the health of minorities and to innovative programs to increase minority representation in research.

Research. In the 1990s the Institute supported four Regional Research Centers on Minority Oral Health. The primary focus of these centers was research on oral health problems prevalent among underrepresented minority populations, with an eye to establishing an evidence base for the development of prevention and treatment regimens. The centers served not only as sites of research, but also as research training centers for minority investigators. Each center represented a partnership between a minority dental school or an academic institution serving a large minority population and an institution with proven expertise in the design and conduct of oral health research.

Research training. More than 15 years ago, the Institute issued a Program Announcement (PA) to create a program to stimulate the entry of underrepresented minorities into research careers. This program is now entitled “NIH Predoctoral Fellowship Awards to Promote Diversity in Health-Related Research (F31).” This competitive diversity supplement program was subsequently adopted on an NIH-wide basis and continues to encourage involvement of underrepresented minorities and others in research at all stages of career development, from high school students through faculty members. NIDCR has consistently been among the top three Institutes at NIH in the proportion of extramural research funds devoted to these supplement programs. From 1998 to 2002, NIDCR funded approximately 73 individuals at the predoctoral, postdoctoral, and investigator levels. NIDCR’s total funding for diversity supplements from 1998 to 2002 was $6,360,166, providing support for 120 positions. The distribution of diversity supplement research trainees is shown in Figure 1.

Figure 1 - Trends in NIDCR-Supported Diversity Supplements, Fiscal Years 1998-2002



Collaborative Activities. The Institute's concern with oral health disparities is reflected in a number of ongoing activities conducted in collaboration with other agencies. NIDCR staff co-lead the oral health and related objectives in *Healthy People 2010*, working with colleagues in the Centers for Disease Control and Prevention (CDC), the Indian Health Service, and the Health Resources and Services Administration (HRSA). Oral, dental, and craniofacial health has been part of the nation's Healthy People research agenda since the late 1970s. Focused upon providing strategies to increase quality and years of healthy life and eliminate health disparities, the Healthy People objectives provide a framework that facilitates coordination among the research, service, education, and policymaking communities.

The Institute was the lead agency in the development of the Surgeon General's Report on Oral Health, *Oral Health in America*. The report emphasizes that oral health is essential to general health and well-being and identified an extensive research agenda. Building on the Surgeon General's Report on Oral Health and *Healthy People 2010*, a *National Call to Action* was released in 2003 by the Department of Health and Human Services to serve as a model to improve the nation's oral health. The *National Call to Action* identifies five action areas, all of which are directly relevant to the goals of the NIDCR Health Disparities Strategic Plan.[4] In addition, the NIDCR is collaborating with the Indian Health Service through a Memorandum of Understanding to enhance research

---

[4] *The Action Areas are: (1) change perceptions of oral health care; (2) overcome barriers to care by replicating effective programs and proven efforts; (3) build the science-base and accelerate science transfer; (4) increase oral health workforce diversity, capability, and flexibility; and (5) increase collaboration.*

capacity, increase research related to the needs of Native Americans/Alaska Natives and foster partnerships to enhance research, research training, and information dissemination.

"Racial differences in health importantly reflect the impact of the social environment and the cumulation of adversity across multiple domains. Efforts to improve the health of racial minority group members and reduce racial disparities in health may have to be equally comprehensive in the implementation of strategies that address the fundamental underlying causes of these disparities."

David R. Williams

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIDCR health disparities plan recognizes that eliminating oral health disparities requires a comprehensive and systematic approach to understand and address the multiple and complex factors that determine oral health. Consequently, the NIDCR Strategic Plan to Eliminate Health Disparities has adopted a multi-faceted approach to addressing oral health disparities. The plan emphasizes three key focus areas—research, research capacity, and information dissemination. Successful implementation of these focus areas will enable us to conduct research to better understand and address oral health disparities; to build a more diverse workforce; and to expedite the transfer of research advances and their adoption by health care providers and by the public. The plan builds on the investments NIDCR has made since the early 1990s to enhance research opportunities for underrepresented minorities, and on more than 50 years of research to understand, treat, and prevent oral diseases. Recognizing the complexity and wealth of factors that may contribute to disparities in oral health, and the considerable diversity between and within the affected communities, the NIDCR strategy to eliminate health disparities is viewed as an incremental long-term approach that involves collaborations with many organizations and institutions: researchers, educators, clinicians, academic institutions, community-based organizations, patient advocates, and professional and voluntary groups.

Addressing Public Comments to the NIH Health Disparities Plan

Several of the major themes that emerged from the public comments to the initial NIH Health Disparities Plan are addressed by this updated NIDCR Health Disparities Strategic Plan.

Theme: "Ensuring that all communications with health disparities populations and their subgroups address their needs and perspectives." The NIDCR has ongoing audience research activities to better understand the oral health information needs, views, and preferences of health disparities populations. Examples of these include focus groups with African American men regarding the topic of oral cancer, and focus groups with Hispanics to explore their education needs about ECC and about general oral health topics.

Theme: "Expand the scope of scientific inquiry…increase scope of research to include cultural, psychological, behavioral, social, racial, gender-based influences on health." The NIDCR Health Disparities Plan places clear emphasis on the need to understand and address oral health disparities in the context of the sociocultural characteristics of the community and taking into account race/ethnicity, behavioral, and biological factors. This emphasis is explicit in the sections entitled "Determinants of Health" and "Strategy for Addressing Health Disparities" and in the various initiatives undertaken to address health disparities such as PAs and Requests for Applications (RFAs). For example, the NIDCR's Centers on Research to Reduce Oral Health Disparities are addressing disparities within the context of the social, cultural, behavioral, biological, and race-based influences on oral health.

Theme: "Improve research infrastructure at diverse dental institutions." NIDCR has initiated a new dental school program to enhance infrastructure in U.S. dental schools, including minority dental school research with a focus on health disparities. These are further described in Section 2.1.1.1.

Theme: "Distribute NIH resources equitably across all population groups." NIDCR has underway a number of efforts to expand the disparities populations that are included in its research portfolio. For example, the Institute issues a PA to encourage research on special needs populations, including those with developmental or acquired physical or mental disabilities, people with mental retardation, people living with HIV/Acquired Immunodeficiency Syndrome (AIDS), and frail or functionally dependent elders. In addition, the Institute is supporting pilot grants for research to prevent or reduce oral health disparities in populations that were not well represented in its health disparities portfolio.

1.0 AREAS OF EMPHASIS IN RESEARCH

This area emphasizes the need to address the full scope of research, with special focus on vulnerable populations. Eliminating oral health disparities will require: basic biomedical and behavioral science research on disease epidemiology, etiology, pathogenesis, and risk factors; translational research to move basic studies into animal and other experimental models; and clinical research on preventive, diagnostic, and treatment modalities and health promotion.

Several overarching research needs are important to the success of this area of emphasis. These research needs include:

- Research to identify biomarkers of disease, which will facilitate early detection and diagnosis of disease and surrogate markers for use in clinical trials involving populations exhibiting oral health disparities.
- Population genetics, molecular epidemiology, and quantitative genetics research to identify genetic variations that underlie complex disease traits in vulnerable populations.

- Epidemiological studies of population subgroups to establish baselines for the incidence and prevalence of specific oral health problems with follow-up to track progress in reducing or eliminating identified health disparities.
- Clinical studies and trials to provide a valid and reliable evidence base for effective prevention and management of oral health disparities. This research can range from single-center clinical trials to multi-center office-based trials to community-based demonstration and education projects.
- Patient-oriented research to understand the bases of health disparities. These studies will explore health care utilization patterns in various ethnic and cultural groups; study the underpinnings of health care-seeking behavior; and investigate the interaction between culture/ethnicity and health care outcomes. A major aim of this research will be to develop evidence-based outreach approaches to educate providers in the diagnosis, treatment, and prevention of oral, dental, and craniofacial diseases and increase adoption of research findings into practice.

1.1 Area of Emphasis One: Eliminate Health Disparities in Oral Infections

The two most prevalent oral diseases are bacterial infections: dental caries, associated with infection by bacteria that produce acids that attack the hard tissues of the teeth, and periodontal diseases, which are infections associated with a number of bacterial species whose byproducts can destroy the soft tissues and bone that support the teeth. Dental caries and periodontal diseases are biofilm-mediated diseases: they occur as a result of the bacteria that colonize the mouth in a complex community that adheres to the tooth surface in a biofilm commonly called dental plaque.

1.1.1 Objective One: Eliminate Health Disparities in Dental Caries

Dental caries is a late manifestation of a progressive disease process—left untreated it results in the destruction of the tooth, eventually causing pain, acute infection, and costly treatment. Despite considerable progress in the prevention and treatment of dental caries, it is a widespread problem, especially among the most vulnerable groups: low-income children and adults, certain racial and minority groups, and the elderly. Although dental caries is a disease that can be prevented and treated, it also represents a disease with health and behavioral sequelae that extend well beyond the mouth. For example, American Indian youngsters with extensive caries avoid smiling because they view themselves as unattractive and may become isolated from their peers because of the appearance of their decayed teeth. A severe and painful form of dental caries seen in infants and toddlers, ECC, has been associated with diminished growth in toddlers and compromised nutrition. Research supported by the NIDCR health disparities initiative will address the treatment and prevention of dental caries, not only as a way of reducing the incidence and prevalence of the disease within socioeconomically and ethnically/racially distinct groups, but also to improve quality of life and prevent complications.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

The Disparities

- Americas' youngest low-income children have almost five times as much dental caries as children of higher income families.
- Nearly twice as many 2- to 9-year-old low-SES children[5] have at least three decayed or filled primary teeth compared to higher SES children.
- For low-income children age 2 to 5 years with caries, almost 80 percent of it remains untreated.
- The rate of untreated dental caries is twice as high among low-SES children than for those at higher income levels at ages ranging through adolescence. In adults, the proportion of untreated dental caries is higher among the poor than the non-poor.
- Alaska Native/American Indian preschoolers have four times as much decay as children in the general population. The rate of early childhood caries among American Indian children is 10 times that of the U.S. population.
- In adults, the proportion of untreated dental caries is higher among the poor than the non-poor and higher among non-Hispanic Blacks and Mexican Americans compared to non-Hispanic Whites.
- Mexican Americans and non-Hispanic Black adults ages 25-74 years are more likely to have complete tooth loss.

1.1.1.1 Action Plan

- Establish Centers for Research to Reduce Oral Health Disparities. In FY2001, NIDCR collaborated with the Center on Minority Research and Health Disparities, the Office of Behavioral and Social Sciences Research, and the Indian Health Service to fund five research centers to support research to understand underlying factors involved in oral health disparities, design interventions to reduce such disparities, and develop and strengthen research capacity. The five centers are located across the country: in Boston, New York City, Detroit, San Francisco, and Seattle. The Centers' approaches to addressing oral health disparities are varied, but they predominantly focus on caries-related research. Examples of the Centers' research activities include studies that are designed to:

    - Develop survey instruments to measure oral health-related quality of life in Hispanic and African American children and adolescents;
    - Explore the relationship between severe ECC and children's growth and development;
    - Identify differences in oral microbial pathogens among children with and without caries, as well as variations among different racial groups of children with caries;
    - Conduct a randomized clinical trial to assess the impact of a combined intervention (chlorhexidine and fluoride varnish) to prevent ECC among infants in a Hispanic community;
    - Determine the social characteristics of parents, families, and neighborhoods that are associated with disparities in oral health;

---

[5] *Age 2-5 and living below the poverty level compared to children of families living at >300% poverty.*

  - Explore the relationships among caries, dietary factors, and lead levels;
  - Assess the impact on access to dental care of a change in the payment system for the state Medicaid program;
  - Conduct a randomized clinical trial to assess whether using chlorhexidine and xylitol by Alaska Native mothers will reduce the incidence of ECC in their infants;
  - Test a web-based computer intervention to reduce dental fear;
  - Develop an information resource for dentists on cultural issues; and
  - Conduct a basic research project on the role that beta defensins play in dental caries development.

Timeline: Funding period: FY2001-FY2007; Expected completion date: FY2007

- Support planning grants for research to prevent or reduce oral health disparities. The Institute is supporting planning grants (R21s) to develop the research collaborations, plans, and infrastructure necessary to conduct scientifically meritorious research on determinants of oral health disparities and prevention or reduction of oral health disparities. This research will concentrate on selected populations currently underrepresented in NIDCR's grant portfolio, such as low-income rural populations and special needs populations (including those with neurodevelopmental disorders). Some of the research also is focused on race/ethnic study populations underrepresented in the NIDCR research portfolio, such as Hispanics (Central American, Cuban American, Puerto Rican, and others), American Indians or Alaska Natives, and Asians or Pacific Islanders.

Timeline: FY2002-2004

- Fund pilot grants for research to prevent or reduce oral health disparities. In collaboration with the National Center for Minority Health and Health Disparities and the National Institute for Nursing Research, NIDCR is supporting pilot research projects that focus on the determinants, prevention/reduction, or impacts of oral health disparities in populations currently underrepresented in NIDCR's grant portfolio. These projects examine the determinants of caries among low-SES rural dwelling children enrolled in the Women, Infants, and Children program; assess professional curricular issues of oral health professionals regarding their preparedness for serving vulnerable populations; and determine psychosocial, structural, and cultural factors that affect parental help-seeking behavior.

Timeline: FY2003-2006

- Support research on special needs and older populations**.** In FY2004, NIDCR, along with the National Institute on Aging, issued a PA to encourage investigator-initiated clinical research focused on the oral health of special needs populations, including those with developmental or acquired physical or mental disabilities, people with mental retardation, people living with HIV/AIDS, and frail or functionally dependent elders. The types of clinical research to be supported under this program are epidemiologic, behavioral/social sciences, health care, patient-oriented, and community-based studies aimed at understanding and improving the oral, dental, and craniofacial health status, quality of life, and health outcomes among elders and other special needs populations.

Timeline: FY2004-2007

- Encourage epidemiological and behavioral research in oral health. NIDCR will stimulate epidemiological and behavioral research to improve oral health or increase the understanding of the determinants of oral health through a PA. Such research projects will contribute to the Institute's clinical research programs by providing a clearer understanding of behavioral and environmental factors influencing oral health, oral health care, and the prevention, diagnosis, and treatment of specific oral diseases/conditions.

Timeline: FY2004-2007

- Continue support and expand existing efforts to sequence the genomes of caries microbial pathogens that may provide important information to design effective therapeutics to prevent caries in populations at high risk. Genome sequences of several pathogens implicated in the development of dental caries have already been completed or are underway including: *Streptococcus mutans*, *Streptococcus sanguis*, and *Actinomyces naeslundii* (an organism that may be associated with root surface caries).

Timeline: ongoing

- Continue support for research to identify new agents that can disrupt the microbial biofilm in order to design preventives or therapeutics that can safely and effectively reduce disparities involving biofilm as a destructive agent. Support research that examines the immunological and genetic factors that make people more or less at risk for developing dental caries.

Timeline: ongoing

1.1.1.2 Performance Measures

The NIDCR is carrying out a formal, prospective evaluation of the Institute's health disparities portfolio. Phase 1 of the evaluation, which involved collecting baseline data, has been completed. Phase 2 is scheduled for completion in 2007. Additional information regarding this evaluation is included in the section entitled "Implementation and Evaluation of the NIDCR Health Disparities Plan." Key performance measures include:

- *Grants*. An assessment of the trends in grant applications and funding rates and levels for oral health disparities research will be carried out. This will include reviewing the characteristics of applications and grants funded through the RFAs outlined in Section 1.1.1.1, as well as investigator-initiated research dealing with oral health disparities.

- *Collaborations*. We will measure the formation of new research collaborations in the area of oral health disparities, the extent of multidisciplinary projects in the portfolio, and the type of organizations that participate in these collaborations.
- *Investigators.* We will review the recruitment of new and experienced investigators to the field of oral health disparities.
- *Community relationships.* Through case studies of the Centers for Research to Reduce Oral Health Disparities, we will determine the extent to which the centers have developed partnerships within their communities that have benefited research, policy, and oral health outcomes.

1.1.1.3 Outcome Measures

- *Publications.* We will review publications in the area of oral health disparities in general and compare their content to those resulting from NIDCR-funded projects.
- *Research quality.* We will analyze indicators of research quality, including citations, journal quality, clinical trial standards, and type of sampling used.
- *Interventions and other science advances.* We will assess science advances and new interventions resulting from the research. We also plan to investigate any effects on the use of existing interventions, if applicable.

1.1.2 Objective Two: Eliminate Health Disparities in Periodontal Diseases

Most adults show signs of periodontal or gingival diseases. About 14 percent of adults ages 45-54 years and 23 percent of 65- to 74-year-olds have severe periodontal disease that puts them at risk for losing their teeth. Smoking is the number one risk factor for developing periodontal disease. Therefore, efforts to reduce smoking will have a direct benefit toward reducing the incidence of periodontitis as well as other diseases. The host immune response also plays a large role in the level of protection or destruction in the oral tissues. Periodontal disease prevalence and severity vary by income, race/ethnicity, and education. Total tooth loss (edentulism) varies considerably according to income, race/ethnicity, and across states in the United States. Edentulism may be the end stage of dental caries and periodontal disease as well as injury. Tooth loss and edentulism can have physical, emotional, and economic consequences that include poor nutrition, speech problems, and negative self-image that may affect one’s ability to gain employment.

There also are other emerging consequences of periodontal diseases that warrant increased investigation. A number of studies indicate that mothers of low birth weight infants born as a result of preterm labor or premature rupture of membranes tend to have more severe periodontal disease than mothers with normal birth weight infants. Researchers have shown up to a sevenfold increase in risk of low birth weight associated with severe periodontal diseases even when controlling for other known risk factors such as smoking, race, alcohol use, age, nutrition, and genito-urinary infections. In addition, recent studies show an association between periodontitis and other systemic diseases, such as atherosclerosis, stroke, respiratory diseases, and diabetes, that warrant further research. The disparity in incidence and severity of periodontal diseases in lower SES and some racial/ethnic minorities puts individuals in these groups at greater risk for tooth loss, and perhaps for serious systemic consequences.

The Disparities

- At all ages people at the lowest SES levels have more severe periodontal disease. That translates to 36 percent of adults in the lower SES group 75 years old and over. At every age, the proportion of low-income individuals with severe disease is at least three times that for individuals in the highest income groups.
- Mexican American, American Indian, and Black adults are more likely to have complete tooth loss. This trend is true for each age group: 25-44, 45-64, and 65-74 years.
- Lower educational attainment is linked with edentulism.
- A higher percentage of non-Hispanic Black individuals at each age group exhibits at least one tooth site with severe periodontal attachment loss compared to other groups.
- Alaska Native/American Indian adults have three times higher rates of severe periodontal disease compared to the U.S. population.
- A form of severe and rapidly progressive generalized periodontitis can occur in adolescents and adults under 35 years. The prevalence of this early-onset periodontitis in 13- to 17-year-olds occurs twice as often in African Americans than in Hispanics and 10 times more frequently than in Whites.

1.1.2.1 Action Plan

In addition to the pilot grants for research to prevent or reduce oral health disparities, research on special needs and older populations, and epidemiological and behavioral research in oral health mentioned in Section 1.1.1.1, in pursuit of this objective NIDCR plans to expand existing studies and encourage new investigations on the diagnosis, prevention, and management of periodontal diseases and their complications as they relate to reducing and eliminating health disparities. What follows is a representative list of research investigations planned or to be expanded.

- Studies to address early-onset periodontitis, which is especially prevalent among African American adolescents. An NIDCR-supported study is assessing the role of FMLP receptors in early-onset periodontitis, to understand why certain populations appear to have increased susceptibility to periodontal infections.
- Microbial genomics of pathogenic organisms: Genome sequences for several periodontal microbial pathogens are now available. These include *Porphyromonas ginvivalis* and *Treponema denticola*. An analysis of these microbial genomes will provide new clues for the design of non-antibiotic therapeutics that can be more effectively used in the prevention of these diseases in populations at high risk.

- Intervention trials to determine whether treatment for periodontal disease during pregnancy results in a reduction of preterm low birth weight infants.
- Research on microbial biofilm (plaque) that forms on teeth and oral surfaces. A challenge will be to delineate the signaling networks that underlie microbial communication within dental plaque and the communication between the host and the oral flora and to determine whether these factors can account for differences in risk factors for various groups of individuals.
- Research to identify new agents that can disrupt the microbial biofilm to design preventives and therapeutics that can safely and effectively reduce disparities involving biofilm as a destructive agent.

1.1.2.2 Performance Measures

The evaluation of the overall health disparities portfolio will assess all areas of oral health disparities research; therefore, the measures outlined in Section 1.1.1.2 are applicable to this objective as well.

1.1.2.3 Outcome Measures

The evaluation of the overall oral health disparities portfolio will assess all areas of oral health disparities; therefore, the measures outlined in Section 1.1.1.3 are applicable to this objective. In the area of periodontal diseases, an emphasis will be placed on assessing the number of high-quality publications that promote the development of new interventions to address these disparities.

1.2 Area of Emphasis Two: Oral and Pharyngeal Cancer

Oral and pharyngeal cancers are among the most debilitating and disfiguring of all malignancies. Worse, the currently available therapies (surgery, radiation, and chemotherapy) often exacerbate disfigurement and loss of function (e.g., speech, taste, swallowing, and vision). As with all cancers, there are health disparities by gender, race, and other factors. For oral cancer, differences by race are reflected in substantially higher mortality rates for African Americans and in higher incidence rates for African Americans compared with Whites. These differences may reflect host susceptibility factors as well as those related to health care utilization patterns. The two major risk factors for oral and pharyngeal cancers are use of tobacco and alcohol, which when used together work synergistically to compound the risk. Research to elucidate a genetic basis for tobacco- and alcohol-induced cancers is growing. There are a number of enzymes that detoxify alcohol or carcinogenic components present in tobacco. Alterations in the genes coding for these enzymes, as well as combinations of inherited genetic polymorphisms, may render an individual who smokes and/or drinks alcohol more or less susceptible to the carcinogenic effects of tobacco or alcohol. Such polymorphisms may provide clues to differences in risk noted for some population groups. For example, a strong association was found between oral cancer in African Americans who were heavy smokers but who lacked a specific tobacco carcinogen-detoxifying enzyme. However, no significant associations between such enzyme genotypes and oral cancer risk were observed in Caucasians. In addition, gene polymorphisms may affect the progression of disease and susceptibility to second primary cancers.

The Disparities

- The incidence rate of oral and pharyngeal cancers in males is about two and a half times higher than in females (16.1 per 100,000 compared to 6.5 per 100,000).
- The average age of diagnosis for African Americans is about 10 years younger than that for Whites.
- African Americans tend to have a higher proportion of pharyngeal versus oral cavity cancers than Whites. Pharyngeal cancers are more difficult to diagnose.
- Newly diagnosed Black males are half as likely to be diagnosed with oral and pharyngeal cancer at the local stage (19 percent) as are their White male counterparts (38 percent). Unfortunately, the 5-year survival rate for those diagnosed at advanced stages (22 percent) is little more than one fourth the survival rate for those diagnosed at early stages (81 percent).
- Between 1997 and 2001, the mortality rate for oral and pharyngeal cancers was 1.65 times higher for Blacks (4.3 per 100,000) than for Whites (2.6 per 100,000), and twice as high for Black males (7.5 per 100,000) than for White males (3.9 per 100,000).
- Adults with less than 12 years of education (8.8 percent) were 2.5 times less likely than those with 13 or more years of schooling (21.8 percent) to ever have had an oral cancer examination; also Blacks (10.3 percent) were 1.5 times less likely to have had an oral cancer examination than Whites (15.5 percent).

1.2.1 Objective One: Eliminate Health Disparities in Oral and Pharyngeal Cancers

To address the health disparities related to oral and pharyngeal cancers, NIDCR plans to expand ongoing studies in basic and clinical research to help identify some of the underlying reasons for disparities in cancer incidence, diagnosis, and survival. In addition, NIDCR has funded targeted community and state-based efforts aimed at risk factor reduction and/or enhanced early detection in groups exhibiting disparities in oral cancer. It is expected that within each area of research, the major focus will be to generate new knowledge that will lead to an understanding of the basis for health disparities, their prevention, and/or their reduction/elimination. Examples of current efforts in this area are:

- Research to examine the role of certain enzymes as mechanisms for differential susceptibility to oral cancer across population groups;
- Research aimed at elucidating the genetic basis for oral and pharyngeal cancers and their relationship to environmental factors;
- Studies to identify biomarkers for oral cancer in blood, saliva, or oral fluids as a means of easy and early detection of oral cancer in groups at high risk or with limited access to care;
- A systematic comparison of current and emerging technologies for the diagnosis of oral cancer in populations at high risk;

- A research project designed to refine an existing intervention directed at cessation of smokeless tobacco use specifically for use with a rural Appalachian population; and
- State-based programs of epidemiological and intervention research aimed at oral cancer prevention.

1.2.1.1 Action Plan

- Support research on genomic/proteomic approaches to understand head and neck cancer. NIDCR is supporting research to foster basic and translational research aimed at deciphering the molecular networks involved in the development of squamous cell carcinomas of the head and neck. This collaboration with the National Institute on Drug Abuse is intended to advance our understanding of the repertoire of proteins expressed and their activities with the functional status of both normal and aberrant cells and lead to the development of novel biomarkers for early detection of pre-neoplastic and neoplastic lesions that also might serve as candidate targets for therapy.

Timeline: FY2004-2009

- Fund Phase II of the State Models for Oral Cancer Prevention and Early Detection. The NIDCR will fund research grants for the design, implementation, and evaluation of interventions for oral cancer prevention and early detection. The interventions must be based on a state needs assessment for these cancers among the public and providers. Many of the projects supported in Phase I of this initiative focused on health disparity populations, and some developed interventions tailored to these groups. The goals of these interventions are to raise awareness about oral cancer risk factors and prevention and to promote the early detection of oral malignancies.

Timeline: FY2004-2009

- Support translational research in dental practice-based tobacco control interventions. The NIDCR and the National Institute on Drug Abuse will partner to stimulate innovative research on dental practice-based tobacco control interventions, as well as studies that use dentistry as a model to clarify processes underlying or influencing the translation of research findings into clinical practice. Tobacco control provides an important, public health-relevant venue for studying the translation of basic and clinical research findings into clinical practice. Clear, science-based clinical guidelines for implementing tobacco prevention and tobacco cessation are available. Also, numerous studies have documented harmful impacts of tobacco use on oral diseases and dental treatment outcomes. As yet, however, evidence suggests that the preponderance of U.S. dental clinicians are not utilizing optimal science-based approaches to prevent or reduce the use of oral health-harming smoked or smokeless tobacco products. This research will stimulate research to: (1) develop and test interventions that translate findings from alcohol, tobacco, and other drug prevention and treatment research into effective, dental practice-based tobacco control strategies; (2) translate findings from other theoretically grounded basic or behavioral science research into effective dental practice-based tobacco control strategies; or (3) clarify processes that underlie or influence the translation of tobacco-related knowledge into clinical dental practice.

Timeline: FY2004-2009

1.2.1.2 Performance Measures

The evaluation of the overall health disparities portfolio will assess all areas of oral health disparities research; therefore, the measures outlined in Section 1.1.1.2 are applicable to this objective as well. In the area of oral and pharyngeal cancers, an emphasis will be placed on measuring whether new interventions for early detection and prevention are developed.

1.2.1.3 Outcome Measures

The evaluation of the overall health disparities portfolio will assess all areas of oral health disparities research; therefore, the measures outlined in Section 1.1.1.2 are applicable to this objective as well. In the area of oral and pharyngeal cancers, an emphasis will be placed on measuring research quality, especially for studies focused on prevention and genetic factors. The evaluation also will consider the extent to which new and experienced investigators are attracted to oral cancer research, and the formation of new research collaborations across disciplines and disease areas.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Oral Health Research Infrastructure

In 2003, NIDCR's Research Workforce activities (Research Training and Career Development Programs and Recruitment/Retention and Outreach Programs) and Research Infrastructure in Dental Schools activities (Research Infrastructure Programs and Curriculum Development Programs) were collectively placed within the Office of the Director, NIDCR, to increase visibility for and to centralize these critical activities. The aims of these Research Infrastructure activities are to collaborate with dental institutions in planning, establishing, evaluating, and sustaining their research infrastructure; and to facilitate the development, implementation, and evaluation of research curricula in dental schools.

2.1.1 Objective One: Enhance Oral Health Research Capacity

NIDCR created a new Dental School Research Infrastructure Program to support the enhancement of research infrastructure in U.S. dental schools, including minority dental school research infrastructure with a focus on health disparities. The program is designed to provide support for a needs assessment and planning phase, followed by an implementation phase. The outcome of this program is to establish a broader base of dental school institutions that have a critical mass of research as an integral component of their educational missions.

2.1.1.1 Action Plan

Continue research infrastructure support for dental institutions that serve dentally underserved communities and populations and also train greater than average numbers of individuals from underrepresented groups. In FY2002, NIDCR and the National Center on Minority Health and Health Disparities awarded planning grants with these intended purposes: (a) to augment and strengthen the institutional infrastructure and capacity for these institutions to conduct basic, clinical, and behavioral research with the objective of reducing oral health disparities through support of assessment and planning activities and, (b) to develop collaborative research arrangements with other, research-intensive institutions. Two dental schools were funded. Each of these dental schools serves dentally underserved communities and also provides training to many members of groups that are widely acknowledged to be severely underrepresented within both dental research and dentistry in general. This program is expiring during the time period covered by this plan, and it will be reviewed and updated.

Timeline: FY2002-2005

2.1.1.2 Performance Measures

The two infrastructure grants for the aforementioned dental schools are included in the health disparities portfolio evaluation. We will assess evidence of strong collaborations between the aforementioned institutions and the research-intensive institution for research and training as evidenced by the development of new investigators and their collaborations with experienced researchers, as reflected in grants and publications. At the end of the funding period, the institutions should have strengthened their capacity to proceed with a submission of scientifically meritorious developmental grants for specific research areas to reduce oral health disparities and to have initiated training and career development programs relevant to the mission of the NIDCR.

2.1.1.3 Outcome Measures

See section 2.1.1.2 above.

2.1.2 Objective Two: Enhance Research Through Training and Career Development

To build added capacity to conduct health disparities research, the Institute will enhance its training and career development programs to encourage individuals from racial and ethnic minorities and individuals from underserved backgrounds to enter science careers and retain them in their career paths. The success of the programs in research training and career development, research infrastructure, and curriculum development depends upon effective recruitment and retention of qualified individuals into research careers. The Recruitment/Retention and Outreach program maintains a close liaison with applicants and others (e.g., grantees, members of advisory groups, members and directors of related scientific organizations, professional leaders, and representatives of industry, federal agencies, and private and public foundations) to ensure the timely exchange of information regarding issues related to the recruitment of future researchers. A particular focus is on recruiting individuals from populations that are currently underrepresented in the conduct of research.

2.1.2.1 Action Plan

- Continue supporting outreach and short-term training activities targeted primarily, but not exclusively, at dental students from groups underrepresented in dentistry, to increase the diversity of the applicant pipeline. NIDCR currently supports two programs focusing on predoctoral students at institutions that serve larger numbers of underrepresented groups. This program is currently under review.
- Support Academic Career Awards in Health Disparities and/or Minority Research Scientists Development Awards in Health Disparities as a means to provide research training and experience in health disparities-related research.
- Expand training and career development opportunities for scientists in underrepresented groups through the support of NIDCR Centers for Research to Reduce Oral Health Disparities.
- Continue support of diversity supplements for research training of underrepresented minorities to increase the diversity of scientists participating in biomedical, behavioral, or clinical research. Between 1998 and 2002, NIDCR supported approximately 73 individuals through diversity supplements at the predoctoral, postdoctoral, and investigator levels.
- Maintain and strengthen ties with other NIH components and federal agencies engaged in science education and promoting science careers for minority and underserved students. Examples include:
  - *Science of the Oral Health Environment*: NIH Office of Science Education (OSE/NIH Curriculum Supplement: http://science.education.nih.gov/customers.nsf/ESDental?OpenForm)
  - Dental and dental research careers: (Lifeworks health and medical science careers – http://science.education.nih.gov/LifeWorks.nsf/feature.index.htm)

2.1.2.2 Performance Measures

Performance will be assessed by increased partnerships between diverse institutions and the number of diversity research supplements.

2.1.2.3 Outcome Measures

We plan to use a variety of methods to assess outcomes, such as the proportion of the number of diversity research supplement recipients who choose research careers, and the increased proportion of the diverse applicant pool in training programs.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

Narrowing the health gap and improving health status ultimately rest on advances in biomedical and behavioral research, the ability of health professionals to adopt and apply research advances, and the knowledge and acceptance of research advances by the public, providers, educators, and policymakers. Emphasis will be placed on promoting the use of evidence-based approaches (i.e., identifying those personal behaviors and clinical practices shown to be the most appropriate and effective in improving health and reducing health disparities). Equally important will be efforts to raise the level of understanding of oral health on the part of the public, policymakers, and non-dental health care providers: why oral health is important and the means that are now available to diagnose, treat, and prevent oral, dental, and craniofacial diseases and disorders.

3.1 Area of Emphasis One: Science-Based Health Communication

Although many oral diseases and conditions can be prevented or controlled, large knowledge gaps among providers and particularly in underserved communities remain significant challenges. There frequently is a large gap between the publication of clinical research findings and related health information and their adoption and use by diverse consumers, including people who have access to the communities of interest, such as educators, health care providers, community groups, businesses and institutions, and places of worship. Oral health materials and educational programs must be culturally appropriate and science based.

3.1.1 Objective One

Ensure the integration of science-based oral health messages and materials into existing federal health communication and education programs for racial/ethnic minorities and the underserved.

3.1.1.1 Action Plan

Maintain and strengthen current collaborations with other NIH components and federal agencies to integrate science-based oral health messages into materials and programs. Examples include:

- Information about the oral complications of diabetes: National Institute of Diabetes and Digestive and Kidney Diseases (National Diabetes Education Program and National Diabetes Information Clearinghouse)
- Oral cancer and oral complications of cancer treatment: National Cancer Institute.
- Oral care for people with developmental disabilities: National Institute of Child Health and Human Development and the CDC (Division of Oral Health and the National Center on Birth Defects and Developmental Disabilities)

- Importance of calcium for teeth and bones: National Institute of Child Health and Human Development
- Spanish-language health information: NIH Hispanic Communications Initiative
- Early Childhood Caries: Administration for Children and Families Head Start program, and U.S. Department of Agriculture's Women, Infants, and Children Program (WIC)

Establish new collaborations with other NIH components and federal agencies to integrate science-based messages. Examples include:

- Oral Complications of HIV: National Institute of Allergy and Infectious Diseases and CDC (Divisions of Oral Health and HIV/AIDS)
- Early Childhood Caries: Health Resources and Services Administration (Maternal and Child Health Bureau)

3.1.1.2 Performance Measures

Performance will be assessed by increases in: (1) the number of materials developed or adapted for diverse populations; and (2) linkages and collaborations with federal, state, and local agencies to improve oral health communication to diverse populations.

3.1.1.3 Outcome Measures

We plan to examine the quality and distribution of material developed or adapted for diverse populations.

3.2 Area of Emphasis Two: Community Outreach

3.2.1 Objective One

Expand outreach and promote partnerships with communities and institutions to disseminate culturally sensitive oral health communications, education programs, and information about government services.

3.2.1.1 Action Plan

To accomplish this goal, Institute staff will:

- Increase outreach to organizations such as the National Hispanic Youth Initiative, National African American Youth Initiative, National Native American Youth Initiative, and Hispanic Association of Colleges and Universities; and

- Establish links with African American, Hispanic/Latino American, and Native American health professional organizations to exchange information and promote participation of underrepresented minority members in biomedical research.

3.2.1.2 Performance Measures

Performance will be assessed by an increase in linkages and collaborations with federal, state, and local agencies to improve oral health communication to diverse populations. In addition, through our case studies of the Centers for Research to Reduce Oral Health Disparities, we will review the extent to which the Centers have developed partnerships within their communities.

3.2.1.3 Outcome Measures

We plan to examine the quality and distribution of material developed or adapted for minority populations, both at NIDCR and through the Centers for Research to Reduce Oral Health Disparities.

3.3 Area of Emphasis Three: Public Health Education

3.3.1 Objective One

Ensure the development, collection, and distribution of proven oral health communication and education methods and materials for racial/ethnic minorities, individuals with disabilities, and other populations associated with health disparities, to oral health education program planners.

3.3.1 1 Action Plan

- Conduct and/or fund health communications research to better understand the oral health information needs and preferences of minorities and the underserved, and to evaluate interventions for health disparities populations. These projects include:
  - Focus groups with African American men regarding the topic of oral cancer;
  - Focus groups with Hispanics to explore their education needs about ECC and general oral health; and
  - Co-sponsoring with other NIH components and Agency for Healthcare Research and Quality (AHRQ) PAs regarding health literacy, with the goal of increasing the scientific understanding of the nature of health literacy and its relationship to healthy behaviors, illness prevention and treatment, chronic disease management, health disparities, risk assessment of environmental factors, and health outcomes, including oral health.
- Support research grants to increase scientific understanding of the nature of health literacy and its relationship to healthy behaviors, illness prevention and treatment, chronic disease management, health disparities, risk assessment of environmental factors, and health outcomes, including mental and oral health.

- Strengthen ties with states that have received and/or are currently receiving NIDCR funds to conduct state-based oral cancer needs assessments and education programs. Distribute results of NIDCR health communications research to states and stay abreast of states' communication research efforts.
- Strengthen ties with NIDCR-funded Centers for Research to Reduce Oral Health Disparities, and distribute results of NIDCR health communication projects to Centers.
- Distribute NIDCR health communications materials through the Health Disparities Centers and make Center materials available nationwide through the NIDCR web site and the National Oral Health Information Clearinghouse.
- Develop, test, and distribute new health communication materials for underserved populations such as English and Spanish language publications on the oral complications of HIV and Spanish language publications on the prevention of oral diseases.
- Update, test, and maintain health information and Spanish-language sections of the NIDCR web site.
- Expand marketing of both print and online materials to oral health education program planners.
- Offer bilingual publication ordering and inquiry response services (English and Spanish).

3.3.1.2 Performance Measures

Performance will be measured by increases in: (1) the number of materials developed or adapted for minority and health disparities populations; and (2) the number of health communications research projects undertaken and completed.

3.3.1.3 Outcome Measures

Outcome measures will include evaluations of the quality and distribution of materials developed or adapted for minority or health disparities populations.

Implementation and Evaluation of the NIDCR Health Disparities Plan

The Institute's Plan to Eliminate Oral, Dental, and Craniofacial Health Disparities is an essential component of the Institute's overall Strategic Plan. As with that plan, NIDCR will make the Health Disparities Strategic Plan available on the NIDCR web site and actively promote it. The cooperation and collaboration of the many organizations and institutions that constitute the oral health community— research, education, and provider organizations; private industry; and dental academic institutions and publishers; as well as other stakeholders concerned with oral, dental and craniofacial health and health disparities, will be essential in disseminating information about the plan's goals and objectives and in aiding in their implementation.

The Institute also has developed a comprehensive evaluation plan for its entire research portfolio and related programs. As described previously, to assess the implementation of this strategic plan and to assist with future planning activities, NIDCR's Office of Science Policy and Analysis staff has designed a prospective evaluation of NIDCR's portfolio in oral health disparities research. The objectives of this ongoing evaluation are to:

1. Review the characteristics of NIDCR's health disparities research from 2000 to 2006, and assess how these characteristics correspond to the objectives of NIDCR's health disparities plan;
2. Identify the publications, interventions, and outcomes that have resulted from NIDCR's 2000-2006 health disparities research;
3. Determine whether additional research capacity has resulted from NIDCR's 2000-2006 activities in the area of oral health disparities; and
4. Determine if the research support mechanism has affected the results of NIDCR's research in oral health disparities, and if so, how.

Although this evaluation will not be completed until 2007, in the fall of 2003 and spring of 2004 data were gathered for the first phase. A variety of methods to obtain information were employed. First, a portfolio analysis was conducted using the Institute's scientific coding system. Second, the literature was analyzed to identify a baseline for health disparities publications. We obtained all publications from center Principal Investigators (PIs), core PIs, and project PIs associated with NIDCR's health disparities centers, from 1990 to the present. The literature also was searched for all oral or dental health disparities publications in 2003 to establish a baseline for the literature as a whole. In addition, we established comparison groups from the health disparities literature of two other conditions—cardiovascular diseases and diabetes. From these comparison groups, we were able to: (1) determine whether researchers in other fields have approached the problem of disparities in similar ways to the oral/dental research community; (2) identify unique elements in oral/dental research; and (3) place the baseline literature in the larger context of the overall health disparities field. We recorded and analyzed information on all authors and their affiliations, disease area, subject populations, publication type, sample type, funding sources, and the purpose or objective of the research. Third, because of the unique role research centers play in NIDCR's health disparities portfolio, we conducted case studies of each of the five NIDCR-funded Centers for Research to Reduce Oral Health Disparities. We reviewed grant applications, progress reports, web sites, pilot project applications, minutes of advisory committee meetings, study protocols, and other documents related to each center. In the fall and winter of 2003-2004, site visits were carried out to each of the five centers. Finally, telephone interviews were conducted with a small number of R01 grantees to obtain similar information as we had from Center personnel. A copy of the report from this baseline evaluation will be made available through the NIH Office of Evaluation, which supported the evaluation with funding from the NIH Evaluation Set Aside fund.

The National Institute of Diabetes and Digestive and Kidney Diseases

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

MISSION/VISION STATEMENT

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports research on many chronic and costly diseases affecting public health. Several diseases studied by the NIDDK are among the leading causes of disability and death in the Nation; all affect seriously the quality of life of those suffering from them.

The strategic vision that guides the NIDDK is improved health and quality of life for all Americans, through basic and clinical research to address the diseases and disorders within the Institute's statutory research mandate. A number of diseases and disorders that disproportionately impact the health of minority populations in the United States receive high priority in NIDDK research areas. These include diabetes, obesity, nutrition-related disorders, hepatitis C, sickle cell disease, and kidney diseases. The NIDDK will continue to support research and to encourage specific efforts in these areas of health disparity to advance the foundation of knowledge in the biomedical sciences.

A focus on basic research has traditionally guided the Institute's programs. This focus is grounded in the belief that a fundamental understanding of biologic systems will ultimately explain the abnormalities underlying each disease and thus is imperative for the development of the most effective strategies for prevention and therapy. In addition to basic research, however, the Institute has a strong commitment to expand advances in the understanding of disease processes into appropriate clinical studies and ultimately into efforts to transmit knowledge and effective technologies to practicing physicians.

The NIDDK's Division of Diabetes, Endocrinology, and Metabolic Diseases is responsible for extramural research and research training related to diabetes mellitus; endocrinology, including osteoporosis; and metabolic diseases, including cystic fibrosis, an area for which the Institute has lead responsibility within the National Institutes of Health (NIH). The Division of Digestive Diseases and Nutrition has responsibility for managing research programs related to liver and biliary diseases; pancreatic diseases; gastrointestinal diseases; including neuro-endocrinology, motility, immunology, and digestion in the gastrointestinal tract; nutrient metabolism; obesity; eating disorders; and energy regulation. The Division of Kidney, Urologic, and Hematologic Diseases supports research on the physiology, pathophysiology, and diseases of the kidney, genitourinary tract, and blood-forming organs to improve or develop preventive, diagnostic, and treatment methods. The Division of Intramural Research conducts research and training within the Institute's laboratories and clinical facilities in Bethesda, Maryland, and Phoenix, Arizona.

Shared interests in the biochemical and genetic processes underlying disease link the programs and divisions of the Institute, and close communication between the NIDDK and other NIH programs also fosters a confluence of fundamental knowledge in these vital areas of investigation.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Healthy People 2010 has as its two major goals to increase the quality and years of life and to eliminate racial and ethnic disparities in health status based on the premise that "the health of an individual is inseparable from the health of the larger community" (Dr. David Satcher, U.S. Surgeon General, Partnership for Health in the New Millennium, January 2000). Although our information on the health status of African Americans, Hispanic Americans, American Indians, Alaska Natives, Asian Americans, and Native Hawaiians and other Pacific Islanders is not as complete as the data we have on the White, non-Hispanic population, it is evident that these groups experience much higher risks and poorer health status than Whites. It also appears that the disparities are growing with regard to access to care, quality of health care, and general well-being and quality of life. For example, of the 38 measures of effectiveness of health care and 31 measures of access to health care assessed in 2000 and 2001 in the National Health care Disparities Report, African Americans received worse quality of care than Whites for about two thirds of quality measures and worse access to care than Whites for about 40 percent of access measures; Hispanics received worse quality of care than non-Hispanic Whites for about one-half of quality measures and had worse access to care for about 90 percent of access measures.

Many diseases that fall within the mission area of the NIDDK show such disparities and a significant gap between the racial and ethnic minorities and the White population. For example:

- Hispanic Americans are twice as likely to die from diabetes.
- American Indians and Alaska Natives have a diabetes rate more than twice that of Whites.
- Arizona's Pima Indians have one of the highest rates of diabetes in the world.
- African Americans have more than four times the rate of end-stage kidney failure.
- American Indians and Alaska Natives have 2.5 times the rate of end stage kidney failure compared to Whites.
- African Americans are less likely than other kidney transplant candidates to be registered on the transplant wait list.
- More than 65 percent of African American and Mexican American women are overweight, as defined by a BMI above 25.
- More than 10 percent of non-Hispanic Black women age 40-60 are severely obese, with BMI over 40.
- American Indian children have obesity rates more than twice as high as the rest of the population.
- Hispanic Americans also have higher rates of obesity and high blood pressure than Whites.
- Asian Americans and Native Hawaiians and Other Pacific Islanders have higher rates of hepatitis and tuberculosis than Whites.
- Sickle cell disease affects nearly one of every 600 African Americans and is a major cause of morbidity and premature deaths.

The higher rates of diabetes and obesity mean that these populations also suffer from higher rates of the complications of diabetes and obesity, such as end-stage kidney failure; the microvascular complications affecting the eyes, nerves, and kidneys; lower extremity amputations; development of type 2 diabetes and obesity in the children of diabetic mothers; and hypertension and coronary heart disease.

Because these population groups tend to be the ones with the highest inequalities in income and education, they also tend to have less access to quality health care and to education and information programs to help them manage their diseases and disorders.

To address these disparities with the goal of reducing and eliminating them, this Institute has utilized multiple strategies, including relevant basic research, specific and focused clinical studies, infrastructure development and capacity building, and outreach programs to racial and ethnic minority communities. As illustrated in the initiatives described below, our approach to addressing these disparities has been consistent with most of the public comments and suggestions received by the National Center on Minority Health and Health Disparities. In reference to specific thematic areas:

Theme 1: Increase numbers of health disparities populations studied by the NIH. Because many diseases in the NIDDK mission area disproportionately affect racial and ethnic minorities, the Institute has always included the affected communities in the relevant clinical trials. For example, the African American Study of Kidney Disease and Hypertension (AASK) has included only African Americans because this is a relatively unique problem for this population. Likewise, the Diabetes Prevention Trial (DPP) and the follow-up Outcome Study (DPPOS), the Look AHEAD: Action for Health in Diabetes, Genetic Determinants of Obesity in Pima Indians, etc., have all included oversampling of the relevant minority populations disproportionately affected.

Theme 2: Use racially and culturally sensitive and appropriate communication. In its community outreach programs, the Institute has always involved members of the relevant minority communities to enable development of culturally and linguistically appropriate programs. For example, the National Diabetes Education Program (NDEP) established specific minority committees to discuss and develop programs specific for each community. Likewise, in the National Kidney Disease Education Program (NKDEP), a pilot program was developed and fielded exclusively in African American communities, with participation and leadership from members from the communities.

Theme 3: Expand scope of scientific inquiry and study access to health care. Produce accurate "health disparities" definitions and data. The outreach programs of the Institute have been careful in using appropriate instruments for data collection and analysis of the magnitude of health disparities. For example, in the NKDEP program, initial assessment involved collection and analysis of data on awareness of and ramifications of kidney disease in African American communities. Likewise, in the NDEP, the minority committees have been involved in collecting information and assessing the magnitude and impact of diabetes in the respective communities.

Theme 4: Improve research infrastructure at academic institutions that serve minority and other underrepresented populations. NIDDK has been aware and concerned about the dearth of minority investigators in its relevant areas. The traditional training programs have done little to alleviate this problem. Our approach has been to attempt to develop programs at multiple stages of the pipeline. We initiated a National High School Student Summer Research Program in which high school students (primarily from minority and other underrepresented populations) are placed with accomplished NIDDK-funded investigators to be mentored in basic, clinical, and health services research. Those who embrace the program and perform well are encouraged to return and funded in subsequent summers until completion of high school. As they enter college, the Summer Internship Program (both intramural NIDDK and extramural) provides additional training for those who were in the high school program as well as other undergraduates who are interested in getting research experience. In conjunction with some national professional organizations such as the National Medical Association and the Association of American Indian Physicians, NIDDK provides travel scholarships for undergraduates, medical students, house staff, and young faculty to attend and participate in programs at the meetings. Finally, the NIDDK has established the Network of Minority Research Investigators (NMRI), in which junior (minority) faculty and senior investigators in the Network participate in Workshops designed to enhance interaction and collaboration among members, and enhance the chances of the junior investigators in succeeding in their academic careers.

Theme 5: Strengthen the capacity of minority communities. The NIDDK has encouraged leverage of resources in research-intensive institutions to serve other institutions. For example, in the AASK clinical trial, the NIDDK encouraged and succeeded in involving a variety of medical schools, including Historically Black Colleges and Universities (HBCUs), through collaborations between Morehouse College of Medicine and Emory University, Meharry Medical College and Vanderbilt University, and Charles Drew University of Medicine and Science and the University of Southern California. After the trial, the medical schools successfully competed and are funded to participate in the AASK Cohort Study.

Theme 6: Distribute NIH resources equitably across all population groups. NIDDK has been aware and concerned that not all communities have equally participated in the research efforts funded by the Institute. Therefore, we have attempted to establish programs that specifically encourage some of these underserved institutions to apply for research funding. For example, American Indians and Alaska Natives (Natives) are disproportionately afflicted with diabetes. In consultation with the Tribal Leaders Diabetes Committee, the NIDDK initiated a program to educate Native youth (K-12) about diabetes through the Diabetes Education in Tribal Schools (DETS) program. The approach is the development of supplemental curricula to be used in Tribal schools. Tribal Colleges and Universities (TCUs) have not traditionally participated in seeking research funding; therefore, they were invited to apply for funding to develop the supplemental curricula. Eight TCUs have successfully competed for funds and are in the process of developing the curricula in the DETS program.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Throughout the process of the development of NIDDK's strategic plan on minority health and health disparities, there has been careful consideration and deliberate planning with initiatives that we believe will be effective in reducing and eventually eliminating disparities. Examples of the initiatives developed through the strategic plan are listed under the Areas of Emphasis in Research, Capacity Building, and Community Outreach.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Diabetes Mellitus

Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. Type 1 diabetes accounts for approximately 5 to 10 percent of all cases of diabetes in the United States, and type 2 diabetes for 90 to 95 percent. Gestational diabetes, a transient elevation of blood glucose during pregnancy, occurs in approximately 3 to 5 percent of pregnancies. About 1 to 2 percent of the diabetes syndrome comprises other types of diabetes that have a variety of causes, such as genetic defects in insulin action, diseases of the pancreas, or drug-induced diabetes. Diabetes affects approximately 18 million people in the United States, with one-third of those affected being unaware that they have the disease. Minority populations do not appear to have a higher prevalence of type 1 diabetes. However, they are more frequently affected by type 2 diabetes. Minority groups constitute 25 percent of all adult patients with diabetes in the United States and represent the majority of children and adolescents with type 2 diabetes.

African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Native Hawaiians and other Pacific Islanders are at particularly high risk for the development of type 2 diabetes. Diabetes prevalence rates among American Indians are two to five times those of Whites. On average, African American adults are 1.7 times as likely and Mexican Americans and Puerto Ricans are twice as likely to have the disease as non-Hispanic Whites of similar age. Cuban Americans do not seem to have an elevated risk of diabetes. Some Asian American and Native Hawaiian and other Pacific Islander groups, such as Japanese Americans and Samoans, also have elevated rates of diabetes.

All patients with diabetes are at high risk for microvascular complications affecting the eyes, nerves, and kidneys; for lower extremity amputations; and for coronary heart disease. Diabetes patients from racial and ethnic minorities, however, are more likely to develop the microvascular complications of diabetes and to have lower extremity amputations compared with non-Hispanic White patients with diabetes.

The rates of coronary heart disease in minority populations may not be greater than in non- Hispanic Whites with diabetes; however, the frequency of cardiovascular complications in all patients with diabetes is two to five times that of people who do not have diabetes.

Much of the racial and ethnic disparity in diabetes microvascular complications may be due to higher levels of risk factors for these conditions in minority patients with diabetes, such as hyperglycemia and hypertension. However, there also seems to be a genetic component that influences the development of certain of the microvascular complications of diabetes. In addition, there may be other physiologic, metabolic, behavioral, and health care differences that account for part of the disparity in the frequency of diabetes complications.

Diabetes in pregnancy is associated with increased risk of congenital malformations and of complications during delivery and in the perinatal period. Due to the intrauterine environment, offspring of diabetic pregnancies have greatly increased risks of obesity and type 2 diabetes during childhood and adolescence. Women from minority groups, especially American Indian women, are much more likely to have type 2 diabetes during their childbearing years. In American Indian populations, maternal diabetes during pregnancy increases the risk of type 2 diabetes in childhood tenfold and is the most important risk factor for the development of type 2 diabetes in childhood. This finding provides an opportunity for prevention by especially targeting women of childbearing age and the children of diabetic mothers for intensive intervention.

Type 2 diabetes, once considered a disease of adults only, has been increasing in children and adolescents. Childhood diabetes clinics have reported that as many as one-third of their new-onset diabetes patients have type 2 diabetes. More than three-quarters of these children are minorities. Rates of type 2 diabetes in adolescent Pima Indians have doubled in the past 30 years. Thirty years ago, type 2 diabetes was not found in Pima children in the age group of 5- to 9-year-olds. Now more than 1 percent of Pima children this age have type 2 diabetes. Type 2 diabetes in childhood and adolescence leads to the development of serious kidney, eye, and heart disease in young adulthood in many of these children. Currently, there are no approved medications for the treatment of childhood obesity. Low-calorie diets, behavior modification, and exercise are the mainstays of treatment but have had limited success in the past.

1.1.1 Objective One: Monitor the Prevalence and Control of Diabetes in National Surveys of Minority Populations

National health surveys are conducted by the National Center for Health Statistics (NCHS) on an ongoing basis to measure the health of the U.S. population. The samples that are obtained from these surveys are representative of the U.S. population and the resultant estimates reflect the rates of occurrence of disease and risk factors for disease in the entire population. The National Health Interview Survey (NHIS) has been conducted annually since 1957 and obtains by face-to-face interviews information on demographics, health conditions, health status and limitation of activity, injury, health care access and utilization, health insurance, income, and health behaviors. In 2002, interviews were obtained for more than 35,000 adults age 18 years and older and more than 12,000 children under age 18 years. The National Health and Nutrition Examination Survey (NHANES) conducts face-to-face interviews, although less detailed than those of the NHIS, and examinations in approximately 5,000 individuals each year. Patients are examined for height and weight, anthropometry, and blood pressure, and blood is obtained to measure an extensive set of metabolites. Dietary history is obtained. Depending on the year, special examinations are conducted and may include measurement of undiagnosed diabetes and prediabetes, cardiovascular disease (CVD), cardiovascular fitness, bone density, audiometry, vision, and oral health. These surveys oversample individuals in certain minority groups so that reliable statistics may be obtained. Other surveys such as the National Hospital Discharge Survey, National Ambulatory Medical Care Survey, National Health Care Survey, and National Home and Hospice Care Survey measure other aspects of health, disease, risk factors, and access to care. The scientific community uses these surveys as well as the Behavioral Risk Factor Surveillance System conducted by the Centers for Disease Control and Prevention (CDC) and vital statistics data to monitor the health of the nation.

1.1.1.1 Action Plan

In 2003, the NHIS administered a detailed questionnaire to persons with diabetes that included questions on: age at diagnosis and duration of diabetes, glycemic treatment, frequency of visits to a doctor and nurse or dietician, self-monitoring of blood glucose, knowledge of HbA1c for measurement of glycemic level and appropriate targets, frequency of HbA1c measurement and knowledge of HbA1c level, frequency of checks for sores/irritations on feet, and last occurrence of a dilated eye examination. Other data on prevalence of hypertension and hyperlipidemia, treatment of these conditions, prevalence of kidney and CVD, and access to medical care were also collected. These data are currently being edited. The NHANES is measuring fasting plasma glucose, HbA1c, insulin, and C-peptide in persons with diabetes; the survey is also measuring core factors as described above. In 2005-2006, NHANES will add a more extensive questionnaire modeled after that of the NHIS 2003, and also include questions on knowledge of appropriate blood pressure and lipid levels. During 2005-2006, an oral glucose tolerance test will also be administered. The NIDDK is collaborating with the CDC (NCHS) with funds for data collection and analysis.

1.1.1.2 Performance Measures

The NCHS has been conducting surveys for almost 50 years and has a detailed set of procedures for cognitive testing of new questionnaire items and field testing of questionnaires and examinations. Participation rates are around 70 percent; statistical adjustments are done to ensure data are representative of the U.S. population. NIH and CDC sponsors work closely with the NCHS to provide scientific input, quality control, and quality assurance. External review groups and interest groups are convened by the NCHS and NIH to provide input and guidance on planning and conducting surveys. Data are made available to the public on a timely basis. Data are disseminated in important journals and government publications on an ongoing basis.

1.1.1.3 Outcome Measures

Resultant data on minority groups on prevalence of diabetes and prediabetes, complications and co-morbidities of diabetes, mortality, risk factors of diabetes and diabetic complications, control of diabetes/risk factors/co-morbidities, and access to medical care will be analyzed by NIH and CDC program staff, Healthy People 2010, other federal agencies, and the general scientific community. These data will be monitored on an ongoing basis for assessment of the burden of diabetes and related conditions in minority groups.

1.1.2 Objective Two: Pima Indian Epidemiology Study of Diabetes

Our mission is to help provide knowledge and assistance to the Gila River Indian Community (GRIC) in controlling the epidemic of diabetes, overweight, and related diseases affecting the kidneys, eyes, and heart. The NIDDK, in collaboration with the GRIC of Arizona, has conducted a longitudinal epidemiological study among the Pima Indians since 1965.

1.1.2.1 Action Plan

Community residents at least 5 years of age are invited for a biennial health examination focused on diabetes, obesity, and complications of diabetes. Inclusion of almost all residents, together with data obtained on family relationships and data from pregnancies and deliveries, has provided a wealth of information on the incidence rates and risk factors for type 2 diabetes in this population, including familial effects and the long-term effects of prenatal and neonatal conditions, such as birth weight and maternal diabetes. This study provided much of the data used to develop international criteria for diagnosis of diabetes and other states of abnormal glycemia and to plan diabetes prevention clinical trials. It forms the basis for studies of the genetics of type 2 in the Pima Indians and of studies of complications, especially renal disease, described elsewhere. Many participants in this population study also participate in multi-center clinical studies described elsewhere in this document, including the Diabetes Prevention Program Outcomes Study (DPPOS), Look AHEAD, and the Family Investigation of Nephropathy in Diabetes (FIND). Other sub-studies conducted entirely within this community include an investigation of subclinical heart disease and its risk factors in young adults with early-onset type 2 diabetes (in collaboration with the National Heart, Lung, and Blood Institute [NHLBI]), studies of the genetics of diabetic retinopathy (in collaboration with the National Eye Institute), and a clinical trial of delaying progression of diabetic nephropathy by inhibition of the renin-angiotensin system.

This study also contributes to the training of minority researchers. Many of the research staff are American Indian. In the last few years, several American Indian staff employed by the Intramural Research Training Award (IRTA) mechanism are now attending medical school. A former American Indian summer student employee at NIDDK in Arizona subsequently attended medical school and residency training and then returned to NIDDK as a staff clinician. He now has a university faculty position.

1.1.2.2 Performance Measures

The performance measures will include continued participation in this study by community residents.

1.1.2.3 Outcome Measures

The research is expected to lead to new knowledge, the application of which will lead to reducing the average BMI and the incidence rates of type 2 diabetes and its complications, such as diabetic nephropathy.

1.1.3 Objective Three: STOPP-T2D Prevention Trial

The increase in the number of children with diagnosed type 2 diabetes is described above. In addition, data from NHANES III suggest that up to one third of adults who have type 2 diabetes may go undiagnosed. A similar situation may exist with children. In fact, the diagnosis of type 2 diabetes in children is often made because of routine laboratory screening conducted as part of a school physical examination and not because the child presents to a health care provider with specific complaints. Thus, many children who do not receive such screening may go undiagnosed until they become symptomatic, at which time they may have been hyperglycemic for many years and are at high risk of developing diabetic micro- and macrovascular complications.

In addition, significant numbers of children may not have frank diabetes, but may be at high risk of developing diabetes based on the presence of insulin resistance, impaired fasting glucose, or impaired glucose tolerance. Furthermore, the combination of insulin resistance, hypertension and dyslipidemia (syndrome X), which is being documented with increasing frequency among obese adolescents, is associated in adults with the development of accelerated CVD. It is, therefore, imperative to establish appropriate screening criteria and effective primary prevention programs to avoid a potential major public health burden.

NIDDK and others have demonstrated that lifestyle interventions can delay or prevent the onset of diabetes in high-risk adults. These interventions may not be directly applicable to the pediatric population. The majority of children with type 2 diabetes are in the pre-adolescent or adolescent age range. The adolescent period presents special challenges to health care providers and families when attempting to promote behavior and lifestyle changes. Prevention and treatment programs also must consider cultural differences among racial and ethnic groups that may influence acceptance of treatment regimens. This is especially important for type 2 diabetes in children, which disproportionately affects minority groups. In addition, children represent a unique “target” population, which may be amenable to population-based public health interventions through schools.

NIDDK has, therefore, initiated a primary prevention trial (STOPP-T2D, Study to Treat or Prevent Pediatric Type 2 Diabetes) aimed at decreasing risk factors for type 2 diabetes in middle school children. There are seven field centers, plus a coordinating center, participating in the STOPP-T2D consortium. The study group plans a population-based, primary prevention trial, carried out in middle schools, with the school as the unit of randomization. It is anticipated that there will be 56 control and 56 intervention schools. It will be a three-year intervention, starting in sixth grade. There will be three components: (1) enhanced physical activity in the school by increasing the time devoted to moderate-vigorous activity in gym class; (2) environmental change in the school targeting the food service, by changing foods available in the cafeteria and vending machines; and (3) behavior curriculum aimed at increasing physical activity in and out of school, decreasing sedentary behavior out of school, and changing dietary habits. The primary outcome will be a comparison of the prevalence of abnormal glucose and insulin levels and overweight between control and intervention schools.

1.1.3.1 Action Plan

The purpose of STOPP-T2D is to develop a school-based intervention to prevent or decrease risk factors for type 2 diabetes. An NIDDK Request for Applications (RFA) was issued in 2001 seeking centers to participate in this study. After peer review of applications submitted to the RFA, three field sites plus the coordinating center were chosen to participate. The investigators from these sites began planning for the trial and conducted a pilot study in spring 2003 to: (1) determine the prevalence of risk factors for type 2 diabetes in middle school children; and (2) assess the feasibility of recruiting minority youth to participate in a school-based study. Based on this pilot, it was determined that more sites needed to be recruited to participate in the study. A second RFA was issued, and four new sites were added in February 2004, to provide increased minority representation and an adequate number of schools. The sites are now piloting the interventions that are being developed, and the full trial is expected to begin in fall 2006. For the full trial, all schools recruited will have a student body that is at least 51 percent minority.

1.1.3.2 Performance Measures

The initial pilot conducted by three of the seven STOPP-T2D sites was successful in recruiting 1,700 eighth graders in 12 schools, including 23 percent African Americans, 53 percent Hispanic Americans, 15 percent Caucasians, 3 percent American Indians, and 6 percent other (mainly Asian Americans). The students participating in the pilot study were representative of the demographic makeup of their respective schools. It is anticipated that the addition of the four new sites will substantially increase African American and American Indian representation. All schools recruited for the full trial will have a student body that is at least 51 percent minority. The study has developed a detailed recruitment plan. The Recruitment and Retention committee will track enrollment data for the pilots, as well as the main trial, focusing on the goals set for racial and ethnic minority recruitment.

1.1.3.3 Outcome Measures

The STOPP-T2D study will determine how well its intervention decreases risk factors for type 2 diabetes in a middle school setting. Outcomes will be compared between control and intervention schools (i.e., the school, not the individual student, is the unit of randomization). The final primary and secondary outcome data will be published.

1.1.4 Objective Four: Diabetes Prevention Program Outcomes Study (DPPOS)

A long-term follow-up of participants in the Diabetes Prevention Program (DPP), entitled the Diabetes Prevention Program Outcomes Study or DPPOS, has been initiated following the early conclusion of the DPP as a result of highly significant and positive outcomes of the study interventions. The results of the DPP demonstrated that lifestyle and drug interventions could markedly reduce the risk for developing type 2 diabetes in a group at high risk due to the presence of impaired glucose tolerance, by 58 percent for lifestyle and 31 percent for metformin. The DPP included 45 percent of the study cohort from African American, Hispanic American, Asian American, Pacific Islander, and American Indian populations. In addition, 20 percent of our study population was older than age 60 and 68 percent of the participants were women. Importantly, it was shown that interventions were similarly effective in men and women and in all of the racial/ethnic groups that we included in the study.

While the primary goal of the DPP was to prevent the development of diabetes, an important secondary goal was to decrease the rate of CVD and its risk factors. These clinically important outcomes were considered as secondary during the DPP due to a lack of sufficient power in the time allotted to the study to detect potential differences between the treatment groups. The DPPOS will provide insights regarding the clinical course of the metabolic disorders leading to increased risk for type 2 diabetes, will provide information on the persistence of the prevention or delay of type 2 diabetes, and will allow determination of the impact of study interventions on CVD risk outcome. Of major interest is the outcome of continued lifestyle change, long-term weight loss, and metformin intervention in the gender and minority subgroups during the DPPOS.

1.1.4.1 Action Plan

Recruit participants enrolled in the DPP to enroll in the DPPOS, with focused efforts to enroll racial/ethnic minorities.

1.1.4.2 Performance Measures

Determine recruitment success. Recruitment is now at 85 percent of the original DPP cohort, and the success in recruitment is equal among subgroups that participated in the DPP, including minority groups.

Maintain adherence to study interventions. Continuous study oversight is provided by a number of study subcommittees that follow study conduct and provide corrective plans with ongoing measures of success. In addition, the NIDDK-appointed Data Safety Monitoring Board oversees data quality and participant safety through regular meetings and recommendations to the NIDDK Director.

1.1.4.3 Outcome Measures

Publication of DPPOS results regarding the rate of conversion to type 2 diabetes between the intervention groups analyzed by intention to treat and the impact of study interventions on CVD risk outcome. These publications will focus on subgroup analysis, particularly evaluation of results by race/ethnicity, age, and gender.

1.1.5 Objective Five: Identifying Genetic Causes of Type 2 Diabetes Mellitus in the Pima Indians

The Phoenix Epidemiology and Clinical Research Branch of the NIDDK has been studying the etiology of type 2 diabetes among the Pima Indians of Arizona since 1960s. This Native American population has the highest reported prevalence and incidence rates of this disease. Previous work demonstrated that there were environmental and significant genetic determinants of the disease in this population, particularly among those with early onset of the disease. A genome-wide linkage scan to identify diabetes susceptibility genes was completed in 1998. The scan identified a region on chromosome 1q that was linked to diabetes with an age of onset before the age of 45 years. In subsequent years the linkage to diabetes in this same genomic region was replicated in several Caucasian populations—the Amish, pedigrees in Utah, in the United Kingdom, and in France. Also, replication in the same area was identified in at least two Chinese populations in Shanghai and Hong Kong. This genomic region on chromosome 1q 21-23 is now the most replicated type 2 diabetes linkage in man.

1.1.5.1 Action Plan

NIDDK has funded a consortium of the scientific groups studying the various populations with linkage to type 2 diabetes on chromosome 1q. This consortium is working together to complete a very dense simple nucleotide polymorphism (SNP) map across this genomic region in collaboration with the Sanger Center in the United Kingdom.

1.1.5.2 Performance Measures

The consortium has met on several occasions and the DNA from all populations, including samples from approximately 4,000 individuals has been deposited with the Sanger Center, which has completed the first 1,500 markers across this genomic region. Preliminary analyses have identified a couple of areas of association in more than one population; however, the entire region around the various linkages has not yet been fully mapped. The second installment of 1,500 genotypes in these 4,000 samples should be completed by September. A working statistical and analytical committee has been formed, and a detailed plan of analyses has been worked out. The consortium is now working to develop an application for another year of funding to fully complete the linkage disequilibrium map in this region.

1.1.5.3 Outcome Measures

It is expected that this joint effort will identify a gene (or genes) associated with increased susceptibility to type 2 diabetes mellitus in all these various ethnic groups—although the allelic polymorphism responsible for the association is likely to be dissimilar across groups. The consortium, in this early phase, is expected to demonstrate an ability to work collaboratively in identifying these genes.

1.1.6 Objective Six: Determine How Best to Treat Type 2 Diabetes in Children, With an Emphasis on Disproportionately Affected Minorities

Type 2 diabetes traditionally has been viewed as a disease of adults; however, recent epidemiological data reveal an increasing number of cases of type 2 diabetes in the pediatric population, especially among adolescents and in certain minority populations, particularly African Americans, Hispanic Americans, and Native Americans. In general, population-based screening data are not available; however, data culled from diabetes clinics in several locations suggest that the percentage of children diagnosed with diabetes who are classified as having type 2 diabetes has risen from less than 5 percent (prior to 1994) to 20-40 percent (after 1994). The increase of type 2 diabetes in children and adolescents is presumed to be a consequence of widespread obesity and decreased physical activity.

Clinical trials to develop effective treatment regimens for this age group are needed. The drugs currently available for the treatment of type 2 diabetes in adults have not been used widely in children. In addition, lifestyle interventions tested in adults may not be directly applicable to the pediatric population. The majority of children with type 2 diabetes are in the pre-adolescent or adolescent age range. The adolescent period presents special challenges to health care providers and families when attempting to promote behavior and lifestyle changes. Treatment options need to be studied in this population to determine the most efficacious, safe, and cost-effective strategies to achieve euglycemia in the pediatric age group. Treatment programs also must consider cultural differences among racial and ethnic groups that may influence acceptance of medical regimens. This is especially important for type 2 diabetes in children, which disproportionately affects minority groups.

NIDDK has begun a major clinical trial, Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY), to address these issues. There are 12 clinical sites participating in the TODAY study, plus a coordinating center. The sites provide geographic distribution across the country as well as access to the minority groups disproportionately affected by type 2 diabetes. The trial will compare the efficacy of three arms: (1) metformin alone; (2) metformin plus intensive lifestyle; and (3) metformin plus rosiglitazone. All subjects will receive standard diabetes education. The primary outcome will be time to rescue, defined as a hemoglobin A1c less than 8.5 percent for 6 months. Secondary outcomes include beta cell function, co-morbidities (dyslipidemia, hypertension), risk factors for vascular complications, side effects/QOL, and cost analysis. Recruitment of 750 children

(250 per arm) will take place over 3 years ,and the total study duration will be 5 years. The TODAY study began recruiting participants in May 2004.

1.1.6.1 Action Plan

The purpose of TODAY is to identify the best treatment for type 2 diabetes in children and teens, with a focus on minority youth. The 13 sites participating in the study were chosen by peer review of applications submitted to an RFA issued in 2001. The investigators from these sites have developed a design for the trial, including a Protocol and Manual of Procedures, and have obtained approval from the local Institutional Review Boards (IRBs) at all 13 participating sites. Enrollment into the trial began in May 2004. The TODAY study plans to recruit 750 participants into the study, with an emphasis on minority youth. It is anticipated that the distribution of participants will be approximately 33 percent African American, 31 percent Hispanic American, 12 percent American Indian, 20 percent non-Hispanic White, and 4 percent other (mainly Asian American).

1.1.6.2 Performance Measures

The study has developed a detailed recruitment plan. The Recruitment and Retention committee will track enrollment data for the TODAY trial, focusing on the goals set for racial and ethnic minority recruitment. Quarterly reports, by clinical site, will be generated by the TODAY coordinating center. New recruitment strategies will be developed, if needed, to meet study goals.

1.1.6.3 Outcome Measures

The TODAY study will determine how well each of the three treatments controls blood glucose levels, for the treatment group as a whole, as well as by racial or ethnic minority group. The same analysis will be conducted for all secondary outcomes, including risk factors for diabetes complications. The final primary and secondary outcome data will be published.

1.1.7 Objective Seven: Translational Research for Prevention and Control of Diabetes

The NIDDK seeks to foster the development of innovative programs to translate recent advances in the prevention and treatment of diabetes and its complications into clinical practice for individuals and communities at risk.

1.1.7.1 Action Plan

An ongoing Program Announcement (PA), PA 02-153 http://grants.nih.gov/grants/guide/pa-files/PA-02-153.html) and PAR-03-060 http://grants.nih.gov/grants/guide/pa-files/PAR-03-060.html), established a diabetes prevention and control program, and seeks applications for public health, clinical, or behavioral studies to develop and test: (1) improved methods of health care delivery to patients with or at risk of diabetes, (2) improved methods of diabetes self management, and (3) cost-effective community-based strategies to promote healthy lifestyles that will reduce the risk of diabetes and obesity. This PA and PAR establish a grant program to fund trials that test strategies for achieving objectives that have already been proven beneficial, such as: (1) control of glycemia and other risk factors for diabetic complications, including hypertension and dyslipidemia; and (2) altering lifestyle to prevent or delay the onset of type 2 diabetes in at-risk populations, including children and adolescents. Of particular interest are interventions that focus on translating new advances into practice in underserved and minority populations.

1.1.7.2 Performance Measures

The response to PA 02-153 and PAR 03-060 has been very robust, with 129 grant applications received to date. A total of 10 grants have been supported. Some examples are one designed to improve diagnostic methods and improve rates of diagnosis, one to develop “real world” prevention efforts in adults, one to develop type 2 diabetes prevention in children, and one designed to improve glycemic control in patients with diagnosed diabetes. One grant to enhance diabetes self management in low-income Hispanics will be awarded in FY2004.

1.1.7.3 Outcome Measures

The outcome measures will be the number of supported projects successfully completed and the impact of these completed studies to facilitate effective translation of type 2 diabetes prevention and treatment interventions.

1.1.8 Objective Eight: Research to Overcome Health Disparities in Diabetes

The NIDDK seeks research to understand and mitigate issues of health disparities in diabetes and obesity.

It is recognized that there are many diseases and disorders that disproportionately affect the health of racial and ethnic minority populations in the United States. It is evident that African Americans, Hispanic Americans, American Indians, Alaska Natives, some Asian Americans, and Native Hawaiians and other Pacific Islanders experience much higher risks and poorer health status than the general population.

Several of the diseases that disproportionately afflict minorities are high-priority research areas such as diabetes and obesity. African Americans, Hispanic/Latino Americans, American Indians, Alaska Natives, some Asian Americans, and Native Hawaiians and other Pacific Islanders are at particularly high risk for the development of type 2 diabetes. Diabetes prevalence rates among American Indians are two to five times those of Whites. On average, African American adults are 1.7 times as likely and Mexican Americans and Puerto Ricans are twice as likely to have the disease as non-Hispanic Whites of similar age. Japanese Americans and Samoans also have elevated rates of diabetes.

1.1.8.1 Action Plan

An ongoing Program Announcement, PA 04-074, Health Disparities in NIDDK Diseases, http://grants.nih.gov/grants/guide/pa-files/PA-04-074.html, established an ongoing program to foster research into health disparities in diabetes mellitus and obesity (as well as other diseases of NIDDK interest).

1.1.8.2 Performance Measures

This PA was published March 11, 2004. To date, five applications have been received responsive to this PA. In response to prior Program Announcements regarding health disparities in diabetes and obesity (PA 02-165 and PA 02-117), 40 applications were received and of those two studies were funded. One study was on racial difference in diabetes-depression co-morbidity and the other was on dysregulated muscle lipid metabolism in African Americans.

1.1.8.3 Outcome Measures

The success of PA 04-174 will be the metric of applications received and number funded. In terms of success of translational efforts for prevention of diabetes, rates of newly diagnosed diabetes by racial and ethnic groups (adjusted for increasing rates of obesity) will be made. Also mean achieved HbA1c as measured in large epidemiological studies in all racial and ethnic groups as data are available will be a measure of translational efforts of diabetes treatment.

1.2 Area of Emphasis Two: Obesity

Obesity and overweight represent the most common nutritional problem in the United States, affecting nearly two thirds of the adult population, or more than 130 million Americans.

Obesity is a major contributor to diabetes, hypertension, heart disease, stroke, osteoarthritis, and certain types of cancer.

Obesity is more common among minority individuals in the United States. More than 70 percent of non-Hispanic Black and Mexican American women are overweight, as defined by a BMI 25 or higher.

The prevalence of obesity (BMI 30 or above) in the United States is increasing in all racial and ethnic groups, but it affects minority populations disproportionately. More than 15 percent of non-Hispanic Black women ages 40-60 are extremely obese, with BMI of 40 or more.

Rates of obesity in American Indian children are more than twice as high as in the Nation’s population as a whole.

Overweight in childhood is associated with higher cholesterol levels and high rates of hypertension, type 2 diabetes, and early coronary heart disease.

Although family-based interventions for obesity treatment have shown promise in research studies, there are few proven interventions to successfully prevent or treat pediatric obesity. Currently, there is only one approved medication for the treatment of obesity in children ages 12 and older, and none for younger age groups. Although some children with extreme obesity are being treated with bariatric surgery, there are few data regarding its safety or efficacy.

Obesity is an important area of research supported by the NIDDK, including basic research on genetics, metabolism, appetite, energy expenditure, and body composition, as well as clinical and community-based research to develop and test effective methods for preventing and treating obesity.

1.2.1 Objective One: Look AHEAD: Action for Health in Diabetes

Numerous studies have demonstrated the beneficial impact of short-term weight loss on risk factors such as dyslipidemia, hyperinsulinemia, hypertension, and elevated plasma glucose. Based on long-term epidemiological evidence of the health hazards of overweight and obesity and on short-term clinical trial evidence, public health policy recommends weight loss for obese individuals (BMI 30 or above) or overweight individuals (BMI 25.0 to 29.9) with one or more additional co-morbidities.

Although a substantial proportion of the U.S. population is attempting to lose weight, few studies have examined the health effects of intentional weight loss over a period greater than 1 year and very few beyond 4 years. Moreover, several major observational studies show a significant association between weight loss and mortality that persists even after attempts to correct for confounding factors (e.g., smoking or preexisting illness). However, most of these observational studies are unable to distinguish between voluntary and involuntary weight loss.

NIDDK undertook a major clinical trial, Look AHEAD: Action for Health in Diabetes, to address these questions. Extensive public input went into the development of the Look AHEAD concept from meetings of investigators from across the United States in early stages to final review by the National Diabetes, Digestive and Kidney Diseases Advisory Council and by a Protocol Review Committee during the final stages.

Look AHEAD is a large clinical trial at 16 clinical centers across the United States that will investigate the benefits and risks of interventions designed to sustain weight loss over the long term. Look AHEAD completed enrollment of 5145 participants on time in April of 2004, 2½ years after the start of randomization. The study exceeded its goal of recruiting 33 percent minority participants, with a final cohort that included 36.9 percent minority individuals. All Look AHEAD participants are overweight or obese and have type 2 diabetes. Participants were randomized at entry to receive either an intensive lifestyle intervention designed to achieve and sustain weight loss or a diabetes support and education control condition. The long-term health benefits of this intervention are being assessed, with the primary endpoints being combined cardiovascular deaths (including fatal myocardial infarction and stroke), nonfatal myocardial infarction, and nonfatal stroke. Look AHEAD participants will be followed for 9 to 11.5 years, depending upon time of entry.

A trans-NIH RFA for Ancillary Studies in Conjunction with Look AHEAD was released on August 2, 2000, as part of the NIDDK Strategic Plan on Minority Health Disparities. This RFA solicited R01 grants to expand research on the well-described, diverse population of obese individuals with type 2 diabetes undergoing long-term weight loss interventions in Look AHEAD.

A recent RFA for Ancillary Studies to Obesity Related Clinical Trials (DK-03-022) also solicits grants to expand research on major clinical trial populations, including several trials with enhanced minority participation (Look AHEAD, DPPOS, and TODAY).

1.2.1.1 Action Plan

The purpose of Look AHEAD is to assess the long term health impact of interventions designed to achieve and sustain weight loss over the long term. The action plan for Look AHEAD includes:

1. *Recruitment of 5000 obese individuals with type 2 diabetes including 33 percent minority population members.* Look AHEAD has already exceeded this goal.
2. *Meet weight loss feasibility criteria defined in the Look AHEAD protocol.* These criteria require that the first 25 percent of Look AHEAD participants who complete 1 year (and then 2 years) of weight loss achieve a predefined level of weight loss or physical activity in order to ensure that the study is feasible. Look AHEAD has already met its 1-year criteria.
3. *Deliver an intensive 4-year weight loss intervention to this population*. Look AHEAD is developing a long term intervention and administering it successfully at all centers. The intervention includes flexibility to accommodate the needs of various ethnic and minority populations, and intervention materials also have been translated into Spanish.
4. *Publish intermediate data at predefined times.* Because of the importance of obesity research, Look AHEAD investigators have adopted a policy of encouraging publication of intermediate data at regular time points as defined in the study publication policy. These intermediate publications will include publication of baseline data (under development now that all participants have been recruited), publication of data on weight loss after all weight loss participants have had the chance to participate in the weight loss intervention for 1 year, publication of the impact of weight loss on defined intermediate outcomes such as diabetes control, blood pressure, bone density, lipid measures, etc., and publication of the impact of 4 years of intervention on a broader range of measures, including assessment of the cost-effectiveness of the intervention. Final study publications detailing the effect of weight loss interventions on cardiovascular events will appear in 2013, at the end of Look AHEAD.
5. *Encourage ancillary studies to Look AHEAD.* An RFA was issued in 2000 to solicit a range of basic, clinical, and behavioral ancillary research studies consistent with the aims of Look AHEAD. Nine ancillary studies were funded under the RFA (four by NIDDK; four by the

National, Heart, Lung, and Blood Institute; and 1 by the National Institute for Nursing Research). These include topics such as sleep apnea, insulin resistance and fat cell size, eating disorders, changes in organ and tissue mass, sexual dysfunction, and fatty liver disease. Several of these included targeted hypotheses relating to racial/ethnic disparities.

Timelines for Action Items Above

1. Completed on time in 2004.
2. Expected to be completed by the end of 2004.
3. Expect to complete 4-year interventions in all participants by midyear 2008.
4. Expect publication waves in 2005 (baseline data), 2006 (1-year data), and 2009 (4-year data). The end-of-study publication is anticipated to occur in 2013.
5. Nine ancillary studies were funded in 2000. Additional Look AHEAD ancillary studies may be funded in September 2004, July 2005, or April 2006 if these compete successfully with ancillary studies to other clinical trials and networks.

Date for Achieving Objective

Look AHEAD is powered to demonstrate an 18 percent difference in cardiovascular events between the two intervention groups by December 31, 2012, if there are no unexpected trends in event rates. Publication of the data will occur in 2013.

1.2.1.2 Performance Measures

1. The performance measure will be the number of participants screened and randomized. Look AHEAD has exceeded its goal for total participants and percentage minority participants.
2. There are two performance criteria for weight loss feasibility (for the first 25 percent of Look AHEAD participants):
   - For the first year of intervention, the intensive weight loss group should achieve at least a 5 percent absolute weight loss on average from baseline *and* a difference of at least 5 percent weight loss above that in the control condition. Look AHEAD has met this criterion already.
   - For the second year of intervention, the intensive weight loss group should sustain at least a 5 percent difference above the control condition *or* at least a 5 percent fitness difference above the control condition. Look AHEAD will be evaluated on this criterion in the summer of 2004, when the data become available.
3. Look AHEAD has ambitious plans developed for its weight loss intervention and has successfully delivered the intervention to over 400 individuals beyond the 2year mark at this point. Performance is measured by an array of reports generated by the Look AHEAD coordinating center that include percent weight loss, minutes of exercise, use of meal replacements, and attendance at clinic visits. Monitoring of these reports is performed by a central study committee, the Lifestyle Resource Core.

4. Look AHEAD publications will be used to assess performance toward its goals of releasing study information in waves after participants all have been recruited and when they all have reached 1 year and 4 years of intervention. Look AHEAD already has published its design paper and has a number of baseline papers in preparation.
5. Look AHEAD has 9 ancillary studies funded under a trans-NIH RFA and has permitted four additional ancillary studies with non-NIH funding. Despite the large number of ancillary studies already associated with Look AHEAD, the trial remains committed to collaboration with ancillary investigators, provided that additional studies do not pose an undue burden to Look AHEAD participants or staff. Consistent with this, two additional proposals were approved to apply to a new RFA for Ancillary Studies to Obesity-Related Clinical Trials (DK-03-022). These proposals will be reviewed in the summer of 2004 and will compete against proposals for ancillary studies in other large clinical trials and networks.

1.2.1.3 Outcome Measures

Look AHEAD's primary outcome is assessment of the long-term impact of weight loss interventions on heart attacks, strokes and cardiovascular-related death. This study has the potential for a major impact on public health and the practice of medicine. Data on intermediate outcomes will be released throughout the study as described in the Action Plan above. The final primary and secondary outcome data are expected to be published in 2013.

1.2.2 Objective Two: Environmental Approaches to the Prevention of Obesity

Obesity is the most common nutritional disorder in the United States, and its prevalence is increasing in both children and adults. Minority populations, particularly African American, Hispanic, and Native American women, are disproportionately affected. Although genetic factors are believed to contribute substantially to a predisposition toward obesity, environmental factors play an important role. The dramatic increase in obesity prevalence over the past 2 decades is believed to be a consequence of environmental factors that favor increased energy intake along with decreased energy expenditure. It has been suggested that although genetic factors may account for a significant proportion of within-population variability in body weight, environmental factors may account for most variability in body weight between populations or over time. Genetic approaches will undoubtedly provide important insights into the control of body weight, which eventually may lead to improved efforts in prevention and treatment. However, it is unlikely that addressing genetic factors alone will overcome the substantial environmental pressures for overconsumption and sedentary behavior that currently affect Americans. Environmental factors believed to play a role in the development of obesity include those that increase energy intake, such as advertisements for and the low price of high energy density foods, the consumption of larger portion sizes, greater frequency of restaurant meals, and the use of more fast foods and convenience foods. For infants, bottle-feeding may also increase energy intake relative to breastfeeding. Numerous environmental factors also lead to decreased energy expenditure. Work is more likely to be sedentary than in the past, with near universal use of automated equipment and electronic communications. At home, wireless phones, remote controls, and various labor-saving devices for household chores also decrease physical activity. More time is spent using the computer, watching television, and playing video games, particularly among children and adolescents. At the same time, the number of schools requiring daily physical education has declined. Suburban communities often lack sidewalks, and the lack of neighborhood resources makes it difficult to walk even short distances to stores and recreation. Many individuals report difficulties going out to exercise because their neighborhoods are perceived as unsafe.

In addition, children in day care or in before-school and after school care often lack facilities to engage in, or have adequate supervision for, active play. Prevention of obesity is frequently attempted through educational approaches aimed at improving knowledge and motivation, with a consequent presumed impact on individual lifestyle choices. Such approaches have been largely ineffective at preventing weight gain. Other prevention strategies have focused on changing individual behaviors related to dieting and physical activity but have limited applicability to large populations. In contrast, environmental and policy approaches attempt to modify the environment in which such choices are made rather than rely on individual will. Policy approaches are environmental interventions that involve establishing social, economic, or legal structures within a formal governmental or nongovernmental organization. Environmental changes that reinforce factors supporting healthy lifestyles and that reduce barriers to healthy lifestyles also may serve to diminish health disparities, as barriers may be more prevalent in disadvantaged and ethnic minority communities.

Approaches that modify the environment to promote healthful eating, increase physical activity, and decrease sedentary behaviors offer the potential for safe and effective programs for obesity prevention that could be widely disseminated. The NIDDK invited applications to study promising interventions that would target environmental factors that contribute to inappropriate weight gain in children, adolescents, and adults. Investigators were required to collaborate with organizations and institutions, such as schools, supermarkets, restaurants, religious organizations, recreational facilities, industrial facilities, governmental or community groups, and worksites, to develop approaches that, if successful, could potentially be translated into large-scale interventions. The need for an obesity prevention initiative has been recognized by a number of NIH advisory groups. In 1994, the National Task Force on Prevention and Treatment of Obesity developed a long-range plan focused on the prevention of obesity and recently reaffirmed obesity prevention as a priority area for clinical research. The NHLBI/NIDDK *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* includes a discussion of the importance of preventing obesity and suggestions for strategies to be attempted. This review includes recommendations for research on obesity prevention. The 1998 NHLBI *Report of the Task Force on Behavioral Research in Cardiovascular, Lung, and Blood Health and Disease* also recommended the development of obesity prevention research efforts. In December 2000, the Surgeon General held a listening session in an effort to develop a national action plan to combat overweight and obesity. The session identified obesity prevention as a critical target and suggested that efforts focus on environmental factors, including the family and community, schools, worksites, the health care delivery system, and the media.

1.2.2.1 Action Plan

A RFA, Environmental Approaches to the Prevention of Obesity (RFA-DK-02-021), was issued in October 2002, led by NIDDK with participation of NHLBI, the National Institute for Environmental Health Sciences (NIEHS), the National Institute for Child Health and Human Development (NCMHD), the Office of Research on Women's Health (ORWH), the Office of Disease Prevention (ODP), and the CDC. The sponsoring organizations encouraged the submission of grants for innovative studies, with a goal of modifying the individual, family, group, or community environment such that inappropriate weight gain is prevented by improvements in diet, increases in physical activity, and/or decreases in sedentary behaviors. Applications addressed the content of the intervention (e.g., relative focus on aspects of diet, physical activity, sedentary behaviors, combinations of these, other factors), the setting of the intervention (e.g., in health care settings, community groups, recreational facilities, home, school), and the method of intervention delivery (e.g., individual, family, group, community). Applications targeting groups or populations at high risk for the development of obesity were encouraged.

1.2.2.2 Performance Measures

The response to this RFA was substantial, with 80 applications received. Funding was available to support 16 research investigations. Among these studies, two focused on the home environment, seven were based in the school or after school environment, two in day care centers, one at a neighborhood playground, and two in multiple environments involving the home, school, stores, parks, and restaurants. Included are studies that focus on American Indian children, low-income women, African American schoolchildren, and the Latino home and community environment. The school-based studies include inner-city schools with predominantly minority enrollment. These studies are currently ongoing.

1.2.2.3 Outcome Measures

The outcome measures will include the successful modification of the environment to promote healthful eating, increased physical activity, decreased sedentary behaviors, and the potential for safe and effective programs for obesity prevention.

1.2.3 Objective Three: Site-Specific Approaches for the Prevention or Management of Pediatric Obesity

Within the broader global environment in which we live, there are micro-environments, or specific sites in which people tend to spend the majority of their time. It is largely within these sites that our behaviors are learned, reinforced, modified, rewarded, and practiced. Included among these behaviors are diet, physical activity, and sedentary behaviors. Sites in which people typically spend the most time include worksites, schools, and the home. In addition, there is the broader community, which encompasses institutional settings (e.g., day care, after-school care, faith-based, community/recreational centers, etc.) and environmental settings (e.g., playgrounds, walk/bike paths, shopping malls), where the majority of the population living in urban and suburban areas tend to congregate.

Recognizing that overweight and obesity are resistant to currently available treatments, there is increasing recognition of the importance of prevention. Primary prevention, or the initial prevention of inappropriate weight gain, is believed to be most effective if it is instilled at young ages. There is evidence that overweight tends to track from early childhood throughout the developmental years and into early adulthood. Therefore, greater attention needs to be focused on research efforts to find more effective ways that will lead to the development of appropriate dietary and physical activity behaviors and prevention of overweight early in life. This is particularly important for some racial and ethnic minority populations, which tend to be more severely and disproportionately affected by overweight and obesity.

An initiative is planned to solicit applications for intervention trials that can be conducted in specific sites, focusing on the prevention or management of pediatric overweight. The family/home environment is a key setting in which pediatric obesity prevention may be addressed. In isolation, schools, health care delivery, and other community settings will be less effective if change is not reinforced or does not originate in the rearing environment of the family/home that may be instrumental, and even pivotal, in the prevention of key behaviors that have an impact upon obesity. Research dedicated to the role and mechanism of families in the initiation, support, and reinforcement of fundamental food and beverage consumption, physical activity practices and sedentary behaviors, or behavioral determinants associated with these practices, will be crucial to initiate or sustain changes in dietary and physical activity behaviors related to energy balance. The school environment has been examined for its potential as a viable setting to instill fundamental prevention knowledge and practices, but few school-based interventions have been successful in preventing or decreasing overweight in childhood. Novel, and perhaps more comprehensive, interventions are needed to further develop effective prevention methods in the school setting. Studies that focus solely on clinical trials for the prevention or treatment of obesity in the pediatric primary care setting will be encompassed in a separate trans-NIH initiative, led by NICHD ("Prevention and Treatment of Pediatric Obesity in Primary Care Settings").

Health disparities are, in part, the result of socioeconomic disadvantages impacting upon environmental and situational factors that contribute to pediatric overweight. Exploring novel ways to help children make appropriate food and physical activity choices within the constraints of unsafe neighborhoods, low-income households, the limited availability of low-cost healthy food items, and accessibility of television viewing and other sedentary behaviors is challenging but necessary if advances are to be made in reversing the trend of disproportionate overweight and obesity prevalence among minority populations. This must be done within the context of reaching the children, their parents, and their caregivers at the sites where behaviors are learned, reinforced, and practiced, and where model programs and approaches for the prevention or management of overweight can be tested for efficacy.

1.2.3.1 Action Plan

A trans-NIH initiative will solicit grant applications for the prevention or treatment of pediatric obesity in various site-specific settings. The goal is to explore effective methods in pediatric populations for the primary prevention of inappropriate weight gain among those not overweight, secondary prevention to prevent further weight gain among those already overweight or obese, or tertiary prevention, i.e., weight loss and/or increased fitness among overweight or obese children to prevent the complications of associated co-morbidities. A RFA will solicit meritorious applications for pilot/feasibility studies and, where sufficient preliminary data are available from previous studies, applications for full-scale clinical trials will be considered. Investigators will be invited to submit research proposals that will examine novel approaches for interventions within the various sites where children spend the majority of their time and are most amenable to behavioral approaches that will have a positive impact on their weight status. A comprehensive community approach to prevent pediatric obesity might be one that integrates the primary pediatric care setting, school, family/home, and other key influential entities that constitute the community. Such cross-site interventions will be eligible and encouraged. The evaluation of existing community intervention programs would also be considered appropriate. This initiative is an extension of previous trans-NIH research solicitations initiated by NIDDK, focusing on prevention, with an emphasis on children, populations with low socioeconomic status, and racial and ethnic minority populations, disproportionately affected by overweight and obesity.

1.2.3.2 Performance Measures

The performance measures will include the number of grants funded, the quality of proposals, and the level of funding.

1.2.3.3 Outcome Measures

The outcome measures will include evaluation of interventions to promote healthful eating, increased physical activity, and decreased sedentary behaviors; dissemination of results of these studies through publications in the peer-reviewed literature; presentations to the scientific and medical communities,; and translation of successful interventions into practice.

1.2.4 Objective Four: Genetic Determinants of Obesity in Pima Indians

The Pima Indians of Arizona have the highest prevalence of type 2 diabetes mellitus of any population in the world. Obesity is also extremely common, and several types of analyses in the past decade have indicated that obesity in this population has major genetic determinants. A genome wide scan to identify obesity susceptibility loci was completed in 1998 and identified a locus on the chromosome 11q 23 significantly linked to BMI as well as less strongly to type 2 diabetes. A bivariate analysis indicated that this locus increased susceptibility both to obesity and diabetes (LOD score = 5.0). Subsequently, linkage to obesity was also reported, being maximal in two other genomic scans of Caucasian populations at *exactly* the same micro-satellite marker, d11s4464. This was first reported in males in Caucasian pedigrees in Utah and then more recently in the Framingham population-based study in Massachusetts. The Phoenix Epidemiology and Clinical Research Branch has undertaken to positionally clone this gene and has obtained the DNA from the Framingham samples. The dense SNP map at a density of 25 kb is near completion and two major regions of association to BMI have been identified. SNPs in one of these regions were also associated with BMI in the Framingham population, albeit on a different haplotype. If replicated in an additional sample, this would be convincing evidence that the region harboring an obesity susceptibility allele would have been narrowed to a region as small as one mega-base or less.

1.2.4.1 Action Plan

The Phoenix Epidemiology and Clinical Research Branch of NIDDK is continuing this positional cloning effort and is increasing the density of the SNPs in the one mega-base region of interest. Attempts at replication of the association in this region in other populations are currently pending and should further narrow the region for potential complete re-sequencing in affected and non-affected individuals.

1.2.4.2 Performance Measures

In addition to increasing the density of the SNP map in the region associated with obesity in the Pimas and the Framingham study, collaborative arrangements have been developed with other scientists studying other Caucasian groups as well as Mexican American and Chinese samples to determine whether this region is also associated with obesity in these other populations. Pending completion of these studies, initial screening of genes in this genomic region is being undertaken.

1.2.4.3 Outcome Measures

Identification of the polymorphisms resulting in the linkage and association to obesity in this genomic region 11q 23 and a thorough biologic evaluation of their effects on energy balance using experimental animal models and *in vitro* methodologies.

1.2.5 Objective Five: Longitudinal Assessment of Bariatric Surgery (LABS)

The burden of obesity has become one of the leading health concerns in the United States. Obesity has been identified as the second most common cause of death due to modifiable behavioral risk factors, with over 400,000 attributable deaths in the United States in 2000, representing a 33 percent increase over the last decade.

Unfortunately, the traditional approach to weight loss consisting of diet, exercise, and medication generally achieves no more than a 5-10 percent reduction in body weight, and recidivism after such weight loss exceeds 90 percent within 5 years. Obesity affects a greater number of women than men. For example, the rate of obesity in non-Hispanic African American women is 49 percent versus 28 percent in non-Hispanic African American men. In addition, women are more than three to five times more likely to have obesity surgery.

Bariatric surgical procedures, which restrict stomach size and/or lead to decreased absorption of nutrients, increasingly are being performed to treat extreme obesity. These procedures can have dramatic benefits (such as improved control of blood sugar or even reversal of type 2 diabetes) but also carry substantial risks, including death. Although an increasing number of persons with extreme obesity are undergoing bariatric surgical procedures, there has been little systematic research to help determine the risks and benefits of bariatric surgery. Growth in the use of any type of bariatric procedure over the last decade has been truly remarkable, with more than 120,000 procedures performed in 2003 compared to less than 20,000 performed in 1993.

Recent RFAs for Ancillary Studies to Obesity Related Clinical Trials (DK-03-022) and Major Ongoing NIDDK Clinical Research Studies (DK-04-078) solicit grants to expand research on major clinical trial populations, including several trials with enhanced minority participation (Look AHEAD, LABS, and TODAY).

1.2.5.1 Action Plan

The LABS brings together researchers with expertise in bariatric surgery, obesity research, internal medicine, endocrinology, behavioral science, outcomes research, epidemiology, and other relevant fields to plan and conduct studies that will ultimately lead to better understanding of bariatric surgery and its impact on the health and well-being of patients with extreme obesity.

The consortium will develop a database for collecting standardized information on patients undergoing bariatric surgery at the participating clinical centers. This database will greatly assist in developing evidence-based information regarding the risks and benefits of bariatric surgery. Rigorously collected information on patient characteristics, surgical procedures, medical and psychosocial outcomes, and economic factors will ultimately lead to the development of rational recommendations for clinical care.

The LABS will also support clinical studies, as proposed, designed, and approved by the Steering Committee (see below), which will answer questions regarding the impact of surgical procedures on important clinical outcomes. These may include the impact of bariatric surgery on insulin resistance and resolution of type 2 diabetes, or mechanisms by which bariatric surgery may enhance long-term weight maintenance. Other studies may use bariatric surgery as a model to better understand the causes of and potential treatments for obesity. For example, examining the impact of restrictive versus malabsorptive surgical procedures on hormones presumed to affect appetite may provide insights that will lead to new, non-surgical treatments of obesity that mimic the appetite-suppressive effects of surgery.

A repository of data and biological specimens for future research also will be collected by the centers participating in LABS. These will provide valuable resources for future study of obesity and its complications.

Funding for LABS, a 5-year project, was awarded to the clinical centers and data coordinating center in September 2003. During the first year, investigators are working together to develop the protocols and to obtain appropriate human subjects approvals. The core database also will be developed during the first year and subsequently implemented. It is anticipated that the first participants will be enrolled in the LABS database in the fall/winter of 2004/2005. Short-term and longer-term studies will occur during years 2-4, with continued follow-up and study analysis during the final year.

Currently, there are few data on outcomes of bariatric surgery in minorities due to underrepresentation in the population undergoing surgery. Among the six clinical centers participating in LABS are sites with substantial numbers of patients undergoing bariatric surgery who are members of racial/ethnic minority populations. In addition, the East Carolina site recruits patients from a lower socioeconomic status rural population. Thus, LABS should help to provide data on predictors and outcomes of bariatric surgery in minority and medically underserved populations with extreme obesity.

1.2.5.2 Performance Measures

The performance measure will be the number of participants screened and enrolled.

1.2.5.3 Outcome Measures

The outcome measures will include the establishment of a database of patients undergoing bariatric surgery, establishment of comprehensive data and sample repositories for future research, and conduct of studies that will improve the care of persons with extreme obesity.

1.3 Area of Emphasis Three: Disparities in the Burden of Kidney Disease

The most important consequence of kidney disease is the development of chronic kidney failure. End-stage renal disease (ESRD) is a major public health problem for minority populations in the United States. The incidence rate of kidney failure has steadily increased over the past 2 decades, from 74 per million population in 1980 to 336 in 2001. There are striking racial and ethnic differences in the incidence rates. Racial and ethnic minorities, specifically African Americans, American Indians and Alaska Natives, Pacific Islanders, and Hispanic Americans, have disproportionately greater incidence and prevalence rates. For example, in 2001, the incidence rates

were 254 per million population in Caucasians, 998 in African Americans, 395 in Asians and Pacific Islanders, and 696 in American Indians and Alaska Natives. Incidence rates among Hispanic Americans (471) are 45 percent higher than among non-Hispanic persons (325).
The four major causes of ESRD are diabetes mellitus (primarily type 2), hypertension, glomerulonephritis, and cystic renal disease. There is significant variability in the cause of ESRD among the various racial and ethnic groups. For example, whereas diabetic nephropathy is the predominant cause of ESRD in American Indians/Alaska Natives, Asians and Pacific Islanders, Hispanic Americans, and Caucasians, hypertensive nephropathy is the most frequently reported cause of ESRD in African Americans. However, diabetes mellitus is also an important cause of ESRD among African Americans.

When compared with Caucasians, African Americans show a disproportionate increase in the incidence rate of hypertensive ESRD in all age groups, beginning at age 15, with an overall ratio (African Americans to Caucasians) of 6 to 1. This ratio is nearly 20 to 1 in the 20- to 44-year age group. Other diseases causing ESRD in which African Americans and other racial and ethnic minorities show a disproportionate increase over Caucasians include systemic lupus erythematosus (SLE); focal and segmental glomerulosclerosis (FSGS), especially in children; and AIDS, which is especially an important cause of ESRD in African Americans and Hispanic Americans.

The reasons for the racial and ethnic disparities in the incidence and prevalence rates of ESRD remain largely unknown. The Institute devotes considerable fiscal resources in understanding the basic mechanisms underlying the causes and progression of kidney disease to end stage. Specific programs have been initiated to address the racial and ethnic disparities in the specific areas identified. Following are goals that address specific areas of racial and ethnic disparity.

1.3.1 Objective One

Implement a comprehensive program of epidemiologic research of kidney disease to provide definitive data on the minority health burden and to identify risk factors associated with progression of kidney disease and development of CVD in minority patients with renal disease.

We have two major longstanding activities in this area: the first is support of the United States Renal Data System (USRDS), which performs epidemiological investigation of determinants of morbidity and mortality in the end-stage renal disease population. This program has been critical in establishing the increased burden of kidney disease in minority populations and the magnitude of the associated risk of CVD. The second major effort in this area is the AASK cohort study, which follows the participants in a major clinical trial of hypertension treatment for African Americans with kidney disease.

In addition, a number of investigator-initiated grants are exploring these issues in a variety of populations. Most of these grants examine renal outcomes in initially healthy populations such as the participants in the Nurses Health Study. Although these studies are very valuable, the number of cases of ESRD in these samples is small, limiting quantitative assessment of potential risk factors. In addition, we provide support and expertise for kidney measures in the NHANES studies and for other ancillary studies to trials supported by other Institutes and Centers.

A major new activity is that we have recently established a study network to develop a new prospective cohort study of patients with established chronic renal insufficiency (Chronic Renal Insufficiency Cohort Study, CRIC). The study population is complementary to the USRDS, which examines end-stage renal disease patients, and most of the investigator-initiated studies that use existing cohorts of initially healthy individuals.

1.3.1.1 Action Plan

CRIC has the following primary goals: Recruit and follow a large sample of individuals with impaired renal function to: (1) establish the prognostic implications of proteinuria and elevated serum creatinine; (2) determine the risk factors for rapid progression of renal disease; and (3) determine the risk factors among patients with renal disease for development of CVD.

In addition, a number of secondary goals have been established for this study, including to: (1) describe patterns of nutrition and the development of malnutrition; (2) assess the rates and causes of hospitalization and prevalence and incidence rates of other important co-morbid events and diseases; (3) document the overall and cause-specific mortality rates; (4) estimate health services resource utilization; (5) measure quality of life and psychosocial factors that may be associated with decline of renal function and the development of CVD, productivity, and health resource utilization; and (6) establish a specimen bank for future evaluation of genetic and biochemical risk factors and collect and evaluate information on family members that may be useful in studies of genetic factors associated with increased susceptibility to renal disease.

The ultimate goal of this study is to identify risk factors amenable to intervention(s) that can be evaluated in randomized, controlled clinical trials.

Recruitment will emphasize oversampling of minority populations to ensure representation proportionate to the heavy burden of ESRD on minorities. Five recruiting sites (clinical centers), a single data-coordinating center with central laboratories, and an echocardiography and ultrasound reading center have been established. The protocol development is complete, and IRB approvals have been obtained. We anticipate recruitment of 3,000 subjects.

The AASK Cohort Study is a prospective, observational study that is an extension of the AASK clinical trial. The AASK trial was a randomized clinical trial that tested the effects of the different medications used as first-line antihypertensive therapy (ramipril, metoprolol, and amlodipine) and two levels of blood pressure control (usual control and more aggressive control).

Despite excellent blood pressure control and despite use of reno-protective antihypertensive medication, hypertension-related renal disease commonly progresses. The factors that determine the progression of this condition remain poorly understood. The primary objective of the AASK Cohort Study is to determine prospectively the long-term course of kidney function and risk factors for kidney disease progression in African-Americans with hypertension-related kidney disease who receive recommended antihypertensive therapy. A secondary objective is to determine the occurrence of CVD and assess its risk factors in the setting of hypertension-related kidney disease. Research questions that are being addressed include the following:

1. What is the long-term course of kidney function in this population?
2. What are the environmental, genetic, physiologic, and socioeconomic factors that predict the progression of kidney disease?
3. What are the long-term effects of the AASK trial interventions on the progression of kidney disease?
4. Does the development of proteinuria predict the progression of kidney disease?
5. What is the impact of recommended blood pressure therapy, as determined by the AASK trial, on the progression of kidney disease in comparison to usual care in the community? (Note: this question might be addressed using a corresponding subgroup of the CRIC cohort.)
6. What co-morbidities, particularly CVD, occur in the setting of hypertension-related kidney disease?
7. What risk factors predict the occurrence of CVD?
8. What are the patterns of change in metabolic variables and cardiovascular-renal risk factors during the transition from pre-ESRD to ESRD?

Of the 1,094 randomized participants in AASK, approximately 700 individuals who have not reached ESRD have enrolled in the Cohort Study. In addition, those individuals who reached ESRD during the AASK trial have been invited to attend one visit for collection of DNA. For those who enroll in the Cohort Study, twice each year, approximately every 6 months, exposures are collected. Exposures include environmental, genetic, physiologic, and socioeconomic factors.

1.3.1.2 Performance Measures

The following performance measures will be used to evaluate progress of the CRIC study:

1. Recruitment, including assessment of the adequacy of meeting the age, gender, and racial strata.
2. The data coordinating center will assess protocol adherence and report quarterly on protocol adherence.
3. Measures will be instituted for the completeness of the repository samples and data sets.

The following measures will be applied to other aspects of the portfolio:

1. We will track the extent of utilization of the USRDS tapes and the publications that come from uses of these data sets.
2. We will track the extent to which AASK samples and data sets are made available through the NIDDK repository, and the utilization of these resources.

1.3.1.3 Outcome Measures

The first outcome from this overall research program is definitive data to evaluate the minority health burden of kidney disease. This program has the goal of ensuring the availability of definitive data on prevalence and incidence of kidney disease in the major minority groups. These data are critical to identify trends, to track health care utilization, to inform health policy, and to guide research administration.

The second type of outcome is identification of potential risk factors for progressive kidney disease and CVD; critical in the assessment of outcome effectiveness will be the assessment of the quality of the peer-reviewed publications emanating from the studies. Impact will be assessed by monitoring professional meetings, by citation analysis, and by assessment of the impact factor of the publications.

Our third measure of outcome will be assessment of the extent to which these epidemiological studies serve as national resources for investigators outside the primary investigator groups. We will track the extent of utilization of the USRDS tapes and the publications that come from these data sets. Qualified investigators need to have access both to patient clinical and demographic information as well as to archived biological specimens. These resources will permit interested investigators to test important hypotheses about susceptibility to and progression of chronic renal disease and occurrence of CVD and other co-morbid conditions in minority populations. Measures of effectiveness include the number of investigators using the resource and assessment of the quality of any publications resulting from this use.

1.3.2 Objective Two

Support a robust program of genetic investigation into the factors that predispose to higher rates of kidney disease in minority populations.

We have one major activity in this area, which is support of the Family Investigations of Diabetes and Nephropathy (FIND) consortium. The FIND is carrying out studies to elucidate the genetic susceptibility to kidney disease in patients, especially those with diabetes mellitus. African Americans, Hispanic Americans, and Native Americans appear to have an increased incidence and prevalence of diabetic as well as non-diabetic renal disease, and these populations are particularly targeted in FIND.

Several strategies are available for identifying genomic regions involved in the pathogenesis of kidney disease and in the initiation and progression of diabetic retinopathy and nephropathy. The family study component of the FIND will use genome scans and candidate gene analyses. A second part of the FIND will recruit cases and controls and employ the novel Mapping by Admixture Linkage Disequilibrium (MALD) analytic approach with samples from admixed Mexican American and African American populations.
In addition to the main FIND Consortium studies, an ancillary study to the FIND is examining the genetic factors related to progression of kidney disease. This is a longitudinal study of selected FIND participants and family members, focusing on African Americans.

NIDDK supports several other important activities related to the genetics of kidney disease prevalent in minority populations. A number of investigator-initiated grants are exploring the genetics of kidney diseases in a variety of populations, including Native Americans and African Americans. In addition, the newly formed Focal Segmental Glomerulosclerosis (FSGS) Consortium, which is sponsoring an interventional clinical trial, is also collecting genetic samples for studies to identify genetic regions associated with development of FSGS.

1.3.2.1 Action Plan

In the FIND, recruitment emphasizes oversampling of minority populations to ensure representation proportionate to the heavy burden of kidney disease on minorities. There are eight recruiting sites (participating investigative centers), a single data-coordinating center, and central laboratories. The protocol was finalized in 2000, and recruitment is well under way. In addition, three new minority recruitment centers were added in 2003 to augment recruitment of African Americans.

The recruitment targets are 2,000 pairs of siblings (1,180 affected and 743 discordant) for the family-based study, as well as approximately 1,500 cases and controls for the MALD association study. Genotyping will be carried out by an NIH contract facility, the Center for Inherited Disease Research (CIDR).

1.3.2.2 Performance Measures

The following performance measures will be used to evaluate progress of the FIND study:

1. Recruitment, including assessment of the adequacy of meeting the racial strata.
2. The ability to meet the deadlines for shipping samples to CIDR for genotyping.
3. Progress in analyzing genotyping data from the genome scan of family study participants
4. Progress in developing markers and genotyping in the Mexican American and African American MALD studies

For the R01 studies, ancillary study, and FSGS Consortium, the following performance measures will be used to evaluate progress:

1. Recruitment, including assessment of the adequacy of meeting the racial strata.
2. Collection and reposting of appropriate samples and data

1.3.2.3 Outcome Measures

The outcome measures will include successful production of genome scan data and evaluation of those data to identify genetic loci significantly associated with diabetic nephropathy in minority groups. Other important outcome measures are the production of maps of markers suitable for MALD analyses in both Mexican Americans and African Americans, and the use of those markers to carry out mapping of genetic loci significantly associated with kidney disease in each group. Critical in the assessment of outcome effectiveness will be the assessment of the quality of the peer-reviewed publications emanating from the study. Impact will be assessed by monitoring professional meetings, by citation analysis, and by assessment of the impact factor of the publications.

Our second measure of outcome will be assessment of the extent to which genetic resources from the FIND and FSGS consortia are used by investigators outside the primary investigator groups. We will track the number of investigators carrying out ancillary studies using the resources and assess the quality of any publications resulting from this use.

1.3.3 Objective Three

To understand the underlying causes of diabetic nephropathy and causes for the higher prevalence in African Americans, American Indians and Alaska Natives, Pacific Islanders, and Hispanic Americans and to identify therapeutic interventions of particular value in these populations.

In spite of substantial research, the pathogenic and the pathophysiologic mechanisms of diabetic nephropathy remain incompletely understood. As a consequence, there is little understanding of the reasons for the marked differences in susceptibility and rates of progression between the different racial and ethnic populations. For diabetic nephropathy, the high rates of susceptibility encountered in Native American populations are particularly noteworthy. Among the best studied are the Pima Indians; approximately 70 percent of diabetics in this population develop kidney disease. The best strategies for prevention in minority populations are a critical topic of investigation. Large clinical trials supported by NIDDK have established the importance of glycemic control, and the Appropriate Blood Pressure Control in Diabetes (ABCD) Trial has established the importance of optimum blood pressure management. These studies examined results in all ethnic populations, but subgroup analyses suggest that the data are applicable to minority groups, especially Hispanics and African Americans.

1.3.3.1 Action Plan

The NIDDK has a substantial portfolio of clinical investigation of diabetic nephropathy in American Indians, supported through the intramural program. In addition to the portfolio of laboratory intervention, we also support several small pilot studies evaluating interventional methods. Several of these clinical studies are evaluating the factors that affect therapeutic response. A randomized study is examining the response to converting enzyme inhibitors. Another randomized, double-blinded, placebo-controlled clinical trial is underway in Pima Indians to determine whether blockade of the renin-angiotensin system can prevent or attenuate the development and progression of early diabetic kidney disease in type 2 diabetes. A clinical intervention is underway in Pima Indians to determine if angiotensin-converting enzyme inhibitors are effective in slowing the progression of advanced diabetic kidney disease. State-of-the-art measures of kidney structure and function are being made serially in Pima Indians to identify the factors responsible for the development and progression of diabetic kidney disease. Other research is using proteomic methods to evaluate potential urinary markers of progression.

1.3.3.2 Performance Measures

The individual studies will be evaluated for successful completion of patient recruitment and completion of protocols. We also will evaluate the quality of institutional oversight of patient safety issues.

1.3.3.3 Outcome Measures

This research has two potential goals:

1. Development of methods to identify minority population members at highest risk of developing diabetic nephropathy. Such methods could lead to earlier and more effective treatment and prevention of progression to ESRD.
2. Development of targeted treatment strategies. When pathophysiologic mechanisms are better understood, it may become possible to stratify treatment interventions to those most effective in specific populations.

1.3.4 Objective Four

To identify better methods to treat kidney disease caused by systemic lupus erythematosus (SLE).

SLE is a disease that impacts particularly on minority Hispanic and African American women. The NIDDK supports a portfolio of investigator-initiated studies that explore basic mechanisms in this disease. Currently supported research in the general area of glomerulonephritis and tubulointerstitial nephritis includes studies of the pathogenic mechanisms of immunologic injury and repair; the elucidation of nephritogenic antigens; the role of chemokines, antibodies, and cell-cell interactions in kidney damage; the genetic determinants that regulate susceptibility and severity; and the mechanisms of kidney fibrosis. In the specific area of lupus nephritis, ongoing studies address immunologic mechanisms of T cell-mediated and antibody-mediated kidney injury, roles of cytokine and complement components in the initiation and progression of lupus nephritis, and genetic determinants of kidney involvement in lupus.

1.3.4.1 Action Plan

The goal of the current portfolio is to identify and characterize genetic determinants of autoimmune-mediated renal diseases, evaluate inciting antigens triggering the immune response leading to renal injury and disease, and assess the biologic role of mediators in amplifying the renal autoimmune response. In addition, the link of these events to kidney fibrinogenesis or to mechanisms of repair and resolution are critical to delineating pathways that might abrogate disease progression. The development of new experimental models of disease, which better reflect the phenotypic features of human disease, are similarly important.

NIDDK-supported clinical studies in lupus nephritis include a program project that is evaluating the genetic determinants of lupus nephritis in humans, a pilot project evaluating new potential urinary markers of renal disease in patients with lupus, and a research supplement facilitating the establishment of a collaborative network of investigators who can study effective treatment options for lupus nephritis and other glomerular diseases. Potentially one focus of this network would be recruitment of minority populations.

1.3.4.2 Performance Measures

The ongoing genetic studies will be evaluated for successful completion of patient and family recruitment, and completion of protocols. The portfolio will be assessed for overall research productivity.

1.3.4.3 Outcome Measures

This research has two potential goals:

1. Development of methods, either genetic or proteomic, to identify minority population members at highest risk of developing lupus nephropathy. Such methods could lead to earlier and more effective treatment and prevention of progression to ESRD.
2. Development of targeted treatment strategies. When pathophysiologic mechanisms are better understood, it may become possible to stratify treatment interventions to patient subsets that would most likely have the greatest benefit from specific interventions.

1.3.5 Objective Five

To identify better methods to prevent progression of kidney disease due to focal and segmental glomerulosclerosis (FSGS) to ESRD, especially in children.

FSGS is also called focal segmental glomerulosclerosis; it is a pathological entity first described by Rich in 1957 characterized by the presence in some glomeruli, but not all, of areas of mesangial sclerosis. Although it is often secondary to other disorders such as HIV nephropathy, heroin use, or certain malignancies, it also appears as a primary, idiopathic condition; it is typically diagnosed on renal biopsy in nephrotic patients whose nephrotic syndrome has failed to respond to steroid therapy. Secondary forms are more common among older adults, whereas the primary form is more common among children and young adults. FSGS is also among the most common renal diseases to recur post renal transplants, often resulting in allograft injury (20 to 30%) or graft loss (40-50%). The disease appears to be more prevalent and more severe in African American and perhaps Hispanic American children. Although steroid therapy is commonly used in the treatment of children with FSGS, approximately 75 percent of patients do not respond to therapy, relapse while on therapy, or relapse rapidly when therapy is stopped. The overall outcome remains unpredictable, with some patients progressing to ESRD within a period of 2 years, whereas others reach that point after an average of 10 years. In some children, the heavy proteinuria may improve with steroid therapy, but at the cost of significant adverse effects. Furthermore, the disease may progress to end stage. Limited data suggest that immunosuppressive agents, such as cyclosporine, may be beneficial in arresting progression of the disease and in reducing the proteinuria.

1.3.5.1 Action Plan

A multi-center, prospective, randomized, double-blind clinical trial in children will help determine the most efficient way to prevent progression of the disease. The estimated sample size of the study will be approximately 300 patients enrolled over a 4-year period and followed for 18 months. If successful, the results of the clinical trial will guide physicians and the health care team in providing the safest and most efficient medical care to children with FSGS.

1.3.5.2 Performance Measures

During the planning phase, which is currently ongoing, the study will be evaluated for timely development of the study protocol. Once recruitment begins, the study will be evaluated for successful patient recruitment and protocol adherence. We will also evaluate the quality of institutional oversight of patient safety issues.

1.3.5.3 Outcome Measures

This research has the main goal of development of better treatment strategies. In addition, ancillary studies may contribute to improved understanding of pathophysiologic mechanisms and reasons for health disparities.

1.4 Area of Emphasis Four: Sickle Cell Disease and Other Hemoglobinopathies

SCD is a generic term for a group of genetic disorders characterized by the predominance of hemoglobin S (HbS). In the United States, these disorders are most commonly observed in African Americans and Hispanics from the Caribbean, Central America, and parts of South America. In African Americans, one person out of every 375 has homozygous SCD, and in addition, one in 12 African-Americans is a carrier for the disorder (sickle cell trait).

Tissue injury usually is produced by hypoxia secondary to the obstruction of blood vessels by an accumulation of sickled erythrocytes. Symptoms of the hypoxic injury may be either acute (e.g., painful events, acute chest syndrome) or insidious in onset (e.g., aseptic necrosis of the hips, sickle cell retinopathy). The effects of acute and chronic tissue injury ultimately may result in failure of organs such as the kidney, particularly as the patient ages.

Sickle cell anemia and its complications (painful hemolytic anemia crises, strokes, and lung, heart, and kidney complications) are a major cause of morbidity and premature mortality in African Americans.

Although the molecular basis of sickle cell disorders has been well characterized, to date neither cure nor satisfactory treatment of this disease has been realized.

Drugs that increase production of red blood cells and normal hemoglobin have decreased the morbidity of SCD. Recent research suggests that drugs such as nitric oxide that increase oxygenation and blood flow through critical organs may decrease the complications of SCD.

Preliminary studies indicate that adult hematopoietic stem cell transplantation (and possibly gene therapy) offers potential cures for sickle cell anemia.

1.4.1 Objective One

To improve treatment of SCD and other hemoglobinopathies by induction of fetal globin gene expression.

A major area of emphasis in our research portfolio is the developmental processes involved in the differential expression of globin genes. The emphasis is on understanding the mechanisms of regulation of fetal hemoglobin synthesis and the development of new approaches to stimulate fetal hemoglobin production in patients with sickle cell anemia and other beta chain hemoglobinopathies. Also, given the phenotypic diversity of SCD, identification of genetic modifiers is a particularly promising approach.

1.4.1.1 Action Plan

We support an active portfolio of investigations aimed at understanding the regulation of fetal globin gene transcription in a stage-specific manner and the identification of molecules that may be used as drugs to enhance the levels of fetal hemoglobin in the circulating red blood cells of children and adults with hemoglobin disorders. Research goals include the following:

1. Identification and characterization of genetic, molecular, and cellular factors involved in the developmental regulation of the fetal and embryonic globin genes;
2. Investigation of the mechanisms involved in the activation and silencing of the fetal globin genes;
3. Studies of the linkage between erythroid cell differentiation and the developmental control of the globin genes;
4. Examination of the relationship between globin gene expression and the signal transduction mechanisms that are involved in erythroid cell maturation;
5. Determination of the mechanism of action of drugs, such as hydroxyurea and butyrate, that affect fetal hemoglobin (HbF) levels;
6. Discovery of new classes of compounds that can induce fetal hemoglobin in cultures of primary erythroid cells and in animal models; and
7. Development of new model systems to study the regulation of fetal globin genes.

1.4.1.2 Performance Measures

The portfolio will be assessed for overall research productivity.

1.4.1.3 Outcome Measures

This research has the goal of understanding the regulation of gene expression and development of new therapies to modify expression of hemoglobin gene variants, to lead, eventually, to improved therapy for these devastating diseases.

1.4.2 Objective Two: To Improve Treatment of SCD and Prevent Its Complications.

A number of new strategies to treat SCD are being tested. Studies in the NIDDK's intramural research program have shown that drugs that increase production of red blood cells and normal hemoglobin have improved the well-being of patients and decreased the morbidity of SCD. Other recent research findings indicate that drugs, such as nitric oxide, that increase oxygenation and blood flow through critical organs may decrease the complications of SCD. The role of stem cell transplantation is being examined. Since many SCD patients at risk of stroke are being transfused, there is a concern that their rising body iron levels may cause complications.

1.4.2.1 Action Plan

Our research portfolio has grants with the following specific aims:

1. Assess the best methods to assess iron overload in patients with hemoglobinopathies that require multiple transfusions for therapy;
2. Develop improved iron chelating drugs for removal of excess body iron;
3. Determine the role of nitric oxide in preventing the microvascular disease of sickle cell anemia; and
4. Improve the potential of hematopoietic stem cell transplantation for correction of sickle cell anemia.

1.4.2.2 Performance Measures

The portfolio will be assessed for overall research productivity.

1.4.2.3 Outcome Measures

This initiative, if successful, will improve treatment of African Americans with SCD, reducing morbidity and mortality by increasing the amount of functional hemoglobin in circulation and by decreasing body iron levels.

1.5 Area of Emphasis Five: Disparities in the Burden of Diseases of the Prostate

Benign prostatic hypertrophy (BPH) and chronic prostatitis are the two most common diseases of the prostate. Their prevalence far exceeds that of prostate cancer. They affect men of all ages and account for the major health care costs in diagnosis and treatment of prostate diseases. They are very commonly present in patients with prostate cancer. They occur at an earlier age than prostate cancer; their causal relationship to the development of prostate cancer is not known.

Although the available data show that prostate cancer has a higher prevalence in African Americans, the racial disparities for these non-malignant diseases have never been accurately assessed. However, it is assumed that they follow a pattern similar to that of prostate cancer.

In addition to racial disparities in disease prevalence, the disparities in types of therapy, effectiveness of therapy, costs of therapy, and early detection and prevention never have been studied or evaluated.

1.5.1 Objective One

To improve the treatment of BPH and chronic prostatitis, and to establish the prevalence of these disorders in minority men.

In the past, the therapy of BPH used to rely principally on surgical intervention, either open (i.e., suprapubic/retropubic prostatectomy) or transurethral approaches (TURP). Over the last decade, medical therapies have become well established as the initial treatment for the symptomatic patient. The data from the recently completed Medical Therapy of Prostatic Symptoms (MTOPS) clinical trial, which was funded by the NIDDK, has provided an important guide to physicians and patients in the selection of the initial therapy for symptoms of BPH. This study established that in selected patients, excellent outcomes can be achieved by the combination of doxazosin (an alpha adrenergic agent) and finasteride (an alpha-reductase inhibitor). Selection of patients who will benefit from the combined approach uses prostate size, symptom severity and the level of circulating prostate-specific antigen. Many men with mild symptoms turn to herbal therapies such as saw palmetto for symptom relief. A number of small studies support the notion that these therapies are effective in reducing symptoms, but their long-term impact on disease is not established. For more symptomatic disease, non-invasive surgical therapies are increasingly being used. However, a number of unresolved issues exist about the durability of responses and the selection of patients for whom these forms of therapy should be the treatment of choice.

There are also a number of unresolved issues related to the epidemiology, diagnosis, and selection of treatment for men with chronic prostatitis. Although there are neither any effective prevention strategies nor treatments for the cure of the disease, there are a variety of treatment protocols that can provide symptom relief for men suffering with this chronic disorder.

1.5.1.1 Action Plan

The current NIDDK portfolio of research on prostate diseases includes one recently completed clinical trial that focused on BPH, the MTOPS, which had a minority enrollment of 18 percent. We are now initiating two trials that will address critical unresolved issues in the therapy of BPH. The Minimally Invasive Surgical Therapies (MIST) Consortium will evaluate the long-term outcomes of various minimally invasive surgical therapies for BPH. The Complementary and Alternative Medicine for Urological Symptoms (CAMUS) Clinical Trial will examine the effectiveness of alternative medicine/herbal therapies for BPH. We anticipate minority enrollment in these studies of 18 to 25 percent. This sample size will be large enough to identify marked disparities in therapeutic response in the major minority populations in both of these new studies. In addition, the NIDDK funded CPCRN (Chronic Prostatitis Treatment Network) is developing a series of clinical trials designed to evaluate innovative approaches to the treatment of that prostate disorder. Minority enrollment is being encouraged, and it is anticipated that minority enrollment will be approximately the same as in the BPH studies.

Several of the George M. O’Brien research centers focus on basic research aspects of prostate disease, including factors that affect normal and abnormal prostate growth and the relationship to the development of malignant prostate growth (i.e., prostate cancer). Individual basic research grants are diverse and include androgen and hormonal regulation of prostate growth, susceptibility alleles for

BPH, molecular epidemiology of androgen gene expression in the prostate, growth factors, and neuro-endocrine factors in prostate growth regulation.

1.5.1.2 Performance Measures

The portfolio will be assessed for research productivity.

1.5.1.3 Outcome Measures

These studies in the NIDDK portfolio will answer the following questions that address the disparity in prostate diseases in minorities:

1. Is a minority male with either BPH or prostatitis more likely to develop concomitant prostate cancer than a White male?
2. Are specific genetic factors are involved in the development of malignant growth from benign prostate tissues?
3. Is the health burden of BPH and prostatitis different for the White and minority male populations?
4. Does the age of onset of disease symptoms differ between White and minority populations?
5. Does the severity of symptoms differ between White and minority populations?

1.6 Area of Emphasis Six: Peptic Ulcer Disease

Peptic ulcer disease is a common gastrointestinal problem throughout the world. In the United States, peptic ulcer disease affects more than 6 million individuals and accounts for more than $5 billion in direct medical costs and more than 2.5 million office visits annually. The disease causes substantial morbidity and an estimated mortality rate of 3.5/100,000 per year.

The most common causes of peptic ulcer disease are *Helicobacter pylori* infection of the stomach and the use of drugs that injure the stomach, such as aspirin or non-steroidal anti-inflammatory agents, such as ibuprofen.

H. pylori infection is acquired by oral-oral or fecal-oral contamination and is associated with low socioeconomic status in childhood.

In developing countries with low socioeconomic status, *H. pylori* infection is highly prevalent, with upwards of 90 percent of the population being infected. In NHANES III (1988-1991), the overall seroprevalence of *H. pylori* in the United States was 32.5 percent. Age-adjusted prevalence was substantially higher among non-Hispanic Blacks (52.7%) and Mexican Americans (61.6%) than among non-Hispanic Whites (26.2%). The high prevalence of *H. pylori* infection among non-Hispanic Blacks and Mexican Americans is partially explained by low socioeconomic status factors associated with infection.

Untreated *H. pylori* infection causes life-long gastritis and is a known risk factor for another disease, gastric cancer.

In untreated individuals, seropositivity for *H. pylori* strongly suggests the presence of active infection. Following treatment, resolution of infection may be assessed by breath or stool tests or using invasive endoscopy-based tests such as biopsy and culture.

Cure of *H. pylori* is possible in up to about 90 percent of patients with multiple different combination regimens that typically include two antibiotics and an acid-blocking drug such as omeprazole. Failure of cure may be due to lack of compliance with medical therapy, due to side effects or other reasons, and antibiotic resistance, which commonly develops. When *H. pylori* infection cannot be cured, serious complications of peptic ulcer disease can be reduced by long-term administration of acid-blocking drugs.

1.6.1 Objective One: Epidemiological and Clinical Studies of *H. pylori* Infection

The goal of this objective is to elucidate the epidemiological and clinical factors that lead to *H. pylori* infection or alter clinical response to treatment or complications. The short-term goal is to track the changes in *H. pylori* seroprevalence in the United States according to ethnic group and socioeconomic status. The long-term goal is to identify modifiable factors that are suitable for interventions that would decrease the prevalence of *H. pylori* infection and reduce the burden of peptic ulcer disease.

1.6.1.1 Action Plan

1. NIDDK co-funds measurement of *H. pylori* seroprevalence in the United States population. NIDDK funds multiple investigator initiated research projects that have as their objective to identify risk factors associated with presence of *H. pylori* infection, response to treatment, or complications. Projects include high-risk populations such as Mexican Americans, children, and Alaska Natives.
2. The timeline for individual projects varies, from as little as 2 years to longer term studies lasting more than 5 years.
3. The completion date for each study varies and is specifically indicated in the funding plan for each project.

1.6.1.2 Performance Measures

The performance measures to demonstrate that the objectives have been met will include the total number of grants awarded, the quality of proposals funded, the number of patients successfully recruited, and the funding level.

1.6.1.3 Outcome Measures

The outcome measures will be the extent to which modifiable factors are discovered that can be applied in practice to reduce the burden of *H. pylori* infection.

1.6.2 Objective Two: Basic Research in *H. pylori* Pathogenesis

The long-term goal of this objective is to support basic research, including translational research that has the potential for development of novel ways to identify, prevent, and cure *H. pylori* infection.

1.6.2.1 Action Plan

1. NIDDK funds multiple investigator-initiated research project grants that investigate areas of research potentially relevant to *H. pylori* infection, including studies of the microbiology of *H. pylori*, studies of the immune and inflammatory response, studies of epithelial integrity and repair, studies of cell growth related to neoplasia, and mechanisms of acid production and inhibition.
2. The timeline for individual projects varies, from as little as 2 years to longer term studies lasting more than 5 years.
3. The completion date for each study varies and is specifically indicated in the funding plan for each project.

1.6.2.2 Performance Measures

The performance measures to demonstrate that the objectives have been met will include the total number of grants awarded, the quality of proposals funded, the number of patients successfully recruited, and the funding level.

1.6.2.3 Outcome Measures

The outcome measures will be the extent to which modifiable factors are discovered that can be applied in practice to reduce the burden of *H. pylori* infection.

1.7 Area of Emphasis Seven: Hepatitis C Among African Americans

Between 3 and 4 million Americans are infected with hepatitis C. The hepatitis C virus (HCV) is the major cause of cirrhosis and end-stage liver disease in the United States, accounting for 8,000 to 10,000 deaths per year and at least 30 percent of all liver transplants done in adults in the United States. The current optimal therapy of chronic hepatitis C is a combination of pegylated alpha interferon and ribavirin given for 24 to 48 weeks. However, treatment is successful in eliminating the virus in only 50 percent of patients with genotype 1, who are the majority of infected patients in the United States.

1.7.1 Objective One: To Elucidate the Reasons for Low Hepatitis C Treatment Response Among African Americans and To Prevent Complications.

Hepatitis C infection disproportionately affects African Americans, who have twice the prevalence of non-Hispanic Whites. Furthermore, African Americans are less likely to respond successfully to therapy, although the reasons for lower response are unknown. In addition, African Americans have a higher incidence of serious complications of chronic liver disease, including hepatocellular carcinoma, one of the most rapidly increasing and fatal malignancies in the United States.

1.7.1.1 Action Plan

NIDDK funds two multi-center treatment studies of Hepatitis C with substantial minority participation. The Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) clinical trial is an 8-year study of therapy for hepatitis C focusing on patients with advanced disease (with severe fibrosis or cirrhosis) who had not responded to conventional therapy and for whom there are no other practical options available. About 28 percent of the more than 1,000 patients randomized belong to ethnic minority groups. Eighteen percent of the total is African American. Patients were randomly assigned to receive long-term treatment with pegylated interferon (a once weekly injection) or no therapy. The purpose of this project is to determine the following: (1) if 4 years of interferon therapy will prevent the progression of advanced fibrosis to cirrhosis in patients with chronic hepatitis C in whom previous interferon therapy failed; (2) if 4 years of interferon therapy in patients with cirrhosis secondary to chronic hepatitis C in whom previous interferon therapy failed will reduce the risk of developing hepatic decompensation, reduce the need for hepatic transplantation, and reduce the risk of developing hepatocellular carcinoma; and (3) if 4 years of interferon therapy will improve the quality of life in patients with advanced fibrosis secondary to chronic hepatitis C in whom previous interferon therapy failed. This study will conclude in 2008.

The Study of Viral Resistance to Antiviral Therapy of Chronic Hepatitis C (Virahep-C) will elucidate the nature and determinants of a response to antiviral therapy among African Americans and non-Hispanic Whites with genotype 1 who have not previously been treated. The purpose of this project is the following: (1) Establish rates of sustained virological response to a 48-week course of combination antiviral therapy among African American and non-Hispanic White patients with chronic hepatitis C; and (2) establish what factors are most predictive of a response to combination therapy in each of the two racial groups of patients infected with hepatitis C. Ancillary studies are prospectively examining the virological, genetic, and immunological determinants of treatment resistance and response. Enrollment of 400 patients, half African-American and half Caucasian, was completed in January 2004. This study will conclude in 2006.

1.7.1.2 Performance Measures

The performance measures to demonstrate that the objectives have been met will include the successful retention and measurement of outcomes of patients.

1.7.1.3 Outcome Measures

The outcome measures will be the elucidation of the reasons for lower treatment response among African Americans and the extent to which treatment against hepatitis C can be shown to prevent the progression and complications of chronic liver disease.

1.8 Area of Emphasis Eight: Nonalcoholic Steatohepatitis

Nonalcoholic steatohepatitis (NASH) is a common but poorly understood liver disease characterized by the accumulation of fat in the liver (steatosis), accompanied by inflammation, cell injury, and fibrosis (hepatitis), that closely resembles alcoholic liver disease but occurs in patients who drink little or no alcohol. NASH most commonly occurs in adults over the age of 40 who are overweight or have diabetes, insulin resistance, or hyperlipidemia. However, the disease also occurs in children and in persons who are not obese or diabetic. Currently, there are no effective therapies for NASH, and its natural history and prognosis are not well understood. The lack of clear understanding of the pathogenesis of NASH and its natural history, prognostic features, and treatment all underscore the need for clinical and basic research into this important liver disease.

1.8.1 Objective One: Natural History, Pathogenesis and Therapy of NASH

Create a multicenter prospective study of patients with NASH to elucidate the natural history, pathogenesis and therapy of this disease.

1.8.1.1 Action Plan

The NIDDK funds a cooperative agreement, the Nonalcoholic Steatohepatitis Clinical Research Consortium (NASH CRN), to focus on the etiology, contributing factors, natural history, complications, and therapy of NASH. Eight clinical centers and a data coordinating center make up the NASH CRN. Approximately 1,500 pediatric and adult participants with NASH will be included in both retrospective and prospective databases. Research to date suggests differences in epidemiology among different racial and ethnic groups; therefore, efforts to include a diverse participant population are critical. A three-arm randomized, placebo-controlled clinical trial (RCT) of an insulin-sensitizing agent or vitamin E will be conducted in 250 non-diabetic adult participants with documented NASH. A trial in pediatric NASH patients will randomize 180 children to receive treatment with vitamin E, metformin, or placebo. Treatment will be for 2 years. Enrollment into both trials and the database will begin in 2004. The NASH CRN is funded through 2007.

1.8.1.2 Performance Measures

The performance measures will include the successful enrollment, retention, and measurement of outcomes of study participants.

1.8.1.3 Outcome Measures

The outcome measures will be the extent to which the natural history, prognostic features, and treatment options can be discovered and applied in clinical practice to reduce the progression, morbidity, and mortality of this important liver disease.

1.9 Area of Emphasis Nine: Organ Donation

Racial and ethnic minorities, particularly African Americans, American Indians, Alaska Natives, and Hispanic Americans, are disproportionately afflicted with organ failure such as ESRD. Although organ and tissue transplantation is the most efficient organ replacement therapy because of the improved survival and improved quality of life for successful transplant recipients, racial and ethnic minority groups are less frequently transplanted. A frequently cited reason for the lower transplantation rate in these minority groups is that their organ donation rate is much lower than their representation in the ESRD patient population, and that with an increased number of minority organs in the pool, there would be a better match, and ultimately, better graft survival.

Over the past decade, several programs have been initiated to increase minority organ and tissue donation. The NCMHD/NIDDK funded Minority Organ and Tissue Transplant Education Program (MOTTEP) was established in which intensive educational and information activities have occurred in 15 cities across the United States. During the same period, the Department of Health and Human Services has intensified educational and information programs throughout the United States through the Organ and Tissue Donation initiative. Perhaps as the result of these combined efforts, organ and tissue donation has increased, especially in minority communities. However, the rate of organ and tissue donation from minorities is lower than their representation in the population with organ failure, especially ESRD. Increasing educational activities in racial and ethnic minority communities, as well as in underserved populations, will enhance their proportion of organs in the pool, and hence increase the chances of a better match and improved graft survival.

1.9.1 Objective One: Minority Organ and Tissue Donation

The program is intended to create an environment supportive of organ donation by:

- Increasing exposure to donation messages and opportunities to express donation commitments. This could be accomplished through: (1) increasing exposure in national and local media; (2) increasing community interventions (at schools, churches, etc.); (3) increasing promotion of organ donation through health promotion and disease prevention efforts; and (4) disseminating and replicating best practices identified through research and evaluation;

- Evaluating the impact of increased support for living organ donation (e.g., provisions to cover child care, travel, and other expenses for living donors);
- Increasing minority cadaveric and living organ donation; and
- Increasing donation from non-traditional donors (older donors, living donors, etc.).

1.9.1.1 Action Plan

A RFA was issued and five institutions were awarded grants in 2002. Each grant is for 5 years. In 2006, the program will be re-evaluated and a new RFA will be issued if there is a continuing shortage in minority organ and tissue donation.

1.9.1.2 Performance Measures

The investigators will be required to evaluate patterns of organ and tissue donation locally and regionally. The performance measures will include assessment of the attitude and patterns and practices of organ and tissue donation in the various communities impacted by the program. These regional analyses will provide insight into the national trends.

1.9.1.3 Outcome Measures

Data analysis from the United Network for Organ Sharing (UNOS) and the USRDS will be used to assess the magnitude of disparities in organ and tissue donation and transplantation nationally.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Training

Many of the diseases that disproportionately afflict racial and ethnic minorities fall within the mission area of the NIDDK. Investigators who address these disease areas should include individuals from communities that are impacted. Unfortunately, there is severe shortage of racial and ethnic minorities in the pool of investigators. Therefore, there is a need for programs designed to increase the number of students from minority and other underrepresented populations in the pipeline for biomedical research careers. The scientific community is interested in attracting qualified minority students into research careers, but few minority students opt for science degrees and research careers, and fewer minority graduates of health professional schools pursue research careers. The shortage of qualified minority investigators in academic research positions exacerbates the situation because this means there are few visible role models for students. One way to address this problem is to expose students from minority and other underrepresented populations to research opportunities early in their education and to provide them with research training opportunities to develop both their research capabilities and their interest in pursuing a career in research. NIDDK's training programs are intended to include most of the stages and steps in the pipeline.

2.1.1 Objective One: National High School Student Summer Research Program (NHSSSRP)

During the last 2 decades it became broadly recognized that disadvantaged segments of the U.S. population were not benefiting from advances in health care to the same degree as the majority (White) population. In 1984, the Secretary of Health's Task Force Report on "African American and Minority Health" identified several areas of excessive deaths, including cardiovascular (and related) diseases, diabetes, cancer, accidents and intentional injuries, digestive diseases, and infant mortality, among others. The Department of Health and Human Services implemented the Healthy People Initiative to address these health disparities. In the latest version of the Healthy People Initiative, Healthy People 2010, a key component of addressing not only health disparities in disadvantaged communities, but also the overall health of the nation, is the recognized need to increase the quantity and quality of women and investigators from diverse racial and ethnic groups with a deep sense of commitment to improving the health care of our increasingly diverse nation who will perform high-quality research that ultimately will lead to reduction/elimination of existing disparities in health outcomes. Such investigators would be well equipped to integrate emerging advances in basic science, behavioral sciences, and clinical studies into new research hypotheses and the dissemination of evidence-based health care. Early exposure to biomedical research by a diverse pool of young students with a high level of interest and deep passion for research may help address this need.

Minority and other underrepresented populations account for a disproportionately low proportion of full-time academic faculty, and are less likely to hold senior academic rank. The paucity of underrepresented minority faculty may contribute to patterns in research and education that ultimately manifest as disparities in health care at a clinical level. The recognition of these disparities has led to substantial efforts to develop and enhance research training opportunities for underrepresented minority and other underrepresented populations as early in their educational careers as possible. The NHSSSRP is designed to enhance exposure to basic and clinical research and academic medicine as viable and desirable career choices among a pool of high school students who come from minority and other underrepresented populations. Such a program serves as an early component of the pipeline that brings students from economically disadvantaged backgrounds and medically underserved populations to the corridors of academia, which, in turn, focuses on producing scientists, physicians, and allied health professionals to practice in their respective communities.

2.1.1.1 Action Plan

The NHSSSRP was initiated in 1995 by placing high school students of high academic standing in the laboratories of accomplished investigators. Since then the program has improved, and a larger number of students are placed in various research environments. Approximately 95 percent of these students are from minority and other underrepresented populations. They undergo 8 to 12 weeks of exposure to scientific research methodologies in the summer and are encouraged to carry out specific research projects under the guidance of the mentors. At the end of the project period, they are invited to the NIH campus, where they meet with other students and discuss their research projects and findings in a formal oral and poster presentation. Currently, of the more than 300 applications that are received, approximately 65 students are selected each summer for the research experience. Students are admitted to the program from all regions of the United States, including Alaska, Hawaii, and Puerto Rico.

2.1.1.2 Performance Measures

The performance measures include the number of students who have successfully completed the program each year. Each student should demonstrate complete comprehension of the projects undertaken and be able to communicate both orally and in writing with others about the project.

2.1.1.3 Outcome Measures

The outcome measures include an increase in the number of students from minority and other underrepresented populations participating in the program who ultimately have selected biomedical sciences and biomedical research as careers.

2.1.2 Objective Two: Diversity Supplement Program to Institutional National Research Service Award (NRSA), T32

Under this program, the NIDDK administratively awards an extra position, designated specifically for a trainee (either predoctoral or postdoctoral), to an existing T32 award (NIH Program Announcement (PA-05-015) entitled “Research Supplement to Promote Diversity in Health-Related Research”). That position then remains a part of the T32 for as long as the named individual is a member of the training program. When the individual no longer receives support from the T32, the funds for his/her position are removed from the grant.

2.1.2.1 Action Plan

To ensure an appropriate training experience, only predoctoral slots are awarded to T32s exclusively supporting predoctoral training; only postdoctoral slots to postdoctoral training programs. Mixed programs (i.e., those supporting both pre- and postdoctoral training) could apply for either. Examples of the program include:

- *Short-term training for medical students:* The NIDDK provides the opportunity for underrepresented and disadvantaged medical students, during a 3-month summer research experience, to be supported via a supplement to any existing NIDDK training grant. These short-term slots are awarded at the predoctoral stipend level, and T32 directors may request support for up to three individuals per year. The parent T32 may be a predoctoral program, a postdoctoral program, or one that supports both pre- and postdoctoral training.

- *Year-off training for medical students:* The NIDDK provides the opportunity for underrepresented and disadvantaged medical students to pursue a longer period of research training to be supported for a full 9-12 month period, while on leave from medical school, via a supplement to any existing NIDDK training grant. These year-off slots are awarded at the predoctoral stipend level. T32 directors could request support for only one individual per year. The parent T32 may be a predoctoral program, a postdoctoral program, or one that supports both pre-and postdoctoral training. The medical student must be in good standing at the medical school and have permission, in writing, from the Dean's office to participate in this program, with assurance that his/her medical studies will continue after the research year has been completed.

2.1.2.2 Performance Measures

The performance measures include the number of medical students, predoctoral students, and postdoctoral fellows who are recruited and have completed the training yearly in both the short-term training and the year-off programs.

2.1.2.3 Outcome Measures

The outcome measures include the total number of trainees recruited into the program who successfully complete the program and have established careers in biomedical research, especially in the NIDDK mission areas.

2.1.3 Objective Three: NIH Predoctoral Fellowship Awards to Promote Diversity in Health-Related Research (F31)

The NRSA Predoctoral Fellowship to promote diversity in health-related research provides up to 5 years of support for research training leading to the Ph.D. or equivalent research degree; the combined M.D./Ph.D. degree; or other combined professional degree and research doctoral degree in the biomedical sciences, the behavioral sciences, or health services research. These fellowships are designed to enhance the diversity of the biomedical, behavioral, and health services research labor force in the United States.

2.1.3.1 Action Plan

Through this program, academic institutions are encouraged to identify and recruit students from minority and other underrepresented populations who can apply for this fellowship. Support is not provided to individuals enrolled in medical or other professional schools unless they are also enrolled in a combined professional doctorate/Ph.D. degree program in biomedical sciences, behavioral sciences, or health services research.

2.1.3.2 Performance Measures

The performance measures include the number of students from minority and other underrepresented populations that successfully compete for the fellowships each year.

2.1.3.3 Outcome Measures

The outcome measures include an increase in the number of students who have received and completed the fellowship awards, and are successful in pursuing careers in biomedical research, especially in the NIDDK mission areas.

2.1.4 Objective Four: Small Grants for Underrepresented Investigators

This program is aimed primarily at recently trained M.D. and/or Ph.D. investigators. The program enables the applicant to accept a tenure-earning position, gain additional research experience while transitioning to independence, and obtain preliminary data on which to base a subsequent research grant application in an area of diabetes, endocrinology, metabolism, digestive diseases, hepatology, obesity, nutrition, kidney, urology, or hematology research.

2.1.4.1 Action Plan

The primary purpose of this program is to foster the research careers of underrepresented and disadvantaged investigators conducting research in areas of interest to the NIDDK. Individuals who have received training through individual postdoctoral fellowships or institutional training grants still require a transition period to demonstrate independence and to generate the preliminary data necessary for obtaining independent funding. This small grant program provides this transitional support and encourages underrepresented and disadvantaged investigators to pursue research careers and become independent scientists.

2.1.4.2 Performance Measures

In the short term, the performance measures include the total number of underrepresented and disadvantaged faculty members who successfully compete for these awards each year. These investigators are in the tenure track of the respective academic institutions, require minimal mentoring, and use this opportunity to transition from trainee status to independent investigator.

2.1.4.3 Outcome Measures

The outcome measures include the proportion of investigators with these transition awards who are successful in competing for higher awards such as R01, become tenured faculty members, and become role models for younger underrepresented and disadvantaged persons. These senior faculty members also will become mentors for younger investigators.

2.1.5 Objective Five: Short-Term Educational Program for Underrepresented Persons (STEP UP)

The NIDDK Short-Term Education Program for Underrepresented Persons (STEP UP) is intended to offer research-education opportunities for underrepresented and disadvantaged students in an effort to encourage them to pursue a research career in an area of science relevant to the interests of the NIDDK. NIDDK supports research in the areas of diabetes, endocrinology, metabolism, nutrition, obesity, and digestive, liver, urologic, kidney, and hematologic diseases, and recognizes the need for a diverse workforce, representative of the population, to pursue this research.

2.1.5.1 Action Plan

NIDDK issued a RFA, DK-03-014, seeking experienced and interested investigators to apply for grants that provide two to three consecutive months of research training and expose talented students to experiences that will help them pursue a biomedical or behavioral research career. In addition to the research experience, institutions provide enrichment activities such as research forums, guest lectures, student presentations, special courses, and social activities. Six institutions received awards and are recruiting high school and undergraduate students from minority and other underrepresented populations for training. These institutions will recruit students from underrepresented communities including African Americans, Native Hawaiians and other Pacific Islanders, and other underrepresented populations. These institutions are encouraged also to reach out to students from the American Indian and Alaska Native communities.

2.1.5.2 Performance Measures

In the short-term, the performance measures will include the success these institutions have in recruiting and training qualified underrepresented and disadvantaged students. The students will be asked to provide comments on the experience and to what degree the research experience stimulates them into making decisions to pursue careers in biomedical research.

2.1.5.3 Outcome Measures

In the long term, the outcome measures will include the proportion of the students participating in the program who follow careers in biomedical research.

2.2 Area of Emphasis Two: Increase the Number of Minority Investigators Conducting Health Disparities Research in Academic Institutions

Many diseases and disorders that disproportionately affect the health of minority populations in the United States receive high priority and are NIDDK research areas, including diabetes, obesity, nutrition-related disorders, hepatitis C, gallbladder diseases, *H. pylori* infection, SCD, kidney diseases, and complications from infection with HIV. NIDDK gives increased priority to support research and to encourage specific efforts in these areas of health disparity to advance the foundation of knowledge in the biomedical sciences. The strategic vision that guides NIDDK is improved health and quality of life for all Americans through basic, clinical, and behavioral research to address the diseases and disorders within the Institute's statutory research mandate. To achieve this goal, NIDDK believes that investigators carrying out the research should have at least equal representation from all racial and ethnic groups. Since racial and ethnic minorities are severely underrepresented among investigators carrying out NIDDK's mission, programs and initiatives are being implemented to ensure their increased number in the research enterprise.

2.2.1 Objective One: Network of Minority Research Investigators

The NIDDK has established a communication network of current and potential biomedical research investigators and technical personnel from traditionally underserved communities: African American, Hispanic American, American Indian, Alaska Native, Native Hawaiian, and other Pacific Islanders. The major objective of the network is to encourage and facilitate participation of members of underrepresented racial and ethnic minority groups in the conduct of biomedical research in the fields of diabetes, endocrinology, metabolism, digestive diseases, nutrition, and kidney, urologic, and hematologic diseases. A second objective is to encourage and enhance the potential of the underrepresented minority investigators in choosing a biomedical research career in these fields. An important component of this network is promotion of two-way communications between network members and NIDDK.

2.2.1.1 Action Plan

The primary goals of the Network are to help minority investigators achieve career success while working on issues concerning health-related racial and ethnic disparities. The activities and programs of the NMRI constitute a unique opportunity for junior investigators to meet and be mentored by NIDDK staff and senior investigators from various organizations and academic institutions across the United States. It is also a chance for the junior investigators to increase their knowledge base and to develop long-term collaborations with fellow investigators. Senior investigators mentor junior investigators and are available to speak at the general sessions and facilitate the breakout sessions at NMRI Workshops, and they have the opportunity to recruit junior investigators to join their staffs and laboratories.

Through the NMRI, the NIDDK will:

1. Increase participation of minority and other underrepresented populations in research in NIDDK areas and establish frequent communication between Network members and the NIDDK program staff about available opportunities.
2. Identify, through discussions with network members, (new) programs and other mechanisms that will increase the participation of underrepresented minorities in biomedical research.

3. Define barriers for participation of underserved populations in biomedical research, and formulate initiatives that will help overcome the barriers.
4. Identify projects at the community level that will help reduce/eliminate health disparities in the respective populations. Example: Initiative 1041: Diabetes-Based Science Education in Tribal Schools, etc.

The NMRI activities and program also cover a broad range of topics of interest to the investigators. For example, such topics as *Health Disparities in the United States, Grant Writing, Effective Networking and Meaningful Collaboration, Funds and Other Resources for Support of Research, Balancing Research With the Rest of Your Life, Postdoctoral Fellow to First Faculty Appointment,* and *Junior Faculty to Tenured Faculty* are covered in general sessions and breakout sessions of NMRI Workshops.

All of the investigators benefit from being NMRI members and participating in current and future workshops because they learn from each other's experiences. Through Workshops, the careers of investigators are elevated to the next level; they form lasting friendships and collaborations, and they know that they are major players in contributing to the eradication of health disparities.

2.2.1.2 Performance Measures

The performance plan includes successful recruitment of senior and junior investigators, medical students, and postdoctoral fellows into the Network. There will be critical assessment of the success with which senior and junior investigators, especially, are able to work together to improve the chances of success and longevity of the junior investigators in the academic environment.

2.2.1.3 Outcome Measures

The outcome measures include the extent to which members of the Network are successful in the academic environment through increased numbers, success in procuring grants from the NIH and other sources, and advancement on the academic ladder.

2.2.2 Objective Two: NIDDK Fellowship to the National Medical Association Convention

The intent of this award is to enhance the potential research careers of residents and fellows and to encourage research in disease areas that disproportionately impact the health of underserved communities. The NIDDK anticipates that through this scientific opportunity, a greater number of physicians from communities underrepresented in science will enter into and remain in research positions.

2.2.2.1 Action Plan

Fellowship awards are provided to individuals from a pool of applicants to attend the annual convention of the National Medical Association. Selections for the award are based on the applicant's general research ambition, letters of reference, and record of excellence in science. Each selected trainee is awarded funds to cover transportation, hotel, and meals for 3 days.

By participating in the scientific symposium, the residents or fellows have the opportunity to interact with preeminent scientists in basic, behavioral, and clinical research. Further, the clinical trainees are exposed to research opportunities through the NIDDK-sponsored workshop at the National Medical Association Annual Convention and Scientific Assembly. The workshop is intended to address some of the difficulties faced by young faculty, especially those from disadvantaged backgrounds, the roadblocks to a successful career in academia, and career development challenges. Some of the questions addressed in the workshop include the following:

- You are finishing your research training and are faced with finding a faculty position. What do you do? What are the most important parameters to consider?
- How do you choose the right institutional match to maximize your productivity and advancement?
- What institutional factors (formal and informal) measure success? How do you find out this information?
- You are a new assistant professor with good research training and strong clinical skills. You are offered a position that includes lab space, start-up funds, etc., and directorship of a diagnostic laboratory at a significant salary augmentation. What factors are important in assessing this offer?
- You are a new faculty member assigned a "career mentor." What should you expect from this mentor? What are your responsibilities? What other (if any) mentors do you need?
- Your "mentor/mentee" relationship does not seem to be working. What should you do?
- You are very busy and think overall that you're doing very well, but at your annual review, your chair expresses concerns about your productivity. How should you respond and what should you do?

2.2.2.2 Performance Measures

The performance measures include the number of trainees from disadvantaged communities who successfully compete for the awards and are exposed to the program. The workshop will be evaluated to ensure that the intent of the initiative is met and that it appropriately addresses career development challenges for faculty from minority and other underrepresented populations.

2.2.2.3 Outcome Measures

The outcome measures include the extent to which participants in the program are successful in the academic environment through increased numbers, success in procuring grants from the NIH and other sources, and advancement on the academic ladder.

2.2.3 Objective Three: Summer Internship Program

This 10-week summer program provides an opportunity for undergraduate students to participate in research under the direction of preceptors in NIDDK laboratories. The purpose of this program is to advance the state of biomedical knowledge and to introduce the students to current laboratory methods in the field.

2.2.3.1 Action Plan

The NIDDK invites students to submit applications for the Summer Research Training Program. Selected students join one of NIDDK's research laboratories for 10 weeks between late May and August. During this period, they are also expected to participate in meetings and seminars in their individual laboratories. In addition, with permission from their preceptors, students may also attend formal lectures and symposia, which are listed in the weekly "NIH Calendar of Events." At the end of the summer, students participate in the Summer Research Program Poster Day. This provides an opportunity for students to present their work before the NIH scientific community.

For participation in the program, each student is provided with housing, per diem, and travel expenses.

Program Highlights

- Independent research in a NIH laboratory
- Weekly research and career development seminars
- Summer seminar series where senior NIH investigators discuss the latest developments in biomedical research
- Poster presentation

2.2.3.2 Performance Measures

The performance measures include the number of students who have successfully completed the program each year. Each student should demonstrate complete comprehension of the projects undertaken and be able to communicate both orally and in writing with others about the project.

2.2.3.3 Outcome Measures

The outcome measures include increases in the number of students from minority and other underrepresented populations participating in the program who ultimately have selected biomedical sciences and biomedical research as a career.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: National Diabetes Education Program (NDEP) Multicultural Campaigns

The NIDDK launched the NDEP with the CDC in 1997 to change the way diabetes is treated. NDEP takes a multicultural approach to address its goals of improving diabetes treatment and outcomes for African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans with diabetes. NDEP promotes early diagnosis and prevention of diabetes, thus reducing morbidity and mortality associated with the disease. NDEP components include public awareness and education campaigns, special population approaches, community-based interventions, health system changes, and an inclusive partnership network. Strategies and activities are being implemented in each of these component areas through established partner-based Work Groups that provide guidance, direction, and resources. Specific Work Groups representing each targeted minority population assist NDEP in developing strategies, activities, and products that are culturally and linguistically appropriate and disseminate the materials to their communities.

In 2003, 18.2 million people in the United States, or about 6.3 percent of the population, are estimated to have diabetes. In addition, 41 million Americans have pre-diabetes, a condition in which blood glucose levels are higher than normal, placing people at increased risk for developing type 2 diabetes. Racial/ethnic minorities are disproportionately affected by diabetes. For example, African Americans are 1.6 times more likely to have diabetes as non-Hispanic Whites of similar ages; Hispanic and Latino Americans are 1.5 times as likely to have diabetes as non-Hispanic Whites of similar ages; and, American Indians and Alaska Natives are 2.3 times as likely to have diabetes as non-Hispanic Whites. Although prevalence data for diabetes among Asian Americans and Pacific Islanders are limited, some groups within this population are at increased risk for diabetes. For example, in 2002, Native Hawaiian, Japanese, and Filipino residents of Hawaii ages 20 or older were approximately 2 times as likely to have diagnosed diabetes as White residents of Hawaii of similar ages.

3.1.1 Objective One: Increase Awareness About Prevention of Type 2 Diabetes

NDEP's priority objective is to increase awareness of diabetes and its risk factors and potential strategies for preventing diabetes and its complications among African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans.

3.1.1.1 Action Plan

In response to the growing diabetes epidemic, NDEP is taking the lead on delivering type 2 diabetes prevention messages to these high risk groups. In April 2004, coinciding with National Minority Health Month, NDEP announced the first phase of the national multicultural diabetes prevention campaign, "Small Steps. Big Rewards" (SSBR). The campaign focuses on empowering people at high risk to make modest lifestyle changes that can prevent or delay the onset of type 2 diabetes. Campaign materials include radio and print public service announcements, information kits for communities and the media, and educational materials tailored to different racial/ethnic groups. For example, "We Have the Power to Prevent Diabetes" materials are designed to promote the message among American Indians and Alaska Natives that diabetes prevention is proven, possible, and powerful. The "Prevengamos la diabetes tipo 2. Paso a Paso." campaign spreads the prevention message to at-risk Hispanics/Latinos, with materials available in Spanish and English.

To promote the campaign, NDEP has formed the SSBR Team to Prevent Diabetes, which includes people from across the country who represent each of the high-risk populations. This team will assist in the next phase of the SSBR campaign, which will consist of five media events, or "Steps Across America" Road Shows, in cities where team members reside. The road shows will have messages similar to those of the national launch: (1) Given the diabetes epidemic, each group is at high risk for developing diabetes; (2) Diabetes can be prevented by taking small steps to lose a small amount of weight; (3) Diabetes is not inevitable and prevention is possible, regardless of age, ethnicity, or family history of the disease; and (4) NDEP has free, practical, and reproducible materials and tools tailored for people at high risk. These materials are available in several languages through the NDEP web site, the National Diabetes Information Clearinghouse, and partner organizations.

The schedule for the Road Shows includes the following tentative dates and locations.

Ada, Oklahoma, Summer 2004. Theme: *We Have the Power to Prevent Diabetes* – American Indians and Alaska Natives

Phoenix, Arizona, June 29, 2004. Theme: *Prevengamos la diabetes tipo 2. Paso a Paso* (Let's prevent type 2 diabetes. Step by Step) – Hispanic/Latino Americans

Philadelphia, Pennsylvania, July 19, 2004. Theme: *More Than 50 Ways To Prevent Diabetes* – African Americans

San Diego, California, September, 2004. Theme: *Two Reasons to Prevent Diabetes: My Future and Theirs* – Asian Americans and Pacific Islanders (available in as many as 15 languages)

Jacksonville, Florida, October, 2004. Theme: *It's Not Too Late to Prevent Diabetes. Take Your First Step Today.* – Older Adults

3.1.1.2 Performance Measures

NDEP will conduct a quantitative evaluation for each Road Show site. This information will be presented to the NDEP Steering Committee of community organizations and other federal agencies. Recommendations will be submitted to each work group to improve future planning.

3.1.1.3 Outcome Measures

The outcome measures will focus on the longer-term impact of program activities of NDEP and its partner organizations on the target audiences: African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans—by assessing awareness, attitudes, and behaviors with regard to diabetes prevention and diabetes control and treatment.

NDEP has applied for "1% evaluation set-aside funding" to conduct three surveys of the public and health care providers. These surveys will provide a quantitative assessment of public and health care provider beliefs, attitudes, knowledge, and practices related to prevention and management of diabetes, and also will provide benchmarks against which program effects can be evaluated. These surveys will assess exposure to campaign materials and the impact of the campaign on the awareness level, knowledge, attitudes, and behaviors of target audience members. The data collected through these surveys will supplement available secondary data, gathered from a variety of sources including NHANES, the NHIS, and the Behavioral Risk Factor Surveillance System (BRFSS), to assess and refine overall campaign strategies and tactics. These surveys will yield insight into what the campaigns achieved and what factors contributed to their anticipated success.

3.1.2 Objective Two: Improve Diabetes Control Among Members of Ethnic Minority Groups With Diabetes

NDEP seeks to improve understanding about diabetes and its control and to promote better self-management awareness among African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans with type 2 diabetes.

3.1.2.1 Action Plan

NDEP is conducting a series of diabetes awareness campaigns using the theme "Control Your Diabetes for Life" to encourage people to manage their diabetes to live healthier lives. Campaign messages emphasize that diabetes can be controlled by eating healthy foods in the right amounts, getting regular physical activity, taking diabetes medications as prescribed, and testing blood sugar on a regular basis. Campaign materials offer tips to help people with diabetes keep their blood sugar under control.

Campaign messages are being delivered through television, radio, and print public service announcements in English and Spanish; news coverage; educational materials; and promotion through a broad network of public and private sector organizations. There are campaign messages and materials targeted to ethnic minority populations including African Americans, Hispanics/Latinos, Asian Americans and Pacific Islanders, and American Indians. Materials for this campaign are available in many languages, including English, Spanish, Cambodian, Chinese, Gujarati, Mandarin, Hindi, Hmong, Ilokano, Korean, Laotian, Samoan, Tagalog, and Vietnamese.

Following are NDEP's Spanish-language diabetes control educational materials:

7 Principios para controlar la diabetes para toda la vida
Spanish version of *The 7 Principles for Controlling Your Diabetes for Life*

Tome su diabetes en serio, para que no se vuelva cosa seria. Recomendaciones para sentirse mejor y estar más saludable
Spanish version of *Control your Diabetes. For Life. Tips for Feeling Better and Staying Healthy*.

If You Have Diabetes, Take Care of Your Heart (Si tiene diabetes, cuide su corazón)
An easy-to-read, bilingual (Spanish and English) illustrated brochure that encourages patients to take steps to control not only their blood glucose (sugar) levels, but also their blood pressure and cholesterol. A detachable wallet card allows patients to track these target numbers.

El poder de controlar la diabetes está en sus manos
Spanish version of *The power to control diabetes is in your hands* brochure.

Cuide sus pies durante toda su vida
Spanish version of *Take Care of Your Feet for a Lifetime*. Provides information on foot care and prevention of foot problems.

Movimiento por su vida
This is a music CD created through partnership with the CDC to help Hispanics and Latinos incorporate more movement into their lives. It features six original songs with empowering messages and strong Latin rhythms, with the message that moderate physical activity can make a difference to your health.

Recipe and Meal Planner Guide (Recetas y plan de comidas)
This bilingual (English and Spanish) meal planner is complete with recipes for every day of the week and tips to control diabetes deliciously. Appetizing food photography and a practical design make the meal planner a terrific addition to any kitchen.

3.1.2.2 Performance Measures

NDEP will conduct a Partner Activity survey on a semi-annual basis. This survey will be used to gauge how members of the NDEP Partnership Network are adapting and using NDEP materials. The survey also will assess partner organizations' satisfaction with NDEP materials.

3.1.2.3 Outcome Measures

The outcome measures will focus on the longer term impact of program activities of NDEP and its partner organizations on the target audiences—African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans—by assessing awareness, attitudes, and behaviors with regard to diabetes prevention and diabetes control and treatment.

NDEP has applied for "1% evaluation set-aside funding" to conduct three surveys of the public and health care providers. These surveys will provide a quantitative assessment of the public and health care provider beliefs, attitudes, knowledge, and practices related to prevention and management of diabetes, and will also provide benchmarks against which program effects can be evaluated. These surveys will assess exposure to campaign materials and the impact of the campaign on the awareness level, knowledge, attitudes, and behaviors of target audience members—African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans. The data collected through these surveys will supplement available secondary data, gathered from a variety of sources including NHANES, the NHIS, and the BRFSS, to assess and refine overall campaign strategies and tactics. These surveys will yield insight into what the campaign achieved and what factors contributed to this success.

3.2 Area of Emphasis Two: Prevention and Control of Type 2 Diabetes in the Pima Indians of Arizona

NIDDK began working with Pima Indian volunteers in Phoenix in the mid-1960s after a health survey revealed an astonishing rate of type 2 diabetes in the GRIC. Half of Pima Indians who are age 35 years and older have type 2 diabetes, the highest prevalence in the world. Pima Indians have 10 times the prevalence of type 2 diabetes found in Caucasian populations. Pimas also develop diabetes at a much younger age than other populations, and the number of Pima children with the disease is increasing. In addition, the prevalence of diabetic kidney disease remains high among this population.

3.2.1 Objective One: Increase Awareness About Diabetes Prevention

NIDDK and the Gila River Tribal Council seek to raise awareness of the seriousness of diabetes, its risk factors, and the potential strategies for preventing diabetes and its complications.

3.2.1.1 Action Plan

NIDDK, community leaders, and community members have developed and produced several health education materials to promote the message that diabetes can be prevented. These materials include two videos, "Close to the Heart: Breastfeeding Our Children, Honoring Our Values," which encourages breastfeeding to prevent obesity and type 2 diabetes, and "Message of Hope: We Can Prevent Diabetes in Native American Communities," which translates the results of the DPP clinical trial. Members of the Gila River Indian Tribe participated in the DPP. The DPP was the first major clinical trial in the United States to show that moderate weight loss can delay and possibly prevent type 2 diabetes in a diverse population of overweight people with pre-diabetes, a condition in which blood glucose levels are higher than normal but not yet high enough for a diagnosis of diabetes. In addition, a booklet, "I Can Lower My Risk for Type 2 Diabetes," which also uses the DPP findings to explain and encourage healthy lifestyle choices, will be provided to members of the GRIC.

About 15 percent of American Indians and Alaska Natives who receive care from the Indian Health Service have been diagnosed with diabetes, a total of 105,000 people. On average, American Indians and Alaska Natives are 2.6 times as likely to have diagnosed diabetes as non-Hispanic Whites of a similar age. The available data probably underestimate the true prevalence of diabetes in this population. For example, 40 to 70 percent of American Indian adults age 45 to 74 were found to have diabetes in a recent screening study in three geographic areas. Data from the Navajo Health and Nutrition Survey, published in 1997, showed that 22.9 percent of Navajo adults age 20 and older had diabetes. Fourteen percent had a history of diabetes, but another 7 percent were found to have undiagnosed diabetes during the survey. Because of the high rates of diabetes among American Indians and Alaska Natives, NIDDK has been asked by the Indian Health Service to expand its diabetes prevention and control campaigns from the Pima Indians to other North American tribes. In response, NIDDK is actively assisting Indian Health Service and tribal programs in speaking about diabetes prevention, disseminating prevention educational materials, and training health staff in diabetes prevention.

3.2.1.2 Performance Measures

The performance measures will include quantitative data that documents the successful dissemination of educational materials in the Pima Indian community and in other American Indian communities.

3.2.1.3 Outcome Measures

The outcome measures will include increased awareness about diabetes, its risk factors, and ways to prevent the disease and its complications among Pima Indians. Appropriate evaluation approaches will be developed with the Gila River Diabetes Partnership.

3.2.2 Objective Two: Improve Control of Type 2 Diabetes

3.2.2.1 Action Plan

NIDDK staff in Arizona has greatly expanded their collaboration with the Gila River Health Care Corporation to improve diabetes services in the community and apply all available knowledge for the best treatment of diabetes and its complications. NIDDK continues to provide laboratory service to the Health Care Corporation's hospital, including tests to monitor diabetes control and to detect and monitor early diabetic kidney disease. NIDDK staff, in collaboration with the Health Care Corporation, has begun examining people with diabetes yearly to help ensure that standards of care for diabetes are being met as much as possible. In addition to providing care to participants in research studies, many NIDDK nurses and doctors volunteer their time and services to the Health Care Corporation.

NIDDK staff was appointed by the former Governor to work with the community's newly formed Gila River Diabetes Partnership. The diabetes partnership was asked to develop a strategic plan to improve coordination of diabetes services delivered using funds provided through a Special Diabetes Programs for Indians grant. NIDDK staff assisted community members in responding to this funding opportunity. They have worked with the Partnership since its inception and will continue to support this community-driven initiative as requested. At the request of the Lieutenant Governor, NIDDK helped organize a Kidney Disease Advisory Board of community members concerned with this serious complication of diabetes.

3.2.2.2 Performance Measures

The performance measures will include data on NIDDK participation in these clinical support activities.

3.2.2.3 Outcome Measures

The outcome measures will include assessments of those attaining standard treatment goals for patients with diabetes.

3.2.3 Objective Three: Improve Infrastructural Support for Diabetes Prevention and Control Activities

3.2.3.1 Action Plan

The diabetes prevention and intervention initiative is an NIDDK activity that provides funds to the GRIC for activities that directly benefit community members with diabetes or who are at risk for diabetes. In the past year, the NIDDK has assisted with many different projects in the community, including providing funds:

- For the Dental Department at the Gila River Health Care Corporation to hire two dental assistants; purchase 50 full dentures, 50 partial dentures, and 50 units of bridgework; and purchase an array of new dental equipment to address periodontal disease associated with diabetes in the community.
- For the Optometry Department at the Gila River Health Care Corporation to purchase equipment that enhances the care of patients with diabetes and glaucoma. Equipment includes a retinal thickness analyzer, which is a state-of-the-art retinal scanning device that will pick up even subtle sight-threatening retinal edema; a pachymeter, which measures corneal thickness; and a retinal camera.
- For the Department of Public Health Wellness Center to install a new wood flooring system in the gymnasium to replace the tile floor. This floor will reduce injuries in those using the gymnasium for exercise and increase the number of people willing to use the gymnasium.
- For the Pharmacy Department at the Gila River Health Care Corporation to purchase video-conferencing equipment to connect the Corporation’s Hospital with the satellite clinics at Ak-Chin and Gila Crossing. This equipment will make it possible to provide the same individual counseling on medicines dispensed and the same level of pharmaceutical care for patients at the satellite clinics that is now available at Corporation’s Hospital. It also has a host of other medical and administrative uses including disease management services for patients with diabetes and other chronic conditions, medical consultations, business presentations, meetings, etc.
- For improving health care data systems at the Gila River Health Care Corporation. These funds were used to enhance the billing and collection systems at the corporation.
- To purchase 45 new computer workstations for the Gila River Health Care Corporation.
- To purchase project management services for the medical information systems enhancements at the Gila River Health Care Corporation.
- To the Department of Public Health Wellness Center for exercise equipment, including six treadmills and 3 elliptical exercisers.
- To the Head Start program for construction of a playground and the purchase of playground equipment.
- For enhancing data integrity in the health care data systems at the Gila River Health Care Corporation. These data improvement activities will ensure that when a physician or other health care provider treats a patient, all relevant health information is available to the provider on a computer screen at the bedside.

3.2.3.2 Performance Measures

The performance measures will include data on NIDDK contributions to the health infrastructure.

3.2.3.3 Outcome Measures

The outcome measures will include implementation and use of these infrastructural enhancements.

3.3 Area of Emphasis Three: National Kidney Disease Education Program (NKDEP)

NIDDK initiated the National Kidney Disease Education Program (NKDEP) in the summer of 2000. Since then, NKDEP has worked to address the serious problem of kidney failure among African Americans in the United States. NKDEP aims to raise awareness of the seriousness of kidney disease, the importance of testing those at high risk, and the availability of treatment to prevent or slow kidney failure. The overarching goal is to decrease the incidence, prevalence, morbidity, mortality and cost of chronic kidney disease (CKD) in the United States. The program initially focuses on those at highest risk: African Americans with diabetes, high blood pressure, or a family history of kidney failure. The NKDEP plans to widen its target audiences, including other racial and ethnic groups, as the program expands.

Approximately 20 million Americans have kidney disease. The number of people diagnosed with kidney disease has doubled each decade for the last 2 decades. In 2001, there were about 400,000 people who had kidney failure and must have dialysis or a kidney transplant to stay alive. This number is expected to reach more than 660,000 by 2010. African Americans are disproportionately affected by kidney disease; they are four times more likely than Caucasians to develop kidney failure. Further, African Americans make up 12 percent of the population but account for 30 percent of people with kidney failure. Because African Americans are at high risk for kidney disease, NKDEP developed the “You Have The Power To Prevent Kidney Disease” campaign. Through print and radio public service announcements, videos, brochures, fact sheets, and the NKDEP web site, the campaign focuses on African American adults at risk and primary care providers who play an important role in detecting and managing kidney disease.

3.3.1 Objective One: Awareness of and Testing for CKD

NKDEP seeks to increase awareness of the seriousness of CKD, its risk factors, and the importance of testing African Americans at high risk for the disease. In addition, NKDEP is designed to promote a multi-disciplinary, coordinated and integrated approach to care for those with CKD to prevent kidney failure.

3.3.1.1 Action Plan

In June 2003, NKDEP launched a year-long pilot education program, “You Have the Power to Prevent Kidney Disease,” in four cities – Atlanta, Baltimore, Cleveland, and Jackson, Mississippi. These cities were chosen for their relatively large African American communities and because some kidney resources already existed. Local coalitions are working with the media to build community partnerships, conduct outreach in dialysis clinics, and hold workshops for health care professionals to encourage those at high risk for kidney disease to be tested and to learn about treatments to prevent or help slow progression to kidney failure. The program uses print and radio public service announcements, videos, fact sheets, brochures and a web site to stress three themes: (1) Know if you are at risk; (2) Have your kidneys tested, and (3) Learn about treatment.

In addition, NKDEP has identified and disseminated simple, easy-to-use tools for clinicians on preventing the development, progression, and complications of kidney disease. These tools include web-based resources such as a referral letter for use in the clinical setting.

3.3.1.2 Performance Measures

The performance measure will include the development of educational materials that are culturally appropriate for the African American community and that are effectively disseminated through NDKEP national partners. NKDEP also is monitoring audience and media reaction to campaign events and materials.

3.3.1.3 Outcome Measures

The outcome measures will assess changes in knowledge, beliefs, awareness, and practices about kidney disease among African Americans and their health care providers. Using “1% evaluation set-aside funding,” NKDEP has conducted baseline surveys of African Americans and health care providers in the four cities. The baseline surveys provide a quantitative assessment of consumer and provider beliefs, attitudes, knowledge, and practices related to prevention and management of kidney disease, and also provide benchmarks against which program effects can be evaluated. The follow-up surveys will assess exposure to campaign materials and the impact of the campaign on the awareness level, knowledge, attitudes, and behaviors of target audience members. Following analysis, the survey results will be used to assess and refine overall campaign strategies and tactics before expanding the campaign to other communities or populations.

3.4 Area of Emphasis Four: Weight-Control Information Network (WIN)

NIDDK’s Weight-Control Information Network (WIN) was established in 1994 to raise awareness and provide up-to-date, science-based information on obesity, physical activity, weight control, and related nutritional issues to health professionals, people who are overweight or obese, the media, Congress, and the general public. WIN produces and disseminates culturally appropriate, evidence-based materials about obesity, physical activity, weight control, and adolescent and childhood obesity to ethnic minority audiences, especially African American and Hispanic/Latino audiences. From brochures about healthy eating for adults, children, and teenagers to videotaped lectures on nutrition and obesity, WIN offers several ways to access needed information.

In addition to creating and distributing consumer-friendly information, WIN developed the “Sisters Together: Move More, Eat Better” pilot program for African American women. Data from the 1999-2000 NHANES indicates that African American women have the highest rates of overweight and obesity among all racial and ethnic groups in the United States. According to NHANES, 64.5 percent of U.S. adults over age 20 are overweight (BMI $\geq$ 25).

3.4.1 Objective One: Expand WIN's "Sisters Together: Move More, Eat Better" Outreach Program

A WIN priority is to raise awareness among African American women about how being more physically active and eating better improves health and helps prevent disease.

3.4.1.1 Action Plan

WIN launched the "Sisters Together: Move More, Eat Better" health awareness program in 1995. A 3-year pilot program in Boston included walking groups, cooking demonstrations, health seminars, distribution of material promoting healthy eating and regular exercise, and media outreach. Based on results of this pilot, in 2001, WIN brought "Sisters Together" to the Washington, DC metropolitan area by sponsoring the "Sisters Together" Walk and Health Fair at the Franklin D. Reeves Center in Washington, DC. More than 300 women and children participated in the event, which featured a 1.8-mile walk and vegetarian cooking demonstrations. At the health fair, "Sisters Together" disseminated a series of free publications designed to encourage African American women of all ages to adopt new exercise and eating habits. Those publications include "Celebrate the Beauty of Youth," "Energize Yourself and Your Family," "Fit and Fabulous as You Mature," and "Walking … A Step in the Right Direction."

WIN plans to implement a nationwide, media-based "Sisters Together" program targeting African American women ages 18 and older. To continue to promote messages and activities to resonate with African American women nationally, WIN will facilitate partnerships with national, state and local groups. Strategies being considered include publicizing the availability of current "Sisters Together" materials and expanding outreach to churches; community organizations; state and local health departments; Black media outlets; and Black organizations, such as the National Black Women's Health Project and the National Caucus and Center on Black Aged.

WIN currently is developing relationships with nontraditional partners, such as hair and nail salons. Further, WIN will develop and disseminate new, culturally relevant messages based on scientific findings about lifestyle interventions, obesity, and physical activity.

3.4.1.2 Performance Measures

WIN is an information dissemination service of NIDDK. The performance measures include tracking the number of responses to information requests and referrals. For example, in April 2004, WIN responded to 802 requests for information: 367 telephone inquiries, 183 faxes, 128 emails, three promotional mailings, two exhibits, and 119 mail inquiries. Of those 802 inquiries, 520 came from consumers, 271 from health professionals, one from the media, and 10 from individuals and organizations of other professions. WIN publications were sent in response to 607 inquiries, and WIN provided 58 referrals in the month of April.

Use of an Office of Management and Budget-approved “Customer Satisfaction Survey” is being explored.

3.4.1.3 Outcome Measures

Because WIN is an information dissemination service of NIDDK, quantitative process evaluation measures such as the number of inquiries via the toll-free number, web site, email, and postal mail will be used to track the performance of WIN’s dissemination program. WIN is exploring an application to collect information on knowledge, attitudes, and practices from NIH’s program for evaluation funding to determine the impact of awareness campaigns.

3.4.2 Objective Two: Promote Healthy Eating and Physical Activity Among Hispanic/Latino Americans Through “Toda la vida”

Among non-Hispanic Black women, 77.3 percent are overweight, compared with 57.3 percent of non-Hispanic White women. Mexican American women also have one of the highest rates of overweight and obesity. Among Mexican-American women, 71.9 percent are overweight, compared with 57.3 percent of non-Hispanic White women.

WIN seeks to provide culturally appropriate materials to raise awareness among Hispanic/Latino Americans about the benefits of healthy eating and physical activity in preventing diseases and disorders such as diabetes, CVD, and some forms of cancer.

3.4.2.1 Action Plan

WIN has developed a series of Spanish-language brochures, “Toda la vida,” that provide culturally appropriate information on healthy eating and physical activity across the life span. WIN disseminates these brochures at local health clinics and national and local meetings of organizations such as the American Diabetes Association and National Council of La Raza. The brochures are available online through WIN’s web site. To continue to promote the brochure series among Hispanic/Latino Americans, WIN plans to expand its local and national outreach of the brochures described below.

Cómo alimentarse y mantenerse activo durante toda la vida: cómo ayudar a su hijo. (Healthy Eating and Physical Activity Across the Lifespan: Helping Your Child). This 23-page brochure is the first in a series of four Spanish-language materials that address healthy nutrition and physical activity over the lifespan. *Cómo ayudar a su hijo* offers culturally appropriate advice to Spanish-speaking parents and caregivers on helping their children develop healthy eating and physical activity habits. It includes traditional recipes and a detachable list of tips that readers can use as a ready reference tool.

Cómo alimentarse y mantenerse activo durante toda la vida: cómo mejorar su salud: consejos para adultos. (Healthy Eating and Physical Activity Across Your Lifespan: Better Health and You). This 26-page brochure is the second Spanish publication in the life span series. Adapted for Hispanic adults, it offers information on BMI, a healthy diet, weaving physical activity into daily life, and weight loss. It also includes four pages of traditional recipes and a detachable list of tips in both Spanish and English.

Cómo alimentarse y mantenerse activo durante toda la vida: sugerencias para personas mayores. (Healthy Eating and Physical Activity Across Your Lifespan: Young at Heart). This 22-page brochure is the third Spanish-language publication in the life span series. Designed for adults ages 65 and older, the brochure includes helpful tips for older adults to improve their eating habits by eating a wide variety of nutritious foods, planning meals, eating breakfast every day, and more. Common health risks associated with being underweight and overweight are listed. The brochure describes the benefits of physical activity and offers suggestions on ways to increase aerobic, strengthening, balance, and flexibility activities.

Cómo alimentarse y mantenerse activo durante toda la vida: consejos para la futura mama. (Healthy Eating and Physical Activity Across Your Lifespan: Fit for Two) This is the final brochure in the Spanish-language life span series. The brochure contains information on nutritional and calorie needs during pregnancy, as well as a description of foods to avoid. The brochure outlines the benefits of physical activity during pregnancy and lists safety precautions. Tips to help pregnant women eat healthy and get active are included. Advice on maintaining healthy habits after pregnancy and returning to a healthy weight after delivery are also addressed.

3.4.2.2 Performance Measures

WIN's performance measures include tracking the number of responses to information requests. For example, in April 2004, WIN distributed 1,450 "Toda la vida" brochures. Establishment of benchmarks for successful quantitative evaluation will be addressed through consultation with the National Diabetes Education Program Evaluation Work Group and application for "1% set-aside evaluation funds."

3.4.2.3 Outcome Measures

Because WIN is an information dissemination service of NIDDK, quantitative measures such as process evaluation of the number of inquiries to the toll-free number, web site, email and postal mail will be used to track the performance of WIN's dissemination program. WIN is exploring an application to collect information on knowledge, attitudes and practices from NIH's program for evaluation funding to determine the impact of awareness campaigns.

3.5 Area of Emphasis Five: NIDDK Information Clearinghouses

NIDDK's research mission includes diseases and disorders that disproportionately affect African Americans, Asian Americans and Pacific Islanders, American Indians and Alaska Natives, and Hispanic/Latino Americans. NIDDK has produced an extensive inventory of publications for these audiences, including information on the following topics: diabetes, kidney failure, chronic hepatitis C virus, peptic ulcer disease, and *H. pylori*. These materials are available through the NIDDK's three information clearinghouses: the National Diabetes Information Clearinghouse (NDIC), the National Digestive Diseases Information Clearinghouse (NDDIC), and the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC).

Because the diseases under NIDDK's purview affect Hispanics and Latinos, the clearinghouse makes information available in Spanish as well as English. For example, 2 million Hispanic Americans, or 8.2 percent of that population, have diabetes. On average, Hispanic/Latino Americans are 1.5 times more likely to have diabetes than non-Hispanic Whites of similar age. Mexican Americans, the largest Hispanic/Latino subgroup, are more than twice as likely to have diabetes as non-Hispanic Whites of similar age. Similarly, residents of Puerto Rico are 1.8 times more likely to have diagnosed diabetes than U.S. non-Hispanic Whites.

3.5.1 Objective One: Awareness and Access to Information

The goal of the clearinghouses is to increase knowledge and understanding about diseases, including diabetes and digestive, kidney, and urologic disorders, among Hispanic/Latino audiences, and the health care professionals who treat them.

3.5.1.1 Action Plan

To carry out their mission, the clearinghouses work closely with coordinating panels of representatives from federal agencies; voluntary organizations on the national level; professional groups; and state health departments to identify and respond to informational needs about diabetes and digestive, kidney, and urologic diseases. This program includes providing materials at varying reading levels and in English and Spanish. Further, to increase awareness and access to materials, information about the clearinghouses will be available through exhibits at meetings of voluntary and professional organizations; toll-free telephone numbers; and web sites and email.

Following are the materials that will be available in Spanish through the clearinghouses:

Diabetes Spanish-Language Materials

7 Principios para controlar la diabetes durante toda su vida
(7 Principles for Controlling Your Diabetes for Life)

NATIONAL **I**NSTITUTE OF **D**IABETES AND **D**IGESTIVE AND **K**IDNEY **D**ISEASES

¿Corro el riesgo de que me dé diabetes tipo 2?
(Am I at Risk for Type 2 Diabetes?)

Diccionario de la diabetes
(Diabetes Dictionary)

El poder de controlar su diabetes está en sus manos
(The Power to Control Diabetes Is in Your Hands)

Guía para personas con diabetes tipo 1 y tipo 2
(Your Guide To Diabetes: Type 1 and Type 2)

Imán de motivación diabética para el refrigerador
(Diabetes Motivational Refrigerator Magnet)

Insuficiencia renal: cómo escoger el tratamiento que más le conviene
(Kidney Failure: Choosing a Treatment That’s Right for You)

La enfermedad renal en la diabetes
(Kidney Disease of Diabetes)

Lo que debo saber sobre alimentación y la diabetes
(What I Need to Know About Eating and Diabetes)

Medicamentos para las personas con diabetes
(Medicines for People With Diabetes)

Medicare tiene más que ofrecer. beneficios adicionales para la diabetes
(Expanded Coverage for Diabetes Care—Medicare and You)

Recetas y plan de comida
(Recipe and Meal Planner)

Recomendaciones para sentirse mejor y estar más saludable
(Control Your Diabetes. For Life. Tips for Feeling Better and Staying Healthy)

Sepa cuánta azúcar tiene en la sangre: hágase la prueba para controlar el azúcar sanguíneo
(Know Your Blood Sugar Numbers)

Si tiene diabetes, cuide su corazón
(If You Have Diabetes, Take Care of Your Heart)

Si tiene diabetes, cuide su corazón presentación en rotafolio
(If You Have Diabetes, Take Care of Your Heart Flipchart Presentation)

Evite los problemas de la diabetes
(Diabetes Prevention Series)

Controle la diabetes
(Keep Your Diabetes Under Control)

Mantenga los dientes y las encías sanos
(Keep Your Teeth and Gums Healthy)

Mantenga los ojos sanos
(Keep Your Eyes Healthy)

Mantenga los pies y la piel sanos
(Keep Your Feet and Skin Healthy)

Mantenga los riñones sanos
(Keep Your Kidneys Healthy)

Mantenga sano el sistema nervioso
(Keep Your Nervous System Healthy)

Mantenga sanos el corazón y los vasos sanguíneos
(Keep Your Heart and Blood Vessels Healthy)

Digestive Diseases Spanish Materials

Cirrhosis of the Liver (Cirrosis del hígado)

H. pylori and Peptic Ulcer (*H. pylori* y úlcera péptica)

What I Need to Know About Constipation (Lo que necesito saber sobre el estreñimiento)

What I Need to Know About Gas (Lo que saber sobre el gas)

What I need to know about Hepatitis A (Lo que necesito saber sobre la Hepatitis A)

What I need to know about Hepatitis B (Lo que necesito saber sobre la Hepatitis B)

What I need to know about Hepatitis C (Lo que necesito saber sobre la Hepatitis C)

Your Digestive System and How It Works (El aparato digestivo y su funcionamiento)

Kidney and Urologic Diseases Spanish Materials

Bladder Control for Women (Control de la vejiga en las mujeres)

Erectile Dysfunction (Disfunción eréctil)

Exercising Your Pelvic Muscles (Ejercicios para los músculos de la pelvis)

High Blood Pressure and Kidney Disease (La tensión arterial alta y la enfermedad de los riñones)

Kidney Disease of Diabetes (La enfermedad renal en la diabetes)

Kidney Failure: Choosing a Treatment That's Right for You (Insuficiencia renal: cómo escoger el tratamiento que más le conviene)

Kidney Failure: Eat Right to Feel Right on Hemodialysis (Insuficiencia renal: Coma bien para sentirse bien durante su tratamiento de hemodiálisis)

Menopause and Bladder Control (La menopausia y el control de la vejiga)

Pregnancy, Childbirth, and Bladder Control (Embarazo, parto y control de la vejiga)

Prevent Diabetes Problems: Keep Your Kidneys Healthy (Evite los problemas de la diabetes: mantenga los riñones sanos)

Talking to Your Health Care Team About Bladder Control (Hablándole a su equipo de atención de salud acerca del control de la vejiga)

What I Need to Know about Kidney Stones (Lo que necesito saber sobre las piedras en los riñones)

Your Body's Design for Bladder Control (El aspecto que tiene el sistema de control de la vejiga)

Your Kidneys and How They Work (Los riñones y su funcionamiento)

Your Medicines and Bladder Control (Los medicamentos y el control de la vejiga)

3.5.1.2 Performance Measures

The performance measures will be the successful development and distribution of culturally sensitive educational materials. The clearinghouses will develop quantitative data to track the distribution of available materials. For example, in the past year, NDIC answered 21,573 requests for information, including 180 emails written in Spanish and 1,012 telephone calls from Spanish-speaking callers. Between April 2003 and April 2004, NDIC distributed 101,618 copies of Spanish-language materials. During that same period, the NDDIC distributed 2,927 copies of Spanish-language materials, and the NKUDIC distributed 6,130 copies of Spanish-language materials.

3.5.1.3 Outcome Measures

Because the clearinghouses are information dissemination services of NIDDK, quantitative measures such as process evaluation will be used to track the performance of the dissemination program. In addition, a customer satisfaction survey on each clearinghouse web site will provide data for program improvement.

The National Institute of Environmental Health Sciences

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL **I**NSTITUTE OF **E**NVIRONMENTAL **H**EALTH **S**CIENCES

MISSION/VISION STATEMENT

The mission of the National Institute of Environmental Health Services (NIEHS) is to reduce the burden of environmental associated diseases by defining:

- How environmental exposures affect our health;
- How individuals differ in their susceptibility to these exposures; and
- How these susceptibilities change with age.

The NIEHS achieves its mission through multidisciplinary biomedical research programs, prevention and intervention efforts, and communication strategies that encompass training, education, technology transfer and community outreach.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIEHS addresses a broad range of diseases and dysfunctions that arise from environmental exposures, individual susceptibility, and the function of time. NIEHS has been a leader in recognizing and addressing the issues related to health disparities, coordinating and co-funding (with the Environmental Protection Agency [EPA] and the Agency for Toxic Substances and Disease Registry [ATSDR]) probably the first major federally sponsored national meeting on Environmental Justice in February 1994, in Arlington, Virginia, where a wide range of grass roots advocacy groups from the East Coast to the U.S. territorial islands in the Pacific gathered to elaborate their issues and concerns and to seek appropriate follow-up with research and public health action. NIEHS is a part of the Interagency Working Group (IWG) for Environmental Justice.

Health disparities in the environmental health sciences exist and are addressed at a number of levels. Individual diseases such as breast cancer, lupus, asthma, and prostate cancer (to cite only examples) occur at a higher incidence in minorities. Exposures to hazardous toxic agents in the workplace, in residential areas, and in individual homes occur with a higher incidence in minorities, among those with lower socioeconomic status, and among other marginalized groups, and these exposures affect more vulnerable members of the population such as children, pregnant women and the fetuses they carry, and the elderly, at a higher incidence than they do the population at large.

NIEHS focuses research on diseases afflicting minority and lower socioeconomic status populations, and on exposures to hazardous environmental agents to better understand how disease is caused and how it can be prevented through remediation and education.

At the same time, minorities and those growing up in lower socioeconomic status become researchers and public health officials in a position to address health disparity issues in far smaller proportion compared to their numbers than do majority segments of the population. Training programs targeted at minority students, as well as education and outreach programs aimed at younger minority and underserved students, strive to encourage and bring along minority and lower socioeconomic status students in understanding environmental health sciences and in pursuing careers in research.

One key NIEHS tactic in gaining perspective on grassroots concerns in environmental health sciences is the town meeting, a well-publicized public gathering that encourages a free expression of ideas and concerns from the public to the Institute Director and senior Institute staff. The objective is to tap into those communities that are not already represented by a formal advocacy group and to learn directly from them what some of the still unmet needs for research and public health action might be. These have been held in every region of the country including Hawaii.

NIEHS Center grants, which fund expansive programs in specialized research areas at universities around the country, each have a mandate to initiate education and outreach programs at their locales, and these programs often are a powerful means of addressing health disparity issues in each of the locales.

In summary, the NIEHS uses a variety of means to implement its program to reduce and eliminate health disparities, through research and training as well as through education and outreach. Described in the strategic plan are those programs conceived most directly to address health disparities, but it is accurate to say that a dimension of benefit in reducing health disparities is an integral part of nearly every aspect of research and training at NIEHS. The reduction and elimination of health disparities is a fundamental part of the NIEHS mission and organizational culture.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Overarching Programs, Centers, and Research Themes Addressing Health Disparities

The first area of emphasis is the global approach to addressing health disparities itself, the combined effects of the various programs and centers, individual research grants, and other research efforts. It is at the center of the NIEHS strategic plan to join and interrelate many different efforts to multiply the benefits for reducing and eliminating health disparities.

It is in the nature of environmental health sciences that a number of dimensions of research are intensely interrelated so that dividing aspects into separate areas of emphasis can fail to capture the breadth and various dimensions of strategies for addressing health disparities. For example, environmental and occupational health may also relate to women’s and children’s health, and certainly women’s and children’s health relate to each other. Likewise, addressing the health of rural populations or behavioral and social dimensions of environmental health of minorities and those of lower socioeconomic status may relate to the various categories mentioned above.

In a 2004 report to the National Center on Minority Health and Health Disparities, NIEHS cited a dozen major programs and center programs as a part of its health disparities initiatives, and this did not include more than 100 individual research grants related to health disparities that are in the NIEHS grants portfolio.

In a similar way, the areas of emphasis in research are usually interwoven to a considerable degree both with the development of research capacities, by way of educating and training scientists and public health professionals from underserved populations, and education and outreach for a wider public within underserved populations.

Therefore, a first area of emphasis in research must bring together some of the larger center programs and other programs, as well as at least a sampling of the wide array of individual research grants and studies within the Institute's intramural research program. This approach will capture the breadth of efforts to address health disparities. It also will require some repetition as particular efforts are broken out as separate areas of emphasis, so it can be seen that the whole interrelated effort is greater than the sum of its parts.

1.1.1 Objective One: To Sustain and Develop Programs and Centers Specifically Dedicated to Eliminating Health Disparities and Those With Substantial Research Directed Toward That Goal

Major NIEHS-funded centers and programs are in place doing health disparities research in the environmental health sciences. One program, Health Disparities: Linking Biological and Behavioral Mechanisms with Social and Physical Environments, established in 2001, fosters multidisciplinary research that will elucidate mechanisms by which social and physical environments interact to lead to health disparities.

The Community-Based Participatory Research (CBPR) Program, initiated in 1995, uses community interest and activism to refine public health intervention efforts for better results. Community-based prevention and intervention research seeks to expand knowledge and understanding of potential causes and remedies of environmentally related disorders, and to expand the communities' capacity to shape research.

The IWG on Community-Based Participatory Research, established by NIEHS in 2002, brings together 26 other Institutes and Centers at the National Institutes of Health (NIH) and other federal agencies with an interest in supporting CBPR methodologies in the conduct of biomedical research, education, health care delivery, and/or formulation of policy. The Working Group's goals are to serve as a focal point to identify and develop new, coordinated activities to increase awareness, understanding and use of CBPR; to critically evaluate the strengths and weaknesses of CBPR; to identify challenges and opportunities for supporting CBPR; to encourage research training and career development opportunities for CBPR researchers and practitioners; and to serve as a network through which information can be shared regarding CBPR activities.

NATIONAL **I**NSTITUTE OF **E**NVIRONMENTAL **H**EALTH **S**CIENCES

The Centers for Children's Environmental Health and Disease Prevention Research, initiated and funded by NIEHS, EPA, and the Centers for Disease Control and Prevention (CDC) in 1999, conduct a wide portfolio of research targeted at environmental exposures and disease dysfunction among minority and otherwise disadvantaged children. Research addresses respiratory disease, pesticide contamination in children's homes, risks of exposures to normal development and learning, culturally appropriate intervention in paths of exposure in homes, airway disease in children in rural settings, childhood asthma in urban settings in children of color, and the impact of nutritional status on children's health. These Centers will be discussed further in the Area of Emphasis devoted to Children's Health, but these Centers are a central part of the global effort to address health disparities.

NIEHS was the lead agency in initiating the Centers for Population Health and Health Disparities in 2003, working with the National Cancer Institute (NCI), the National Institute on Aging (NIA), and the Office of Behavioral and Social Sciences Research (OBSSR), all parts of the NIH. The Centers conduct interdisciplinary research to examine how the social and physical environment, behavioral factors, and biological pathways interact to determine health and disease in given populations. The eight Centers form a network of research teams to explore the complexity of health disparities. Investigators have incorporated a community-based research approach that involves community stakeholders in the planning and implementation of research, with studies focusing on obesity, cardiovascular disease, breast cancer, prostate cancer, cervical cancer, mental health, gene-environment interactions, psychosocial stress, and other factors. Populations will include low-income Whites, African Americans, Hispanics, and the elderly. The Centers have an annual meeting to discuss new findings, new opportunities, and additional collaborations. A steering committee has been established and will meet twice a year and have regularly scheduled interactions to promote Center activities and collaborations. NEIHS funds Environmental Health Sciences (EHS) Centers with the Community Outreach and Education Program (COEP). The COEP translates environmental health research into knowledge for the underserved, low socioeconomic status, and minority communities.

1.1.1.1 Action Plan

These centers and programs target certain populations, diseases, and exposures. Communications between center directors and all health disparities researchers amplify the benefits of individual centers and programs through communications and collaboration. Rigorous scientific review allows improvement of research or redirection of funding when a particular program is not yielding the desired benefits for public health. Excellence in research as well as excellence in translating the research into public health benefits are the plan of action for using funded centers and programs for reducing and eliminating health disparities.

Timeline

- Health Disparities: Linking Biological and Behavioral Mechanisms with Social and Physical Environments, established in 2001, current funding ES00-004, FY2000 to FY2004
- CBPR Program, ES01-003, FY2001 to FY2005
- Centers for Children's Environmental Health and Disease Prevention Research, ES00-008, FY2001 to FY2005, ES03-004, FY2004 to FY2008
- Centers for Population Health and Health Disparities, ES02-009, FY2003 to FY2007

1.1.1.2 Performance Measures

The quantifiable end products of research are published articles in peer-reviewed journals and the impact from such publications reflected in publications by others citing these articles. Success can also be marked when insights from publications impact the means of diagnosis, treatment, and prevention of environmental disease and/or contribute to the ability to educate the public on environmental disease in a more effective way.

1.1.1.3 Outcome Measures

Outcome measures from Centers and major programs addressing health disparities are reflected when research, publication, community interaction, and health education result in decreased incidence of environmental disease in a minority, lower socioeconomic status population or other marginalized populations. Improved public health and elimination of health disparities is the ultimate goal.

1.2 Area of Emphasis Two: Research Addressing Health Disparities Relating to Specific Populations, Diseases, and Environmental and Occupational Exposures

The first area of emphasis spotlighted the global approach to health disparities, the overarching approach; the second area of emphasis spotlights the various targeted ways to address health disparities, in terms of specific vulnerable groups, such as women, children, or designated ethnic groups, or in terms of specific diseases or exposures. These efforts comprise scores of programs and individual research grants, and all of these cannot be named and described in the space allotted. However, this area will, through selected examples, bring to light an active Institute response to public comment from individuals, advocacy groups, the NIEHS Public Interest Liaison Group, and other channels of public comment such as the NIEHS town meetings.

These targeted research efforts aim to better define exactly how minorities and lower socioeconomic status populations experience a higher incidence of exposure to toxic agents, and the diseases that these exposures cause, and how these patients often have less access to the means to be diagnosed and treated or the means to minimize or prevent the health effects of exposures. The strategic plan of NIEHS calls for continual publication of health disparity studies in professional journals to heighten the awareness of physicians and public health officials of health disparities and to better enable the reduction or elimination of these disparities through direct action and better health care delivery.

1.2.1 Objective One: To Address Health Disparities in Environmental Health That Affect Children

Children are one of the most vulnerable populations. Their rapidly developing bodies take in proportionately more food, water, and air than adults. Their bodies are still in a state of rapid change requiring optimal environmental support, and their bodies' defenses are not fully developed, making them more subject to toxins in their surroundings. Young children put hands and objects in their mouths, often place their hands on the ground or on public surfaces, and do not wash their hands as regularly as adults. It is often pointed out that children are not just little adults but have a greater need for protection from environmental contaminants in order to avoid developing disease. Nearly every environmental hazard is a greater risk to children, and at lower doses, than it is to adults.

Minority children, children of lower socioeconomic status, and other children in marginalized populations have greater risk of diseases from exposure to environmental agents brought home from their parents' workplaces, from the residential areas in which they live, from the residences themselves, which may be older or less well constructed, and from less available health care and health education. In addition, children of lower socioeconomic status often have less sufficient nutrition, in terms of fresh fruits and vegetables and an overall balanced diet, and in terms of vitamin supplementation, to bolster them against the exposures they encounter.

The NIEHS has initiated an expansive portfolio of research related to children's health and health disparities among minority and lower socioeconomic status children, and seeks to sustain and develop this research as a part of its strategic plan.

The eleven Children's Research Environmental Health Centers, funded by NIEHS, EPA, and CDC, provide a basis for scientists to interact on issues of children's health and disease; facilitate the translation of basic science into strategies that reduce disease; and establish a national network that fosters communication, innovation, and research excellence. Various of the centers study specific populations of children such as urban populations in communities of color, understudied populations of Latino farm workers, children from rural communities, and children living in poverty in inner-city communities.

The Children's Research Environmental Health Centers provide a national base for studying the relationship of asthma and other respiratory disease in children, and the diseases associated with exposure to pesticides suffered by the children of farm workers, as well as the risks to normal development and learning related to pesticide exposure.

One study at a Center showed that the prenatal health effects of environmental tobacco smoke (secondhand smoking) were greater for socioeconomically disadvantaged children than for children from more affluent homes. Another Center study showed that newborns are more susceptible than their mothers to DNA damage from polycyclic aromatic hydrocarbons, vehicle exhaust, power generation, residential heating, and tobacco smoking.

The most recently funded Children's Research Environmental Health Center addresses the health effects of heavy metal exposure on children living in the Tar Creek Superfund Site in Oklahoma, an area of low socioeconomic status and largely Native American communities of more than 10 different Indian tribes.

A number of studies relating to children's health in underserved populations are conducted not at Centers but through grants to individual researchers or by scientific staff at the NIEHS campus itself within the Division of Intramural Research. For example, such studies have looked at gene-environment interactions in asthma development, air quality in barrios as related to children's health, social factors in the environment in pediatric asthma, reducing pesticide exposures to farm workers' children, and the reduction of initiation of childhood asthma through the reduction of dust mite and roach allergens in the home.

With the National Institute of Child Health and Human Development (NICHD), the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK), and the NIA, NIEHS is funding research on the fetal origins of disease, to determine the mechanisms by which the intrauterine environment programs fetal metabolism to predispose individuals to chronic disease later in life and to determine whether these mechanisms contribute to disparities in the prevalence of obesity, diabetes, hypertension, atherosclerosis, and asthma among various races and ethnic groups. With the National Institute of Nursing Research (NINR), NIEHS is funding research to study the role of gene-environment interactions underlying the health disparity of premature birth.

1.2.1.1 Action Plan

The NIEHS plans to sustain and develop research related to disparities in children's health to better enable the reduction and elimination of such disparities through increased knowledge in the medical and public health communities of the greater burden of environmental exposures and disease experienced by children in minority populations and those of lower socioeconomic status. This effort correlates closely with Objective Two, below, to better address health disparities of women as they experience pregnancy, when their health and the health of their fetus and future child can be impacted by environmental exposures.

Publication of studies on health disparities in children raises awareness in the medical and public health communities and underscores the cost benefits and human benefits of committing resources to the betterment of children's health. Children, as our human future, are often the leveraging point for getting the community to take action in public health in general.

Timeline

- FY05 or 06, a Town Meeting is planned in Boston on the subject of "Children's Health"
- Centers for Children's Environmental Health and Disease Prevention Research, ES00-008, FY2001 to FY2005, ES03-004, FY2004 to FY2008

1.2.1.2 Performance Measures

Performance can be measured by publications in peer-reviewed scientific journals that reach clinicians and public health decision-makers, as well as local, state, and national legislators. Likewise, significant scientific publications, especially on children's health, fairly often are covered by media, and this further advances the sense of public purpose in improving children's health.

1.2.1.3 Outcome Measures

Ultimate objectives of programs in children's health disparities are measures in regulations, laws, and medical and public health practice that produce lower incidences of environmentally related childhood disease such as asthma, and significantly reduced levels of exposures reflected in lower blood levels of toxic agents such as lead and mercury. The research agencies alone cannot produce these results, but NIEHS and other agencies that fund research can provide the knowledge to justify and prompt these changes.

1.2.2 Objective Two: To Address Health Disparities in Environmental Health That Affect Women

The health status of minority women and women of lower socioeconomic status lags behind that of women in the general population, partly because of reduced access to health care but also because of higher exposures to environmental contaminants at work and at home, as well as less exposure to environmental health messages and education. In turn, the health of women directly affects the development and health of their children both before and after birth, and it affects the health and stability of the family.

One in eight women in the United States can expect to have breast cancer in her lifetime, and the cause of these cases is not known. African American women fare less well than their non-African American peers, suffering higher mortality even when breast cancer is diagnosed in early stages, and the reason for this also is not known.

NIEHS and NCI have funded four new Breast Cancer and the Environment Research Centers to study the prenatal-to-adult environmental exposures that may predispose a woman to breast cancer. The Centers will work collaboratively on several fronts. Using laboratory animals, they will study the development of mammary tissue and the effects of specific environmental agents. In the second collaborative project, the Centers will enroll different ethnic groups of young girls and study their life exposures to a wide variety of environmental, nutritional, and social factors that impact puberty. Early puberty has been shown to increase breast cancer risk later in life.

One of the Centers will examine a population of White and African American students to test the role of diet in the development of adipose tissue and in alteration of hormonal control of sexual maturation. The Center also will carry out complementary studies in rodents.

Another Center will study a series of rodent models of mammary gland development. In addition, investigators will work to understand how environmental exposures may affect the development of puberty in young African American and Latina girls in East Harlem, New York. Such changes in pubertal development may contribute to premenopausal breast cancer, which is more common in African American women. Another Center will study the impact of environmental agents on interactions between epithelial and stromal (connective tissue) cells in normal and cancer-prone mice. An epidemiology study will follow through puberty a multi-ethnic group of 7- and 8-year-old girls.

At another group of Centers, the NIH Centers for Population Health and Health Disparities, already mentioned in Area of Emphasis One, a number of studies in women's health are being done. One Center has as its theme, "The Apparent Disconnect Between Rates of Screening and the Stage of Diagnosis of Breast Cancer by Race and Ethnicity." The disconnect arises because African American women and Hispanic women increasingly report receiving mammography at rates equivalent to those reported by Caucasian women, yet African American and Hispanic women continue to experience higher breast cancer mortality rates compared to Caucasian women. The Center is studying this disparity and seeking to understand its causes in breast and other cancers. Another of these Centers is studying why Black women in the United States and West Africa experience breast cancers that occur at a younger age and are more aggressive and lethal than those of White women. At still another Center, cervical cancer in mainly rural Eastern and Southern Ohio is being studied. Social isolation and excess stress in African American women increase the risk of early breast cancer. An animal model to test this hypothesis will be developed.

In a separate effort being done by NIEHS intramural scientists in the Epidemiology Branch, the Sisters Study on breast cancer is in the process of enrolling 50,000 sisters of women who have been diagnosed with breast cancer. The study will follow the cohort for 10 years or longer, beginning with completion of questionnaires and taking of various samples. The investigators will incorporate proportionate numbers of minorities in the cohort. Over time, information from this large sampling of sisters of breast cancer patients may identify environmental factors that increase the risk of breast cancer. Investigators have set minimum target goals for recruitment of specific minority groups, at least 5,000 (10%) African Americans, 2,500 Hispanics/Latinas, 2,500 Asians/Pacific Islanders, and 750 Native Americans. In early 2003, investigators established a multi-ethnic Recruitment and Retention Advisory Board that will meet with them throughout the study to help devise, monitor, and implement recruitment and retention strategies. To minimize barriers to participation, investigators are translating their web site and questionnaires into Spanish, and recruiting and training Spanish-language interviewers. Women with low literacy will complete all of their questionnaires by telephone.

Also in the Epidemiology Branch, studies are being done on lupus and uterine fibroids, which affect minority women at a higher incidence than other women, to determine the environmental factors related to these health problems.

The Carolina Lupus Study investigates systemic lupus erythematosus (SLE), an autoimmune disease that can cause severe damage to the kidneys, joints, and other tissues. SLE affects primarily women, and African American women are four times more likely to develop SLE than Caucasian American women. NIEHS has collaborated with the National Center on Minority Health and Health Disparities (NCMHD) in the population-based, case-control study focusing on evaluating environmental and occupational factors that play a role in the etiology of the disease and to develop preventive strategies. Ninety percent of study participants are women, and 55percent are African American.

NCMHD and NIEHS also have created a study analyzing possible causes of the difference in risk for uterine fibroids in African American women versus Caucasian American women. Uterine fibroids are a leading indicator for hysterectomy among premenopausal women in the United States.

1.2.2.1 Action Plan

The NIEHS plans to sustain and develop research on health disparities in women's health. This is critical to the well-being of women, the children they bear and raise, and the families that they co-parent or parent. Further, women tend to be the agents of health awareness and care within their families, so promoting their well-being and health awareness can have additional benefits in drawing attention to the health status of all members of the family and in carrying environmental health sciences messages to minority and lower socioeconomic status populations. Because women are the majority in the population, their health represents numerically the largest public health challenge.

Timeline

- Fetal Origins of Disease, HD00-021, FY2001 to FY2005
- Breast Cancer and the Environment Centers, ES03-001, FY2003 to FY2009
- Sisters Study, FY2004 to FY2009

1.2.2.2 Performance Measures

Performance in research on women's health disparities can be measured in the number of funded studies published in peer-reviewed journals and the number of those publications cited by other researchers in the field of study. Performance also can be measured in media coverage generated by published studies that raise the awareness in the medical and scientific community as well as the awareness of the general public on the health issues being addressed.

1.2.2.3 Outcome Measures

Outcomes in research on women's health disparities can be measured in decreased incidence of disease in minority and lower socioeconomic status women; in the improvement of prevention, diagnosis, and treatment of disease in these populations of women; and in the awareness of the means for preventing, diagnosing, and treating diseases among these populations.

1.2.3 Objective Three: To Address Health Disparities in Environmental Health That Relate to Specific Diseases and Exposures

Health disparities exist in a number of populations and related to a number of exposures and diseases beyond those affecting exclusively the health of children and women. Research on these varied health disparity concerns are spread across the various Centers and across the NIEHS extramural grants portfolio and intramural research program, and are numerous and various enough that they can only be highlighted here. Populations studied include the aging, Indian tribes, rural residents, farm workers, minority men, and others. Diseases under study include hypertension, heart failure, diabetes, coronary heart disease, prostate cancer, neurobehavioral dysfunction, and others. As will be detailed in another section, studies are initiated in many instances in response to input from various outreach and public liaison efforts, as varied as town meetings, the Institute's web site, and the Public Interest Liaison Group. Health disparities occur in the complexity of the real world of social networks, economic relationships, family structures, and civic and community relationships, so the variety and number of studies on health disparities reflect this complexity.

One emerging area in health disparities is the study of the built environment and how it relates to health and especially to the epidemic of obesity and obesity-related diseases such as diabetes, cardiovascular disease, and stroke. NIEHS coordinated a major meeting in May 2004 in Washington, DC, on the built environment and health. How we design communities and their infrastructure, how we arrange transportation, shopping, land use, residences, walking and exercise areas, green space, and other dimensions of living arrangements affects how people live and work, their diet, their exercise, their stress levels, and ultimately their health, well-being, and longevity. This is a rapidly developing research area and a promising one in addressing health disparities. Two Town Meetings are proposed on related subjects, one in Atlanta, October 5, 2004, on "The Impact of Urban Sprawl on Health in the Inner City," and a second in Los Angeles, tentatively scheduled in FY05 or 06, on "Obesity and the Built Environment."

Prostate cancer presents a health disparity threat to men parallel to breast cancer in women, and the environmental and genetic triggers are as yet not well defined. At one of the Centers for Population Health and Health Disparities, investigators are studying the gaps in our knowledge about factors that predict for prostate cancer outcomes, and in particular the causes of disparity in prostate cancer outcomes in men of African and Caucasian descent. The mission is to study the complex interaction of biological, clinical, behavioral, and environmental factors predictive of outcomes following diagnosis; to evaluate how these factors explain disparities in cancer outcomes by ethnicity; and to disseminate this information to at-risk populations and to the medical and public health community. Another project, “To Change African-American Men’s Attitude and Beliefs about Prostate Cancer Screening,” is funded to increase prostrate screening for African American men. This project is designed to change African American men’s attitudes and beliefs about prostate cancer screening.

Within the NIEHS intramural research program, a senior scientist is conducting research co-funded by the Department of Defense through the DOD Prostate Consortium that is looking at 1,000 prostate cancer cases at Louisiana State University and 1,000 in North Carolina, half of the cases African American and the other half White, to help understand why Blacks have much higher incidence and severity of prostate cancer. The project, “Genetic Determination of Prostate Cancer Aggressiveness,” is part of a wider consortium addressing “Racial Differences in Prostate Cancer: Influence of Health Care Interaction and Host and Tumor Biology,” funded from August 2003 to July 2006.

In the NIEHS extramural grant portfolio are scores of NIEHS-funded studies addressing health disparities issues related to specific diseases, exposures, and populations. Examples illustrating the expansive areas of interest include: Parkinson’s disease susceptibility genes and pesticides; socioeconomic status and age-related disability in a biracial community; Mohawk culture, behavior, toxicant exposure, and health; sociocultural influences on allergic sensitization; genetic and environmental risk factors in asthma severity; African American community review of genetic research; and effects of volcanic air pollution on respiratory health.

1.2.3.1 Action Plan

NIEHS plans to sustain and develop research in health disparities related to specific diseases, exposures and populations that will in turn expand knowledge on how to reduce and eliminate health disparities. Promising areas of scientific opportunity include studying prostate cancer and possible environmental triggers that cause a higher incidence and severity of the disease in Black men, and studying the built environment and how it may be better designed to enhance human health and reduce or eliminate health disparities. Similar opportunities are being explored through a large number of varied grants and studies funded by the Institute.

Timeline

- Oct. 5, 2004, Town Meeting in Atlanta on “The Impact of Urban Sprawl on Health in the Inner City”
- FY05 or 06, Town Meeting in Los Angeles on “Obesity and the Built Environment”
- “Genetic Determinants of Prostate Cancer Aggressiveness” study funded FY2003 to FY2006

1.2.3.2 Performance Measures

Performance in health disparities research may be measured in publication of research in peer-reviewed journals and in citations of those articles by other researchers working in the field. In turn, scientific publication often results in media coverage that enhances public health and public awareness of environmental health and health disparity concerns and potential remedies.

1.2.3.3 Outcome Measures

Outcomes can be measured by the translation of research results into medical and public health practices that reduce or eliminate the incidence of environmentally related disease and dysfunction.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Recruiting and Training of Scientists From Minority and Other Populations Underrepresented in the Environmental Health Sciences and Related Disciplines

One of the likely causes of health disparities between minorities and the majority population is the underrepresentation or lack of representation of minorities in the professional ranks of scientific research. Minorities too often have not been present in the scientific dialogue to bring the concerns and issues of their families and communities into the scientific discussion, to be sure that their concerns are addressed through research, publication, and action by the public health community.

At the same time it has long been realized that the majority population alone cannot supply all of the ranks of scientific researchers. The talent pool must include young minority scholars who choose scientific career paths, succeed in the rigorous curricula that lead to research careers, and are mentored into and through doctoral and postdoctoral programs and into the research community, where they can make their contributions and let their voices be heard. This recruitment and training cannot be a passive process but requires active outreach, persuasion, and mentoring, to teach gifted young minority scholars about the satisfactions and opportunities available in research careers and to guide them through the intensely competitive world of training for a research career. All young scientists require cultivation and attention—the active concern of their established senior colleagues—and young minority scientists-in-training most especially require this care. Many or most are the first in their family to consider a career in scientific research; some are the first in their family to graduate from college, let alone graduate school. And science must compete for the brightest students with clinical medicine, law, business, non-scientific academic careers, and similar highly rewarding non-science careers. All of hurdles presented to any young scientist, and often more, are put before the young minority scientist.

The contribution of NIEHS to increased research capacity in the field of health disparities is the recruitment and training of young minority scientists with the objective of retaining them in the environmental health sciences in government agencies, universities, private sector laboratories, or similar institutions. Toward this end, various training programs have been established and have successfully recruited, trained, and retained minority scientists in the field of environmental health sciences. NIEHS seeks to continually improve the methods and means of cultivating this essential talent pool for the future.

2.1.1 Objective One: Use Training Grants, Intramural Programs, and Other Mechanisms to Recruit and Train Minority Scientists

Training grants administrated by the NIEHS Division of Extramural Research and Training provide funding for training of graduate students, postdoctoral fellows, and medical fellows and for summer research experiences. Within each grant is the requirement to promote diversity in the biomedical workforce and recruit trainees from groups that have been shown to be underrepresented in scientific research.

2.1.1.1 Action Plan

The Institute also funds research supplements at grantee institutions that are specifically designed to promote diversity in the biomedical workforce through Research Supplements to Promote Diversity in Health-Related Research, PA-05-015. The program is open to those underrepresented in biomedical research, including minority students at all levels from high school through faculty, and to individuals with disabilities. In its previous programs, NIEHS funded training programs specifically for minority students. These programs are under review.

NIEHS has a close working relationship with, and has provided funding to, The Meyerhoff Program at the University of Maryland, Baltimore County, which has one of the largest concentrations of high-achieving African American students majoring in science anywhere in the United States. With a retention rate of 95 percent and high grade point averages (3.53/4.00 in 2002), the Meyerhoff Program takes a leadership role in the training of a diverse scientific workforce. The Meyerhoff Program has expanded its acceptance policies and does not use race or ethnicity as a criterion for selection to the program.

NIEHS reaches out to this outstanding resource and to other venues to promote a diverse applicant pool for its Summers of Discovery summer internships. The Summers of Discovery positions provide hands-on training in laboratory research, one-on-one mentoring by senior staff, a seminar series tailored to participants, an end-of-summer professional scientific poster session well-attended by scientific staff, and occasionally co-authorship for interns on scientific articles appearing in peer-reviewed journals. In addition, the interns receive training in the use of the Institute's world-class technical library as well as training in required laboratory safety and other laboratory skills appropriate to their work. These internships provide excellent resume items and references for continuing in graduate school and attaining appropriate postdoctoral appointments. The skills attained in the laboratory provide solid fundamentals for future leadership roles.

NIEHS funds an Advanced Research Cooperation in Environmental Health (ARCH) Program. The goal of the ARCH program is to establish a group of investigators at institutions with suboptimal research infrastructure, including some Historically Black Colleges and Universities (HBCUs) that can successfully compete for NIH/NIEHS Research Project Grants (RPG) support, typically R01 grants. The ARCH Program is under review.

Timeline

These programs are seen continuing at their current levels through FY2005.

2.1.1.2 Performance Measures

The most direct measurement of performance is by numbers of trainees funded by grants and the number of minority summer interns, postdoctoral fellows, graduate students, and staff fellows in training. Other measures are the number of minorities trained in NIEHS-funded programs who proceed to the next level of training or to full-time tenured employment in environmental health sciences research. Another benchmark is the number of publications authored by these trainees or former trainees in peer-reviewed scientific journals.

2.1.1.3 Outcome Measures

The ultimate outcome measures are the number of former NIEHS-funded trainees who become principal investigators and science administrators and who attain other positions of leadership that result in their being appointed to advisory boards and boards of scientific directors, and other decision-making bodies within the scientific and public health community. This in turn denotes empowerment to make future decisions in the reduction and elimination of health disparities.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Education and Training Programs

Raising awareness about environmental health sciences research and the prevention of environmentally related diseases among minority populations and those of lower socioeconomic status is a key means of reducing or eliminating health disparities. In public health as elsewhere, knowledge is power. NIEHS has initiated various means of expanding awareness among students as well as training hazardous waste and Brownfields workers.

By developing curricula and materials to teach environmental health sciences in the schools at the K-12 level, large numbers of young students are introduced to the concepts they need to address environmental health in their own communities. Because these concepts are introduced early and with progressive sophistication, students exposed to these ideas are in a position to make better decisions as citizens and community members and have the vocabulary and concepts they need to identify environmental health issues and secure action at the community, city, state, or national level.

In its Minority Hazardous Waste Worker training programs and Brownfields Minority Worker Training, NIEHS has created new professional cadres of workers with expertise in hazardous waste cleanup and in the cleanup of urban industrial and residential sites requiring knowledge of hazardous waste cleanup and other specialized skills. These training programs take the energy and talent of local young people in areas with hazardous waste and Brownfields issues and apply this energy and talent to addressing local problems. At the same time, the training programs develop a cohort of workers with the expertise to address these cleanup projects safely and effectively, and in turn, once on-the-job experience is added to training, these programs supply future instructors to teach others these in-demand skills.

3.1.1 Objective One: Worker Training Program and Brownfields Worker Training Program for Underserved/Underrepresented Populations

The Minority Worker Training Program (MWTP) focuses on delivering comprehensive training to disadvantaged and underrepresented minorities in order to prepare them for employment in the construction and environmental cleanup fields. The program was authorized under Section 126(g) of the Superfund Amendments and Reauthorization Act of 1986, Public Law 99-499, and referenced in the 1995 Conference Report 103-311 -U.S. House of Representatives Subcommittee of Appropriations for HUD, VA and Independent Agencies (pp. 61-62): Superfund Minority Worker Training Program. For the past 11 years in urban communities throughout the United States, the MWTP has successfully recruited and trained these groups, prepared them for productive careers, and as a result also has increased their representation in the construction and environmental cleanup fields.

The Brownfields MWTP fosters economic and environmental restoration and expands the reach of the MWTP by providing comprehensive training to disadvantaged residents impacted by Brownfields—unused industrial and residential areas that require cleanup and new construction to again become economically vital areas.

Since 1995, these two programs have funded job training for more than 6,200 people with an overall job placement rate of 67 percent.

3.1.1.1 Action Plan

The Worker Training and Education Program will continue to work with EPA and other federal, state, and local partners to address Brownfields health and safety issues related to cleanup and training in support of rebuilding communities harmed by contaminated sites, disinvestment, and lack of adequate job training.

The program will continue to develop training approaches such as life skills that are culturally sensitive and address the needs of the minority workforce. The program includes life skills training tailored to individual needs, covering a range of subjects such as remedial mathematics, tutoring, budget counseling and cash management, life situational counseling, and job readiness skills. These help prepare students to take apprenticeship and employment exams, as well as to pass the environmental examinations leading to certifications in lead abatement, asbestos abatement, and hazardous waste operations.

Timeline

- Minority Hazardous Waste Worker Training, ES99-009, funded FY2000 to FY2004
- Brownfields Minority Worker Training, ES99-009, FY2000 to FY2004

3.1.1.2 Performance Measures

Performance can be directly measured in the number of students completing training, the number of hours of training, and the number of trainee graduates gaining employment, as well as in the improvement of hazardous waste areas and Brownfields returned to safe, economically productive status, to the benefit of their communities and locales.

3.1.1.3 Outcome Measures

Ultimate outcome measures are improved employment and economic activity in the areas where cleanup occurs and in higher awareness of environmental health and safety in the community, which leads to reduced or eliminated health disparities.

3.1.2 Objective Two: Programs to Develop Environmental Health Sciences Education for K-12 Students and Other Select Groups

The NIEHS funds extensive efforts to expand environmental health sciences education in the United States in general and for minority and lower socioeconomic status students in particular. A senior staff member is assigned to coordinate workshops and programs devoted to environmental health sciences education, and sits on various boards and advisory groups devoted to that objective.

Each of the Environmental Health Sciences Centers funded by the NIEHS Division of Extramural Research and Training is mandated to have a COEP, and these programs have developed a wide variety of expertly designed curriculum materials, including teachers’ manuals, student materials, CD presentations, games, and other interactive materials, which provide strong support to environmental health sciences teaching in schools. A full-time COEP coordinator in the NIEHS Division of Extramural Research and Training also serves as the chairman of an education committee within the

Institute itself, so that there is sharing of ideas and collaboration between internal and extramural efforts in education.

NIEHS operates a kids' page at its web site (http://www.niehs.nih.gov) that has stories, games, songs, and educational material, as well as information for teachers. A printed version of one of the stories, written and produced by the NIEHS Office of Communications and Public Liaison for early-readers, titled "Sharon Finds the Environment," was printed and has been circulated nationally in the tens of thousands of copies, including at Latino health fairs hosted by Wal-Mart. An offer to reprint in Spanish was rejected by Hispanic health fair organizers on the basis that they preferred to have a book they could use to teach their young children English.

3.1.2.1 Action Plan

NIEHS plans to continue development of educational programs and materials through its Center grants program and through staff work, to reach a growing number of students and teachers in K-12, with increasingly tested and sophisticated materials to compete with the many media exposures, computer games, and other commercial and education experiences that are presented to students.

Timeline

The 26 Environmental Health Sciences Centers, with COEP programs, compete for funding as their current grants are completed. Seven will complete in FY2005; three in FY2006; six in FY2007; five in FY2008; and five in FY2009, until the competition for renewal cycle begins again.

3.1.2.2 Performance Measures

Performance can be measured by numbers of schools, classrooms, teachers, and students reached through COEPs at NIEHS-funded Centers, and the number of hits on the NIEHS web site devoted to students and teachers, as well as the number of shipments of booklets, brochures, and materials distributed from the NIEHS Office of Communications and Public Liaison.

3.1.2.3 Outcome Measures

Final outcomes will be reflected in increased awareness and interest in environmental health sciences among minority and lower socioeconomic status high school graduates and college students, as well as an increase in the number of these students expressing an interest in environmental health sciences careers and exhibiting a knowledge of environmentally related health issues in their own communities and constituting a better informed citizenry.

3.2 Area of Emphasis Two: Community Outreach and Interaction to Involve Minorities in Defining Research Needs and Making Decisions in Environmental Health Sciences and Public Health

3.2.1 Objective One: To Build Bridges of Information and Involvement in the Community

The NIEHS has established community outreach as an integral part of its research programs, requiring a community outreach component in each of its Environmental Health Sciences Centers and having established programs in Environmental Justice: Partnerships for Communication, and CBPR. The outgoing NIEHS director has devoted focus and energy during his 13-year tenure to conducting town meetings throughout the United States to encourage the public to raise environmental health issues that may not be addressed by current research and public health policy. A new director may continue this approach or use different means to attain the same goal, but the principle of inviting public input, and especially minority and lower socioeconomic status input, to research planning will continue.

The Environmental Justice: Partnerships for Communication bridges the communications gap between researchers, health care providers, and community residents so that communities have a demonstrable role in identifying and defining problems and risks related to environmental health and in shaping future research approaches to environmental health problems they face. Annual meetings bring the key groups together to share their endeavors that have been effective in addressing public health issues.

The CBPR program implements culturally relevant prevention and intervention activities in economically disadvantaged or underserved populations impacted by an environmental contaminant. The program fosters refinement of scientifically valid intervention methods and strengthens the participation of affected communities. Community-based prevention/intervention research seeks to expand knowledge and understanding of potential causes and remedies of environmentally related diseases, while at the same time enhancing the capacity of communities to participate in the processes that shape research approaches and intervention strategies. The long-range goal of this program is to improve the knowledge and effective response of disadvantaged or underserved community members regarding prevention, detection, and treatment of environmentally related diseases and conditions and thereby reduce the incidence and mortality rates of such illness. The COEP at the EHS centers will increase awareness among minority and low socioeconomic status communities about issues and concepts in environmental health sciences.

Another dimension of NIEHS outreach is its Public Interest Liaison Group, an advisory group made up of representatives of various health and patient advocacy groups and other stakeholders who meet regularly with senior Institute staff to give input on research and program decisions.

3.2.1.1 Action Plan

The Institute plans to continue to shape its research and training programs in cooperation with the public, and to solicit input from minority and lower socioeconomic status populations in addressing issues of concern to those populations. A new soon-to-be-named NIEHS/National Toxicology Program (NTP) director will undoubtedly put her or his own imprimatur on this effort. As the plan and programs in place described herein illustrate, public input has been a guiding and governing influence on the Institute's work.

Timeline

- Town meeting tentatively scheduled in Atlanta, October 5, 2004, proposed topic: The Impact of Urban Sprawl on Health in the Inner City
- Town meetings tentatively scheduled FY05-06, pending new director's approval:
    - In Boston, "Children's Health"
    - In Los Angeles, "Obesity and the Built Environment"
- Environmental Justice: Partnerships for Communication, ES03-007, FY2004 to FY2008

3.2.1.2 Performance Measures

Performance measures include the number of COEPs in place, the number of studies underway with public input from minorities and lower socioeconomic status populations, and the number of opportunities for public input such as town meetings held.

3.2.1.3 Outcome Measures

Outcome is reflected in studies published in peer-reviewed journals drawing on public input for direction and study design, and awareness in communities of empowerment on environmental health sciences issues and the ability of minorities and other underserved communities to have their health disparity issues addressed through research and public health action.

The National Institute of General Medical Sciences

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

MISSION/VISION STATEMENT

The mission of the National Institute of General Medical Sciences (NIGMS) is to support basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines. NIGMS attempts to ensure the vitality and continued productivity of basic biomedical research, while producing the next generation of scientific breakthroughs and training the next generation of scientists. Throughout all of NIGMS's research and research training programs, emphasis is placed on increasing the participation of underrepresented students and faculty in the biomedical research enterprise. One important consequence of a more diverse research community is likely to be increased attention to areas of research that can reduce health disparities.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The MBRS and MARC Programs

Central to NIGMS's efforts to address health disparities are programs designed to increase the capacity and capability of diverse institutions and investigators to successfully obtain research support from NIH and other sources. The overarching goal of these programs is to recruit the diverse workforce of the future into biomedical research careers.

NIGMS has several mechanisms to encourage greater participation of diverse faculty and students in health-related research. The Minority Biomedical Research Support (MBRS) Support of Competitive Research (SCORE) Institutional Development Award program supports research projects that foster diverse faculty and student participation in biomedical research, thereby helping to create a growing and diverse cadre of scientists who are making important contributions in the health sciences. The Research Initiative for Scientific Enhancement (RISE) program develops the research potential of faculty and students. NIGMS also supports several research training programs to increase diversity in the biomedical research workforce: the Minority Access to Research Careers (MARC) Undergraduate Student Training in Academic Research (U*STAR) program, predoctoral fellowships, faculty fellowships, Visiting Scientist Fellowships, ancillary training activities, and the Post-Baccalaureate Research Education Program (PREP). The MBRS and MARC programs are institutional programs and do not use race/ethnicity as criteria for individuals supported by the program.

NIGMS also administers two Bridges to the Future programs to increase the diversity of students in the biomedical sciences during critical transition periods in their education; one program encourages connections between institutions that offer only associate degree programs and colleges and universities that award baccalaureate degrees (the 2-year to 4-year bridge), and another supports interactions between institutions that offer the Master's as a terminal degree and institutions that grant doctoral degrees (the M.S. to Ph.D. bridge).

NIGMS provides technical assistance designed to strengthen the skills of faculty and facilitate the submission of more competitive grant applications. A grant writing workshop is designed as a 10-week activity and is accomplished, in part, via the Internet. Another technical assistance workshop assists supported programs in the design and implementation of evaluations of their activities. NIGMS staff visit institutions and provide information and advice to current and potential grantees.

NIGMS Basic Research and Research Training Programs

In addition to providing these opportunities designed to create a diverse biomedical workforce, NIGMS requires that the pre- and postdoctoral research training programs at all institutions it supports develop and implement plans to recruit a diverse pool of trainees.

NIGMS also supports efforts to ensure that its research programs address the needs and perspectives of health disparities populations and their subgroups. NIGMS held meetings in 1999 and 2000 that sought input from members of various ethnic groups about their concerns regarding participation in genetic research. Following these meetings, NIGMS has taken a lead in encouraging researchers who conduct genetic studies on ethnically or geographically identified communities to engage community members in discussions prior to conducting research. These “community consultations” are designed to increase trust in the research process and to demonstrate respect for the community.

The NIGMS Human Genetic Cell Repository acquires and maintains cell and DNA samples that enable investigators to study the causes of a large variety of genetic disorders. Community consultation is an integral part of the policy developed by the Repository for acquiring samples from named populations. (This policy can be found at http://locus.umdnj.edu/nigms/comm/submit/collpolicy.html.) Samples from identified communities may be submitted only if community consultation is carried out in advance of sample collection. Following sample collection, a community advisory board is established that serves as the liaison between the Repository and the community and is kept informed of the research use of its community’s samples and of research results. The 1999 and 2000 meetings organized by NIGMS also provided input into the National Institute of Health’s (NIH’s) “Points to Consider When Planning a Genetic Study That Involves Members of Named Populations” (http://www.nih.gov/sigs/bioethics/named_populations.html). NIGMS has continued to support meetings with minority communities, and in 2003 co-sponsored the Hispanic/Latino Genetics Community Consultation.

As a part of NIGMS’s research program in pharmacogenetics, a Pharmacogenetics Populations Advisory Group was convened when the initiative was funded to consider possible areas of misunderstanding and the ramifications of such research. The role of this group was to consider issues of stereotyping and stigmatization of communities, and any possible resulting harm to individuals (e.g., discrimination in access to various social benefits) that may arise from membership in an identified group. Members of the advisory group, as well as participants in several follow-up focus groups, believed that the likely benefits of pharmacogenetics research outweighed the risks. They also recommended that clear statements of the goals of the research and the issues involved be provided to the public. This was developed by NIGMS as brochures intended for lay audiences. Investigators are now using these brochures and sharing them with recruits into their research studies. They can be viewed as “thumbnails” on the NIGMS homepage at http://www.nigms.nih.gov/pharmacogenetics/.

Public Comments on the NIH Strategic Plan

This complement of programs addresses needs identified in public comments received on the *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006*. To further enhance these programs, in 2004, NIGMS began funding educational research to identify successful training intervention strategies for increasing the participation and success of students currently underrepresented in the biomedical sciences.

A third theme in the public comments was the need to use racially and culturally sensitive and appropriate communication with health disparities populations. NIGMS has taken a lead in encouraging researchers to consult with communities prior to conducting genetic studies involving ethnically or geographically identified populations. These community consultations ensure that genetic research supported by NIGMS is culturally sensitive and addresses the needs and perspectives of population subgroups under study. A similar role was played by the Pharmacogenetics Populations Advisory Group in guiding NIGMS-supported research in pharmacogenetics. NIGMS has also translated into Spanish some of its own publications on genetic research with identified populations: *Genes & Populations* (http://www.nigms.nih.gov/news/science_ed/genepop-esp/) and *Medicines for YOU* (http://www.nigms.nih.gov/funding/sp_medforyou.html).

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Pharmacogenetics and Genetic Research in Health Disparities Populations

Ethnogeographic differences in drug responses are known to exist between populations. The best known instances are associated with the enzymes of drug clearance. Genetic polymorphisms significantly affect the elimination of several major classes of important drugs in clinical use today, including antidepressants, antipsychotics, several cardiovascular drugs, antiepileptics, and anti-ulcer drugs. For some of the enzymes involved in drug clearance, much less is known. For example, it has been observed anecdotally that African Americans frequently require higher doses of cyclosporine A, an immunosuppressant drug given for transplants and a substrate of an enzyme required to eliminate a very large proportion of medications in use today. However, the basis for the higher dosage requirement is not understood. These genetic differences can have serious clinical consequences, particularly in chronic dosing situations. Knowledge that is acquired by studying the effects of inheritance in any selected groups also can be used to improve the health of individuals with similar genetic characteristics who are members of other population subgroups.

NIGMS's Pharmacogenetics Initiatives are designed to discern the role that human genetic variation plays in drug responses. The goal of the Pharmacogenetics Research Network and Knowledge Base is systematically to collect and interpret information about inherited variations in humans that determine both therapeutic and adverse responses to medications. Basic scientific knowledge is stored in an information repository (the PharmGKB) that is intended for research purposes. (For more information, see http://www.nih.gov/nigms/funding/pharmacogenetics.html.)

1.1.1 Objective One: Support Pharmacogenetic Research

Continue support for the Pharmacogenetics Research Network and Knowledge Base to aid in the discovery of genetic variations associated with clinically important variations in drug responses that occur across populations with different ethnic and racial backgrounds.

1.1.1.1 Action Plan

Promote exploratory clinical studies to identify populations where functional genetic variation is believed to exist and develop common resources for network usage, such as tissue sample banks, with samples obtained by appropriate informed consent.

1.1.1.2 Performance Measures

Receipt of applications and grants awarded in pharmacogenetic research.

1.1.1.3 Outcome Measures

The outcome anticipated from these supplements is new knowledge regarding the relationship between genetic variation and differential responses to pharmacological agents. Significant findings from this research will be communicated through scientific conferences and publications.

1.2 Area of Emphasis Two: The NIGMS Human Genetic Cell Repository

The Human Genetic Cell Repository contains cell and DNA samples that allow investigators to study the causes of a large variety of genetic disorders, some of which affect racial/ethnic populations disproportionately. Among these are samples for the study of adult-onset diabetes, sickle cell anemia, and glucose-6-phosphate dehydrogenase (G6DP) deficiency. The Repository also is collaborating with the National Human Genome Research Institute by acquiring and distributing samples from geographically diverse populations as part of the HapMap Project. The HapMap samples will be used for discovery of single nucleotide polymorphisms (SNPs) that are expected to help scientists identify genes that are involved in complex genetic disorders, such as cardio- and cerebrovascular disease, hypertension, obesity, asthma, prostate cancer, end-stage renal disease, and systemic lupus erythematosus, which occur disproportionately in African Americans.

1.2.1 Objective One: Support the NIGMS Human Genetic Cell Repository

Provide a resource for investigators studying the etiology, diagnosis, and treatment of genetic disorders.

1.2.1.1 Action Plan

Continue ongoing support for the Human Genetic Cell Repository.

1.2.1.2 Performance Measures

Contracts awarded to support the Cell Repository.

1.2.1.3 Outcome Measures

Use of samples from the Human Genetic Cell Repository in genetic research related to health disparities and the development and communication of policies to guide this research.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Institutional Development

NIGMS provides institutional development support to expand faculty research capabilities at institutions that typically do not receive NIH research support, thereby increasing the diversity of the biomedical research workforce and the types of health problems addressed.

2.1.1 Objective One: Increase the Diversity of Institutions Able to Compete Successfully for NIH Support

The SCORE Program is designed to develop biomedical research faculty at institutions that are committed to improving competitive research programs and increasing the diversity of professionals engaged in biomedical research

2.1.1.1 Action Plan

Provide financial assistance to developing research programs in all areas of biomedical and behavioral research. Support faculty-initiated, scientifically meritorious research projects, including pilot research projects.

2.1.1.2 Performance Measures

Continued support for the SCORE program.

2.1.1.3 Outcome Measures

The outcome expected of the SCORE program is expanded research capacity at a more diverse set of institutions. The expected outcomes of NIGMS support and plans to evaluate these outcomes are outlined in applicants' funding proposals, and they vary from institution to institution. These outcomes are peer-reviewed when grantees submit renewal applications at the end of their funding period, and they are one consideration in providing continued funding for a program.

2.2 Area of Emphasis Two: Training and Career Development

Through training and career development, NIGMS encourages diversity in the students who pursue training for scientific careers and strengthens the research skills of diverse students and faculty.

2.2.1 Objective One: Encourage a Diverse Body of Students to Pursue Training for Scientific Careers and Strengthen the Research Skills of Diverse Students and Faculty

Throughout all of NIGMS's research and research training programs, emphasis is placed on promoting greater participation of students and faculty underrepresented in the biomedical research enterprise. One important consequence of a more diverse research community is likely to be increased attention to areas of research that can reduce health disparities.

2.2.1.1 Action Plan

Provide support for training and career development through several ongoing programs:

Research Initiative for Scientific Enhancement. RISE provides support for faculty and student development activities, which can include on- or off-campus workshops, specialty courses, travel to scientific meetings, and research experiences at on- or off-campus laboratories. Support is available for evaluation activities, as well. RISE also offers some support for institutional development, which includes limited funds for the renovation or remodeling of existing facilities to provide space for an investigator to carry out developmental activities, limited equipment purchases, and the development of research courses.

The Initiative for Maximizing Student Diversity (IMSD). IMSD encourages domestic private and public educational institutions with fully developed and funded research programs to initiate and/or expand innovative programs to improve the academic and research capabilities of underrepresented students and to facilitate their progress toward careers in biomedical research. The application may be directed toward the development of underrepresented scientists who are in any phase of their career development, from the undergraduate level through the Ph.D. Awards under this program use the institutional education project grant mechanism.

Minority Access to Research Careers Training and Fellowships. MARC supports special research training opportunities for students and faculty. MARC programs also enable grantee institutions to develop and strengthen their biomedical research training capabilities. As a result, these schools are able to interest students in, and prepare them for, pursuing doctoral study and biomedical research careers. MARC training grants and fellowships include U*STAR institutional grants, predoctoral fellowships, faculty predoctoral and senior fellowships, and a visiting scientist program.

The Post-Baccalaureate Research Education Program. PREP Awards encourage students who hold a recent baccalaureate degree in a biomedically relevant science to pursue a research doctorate. PREP scholars work as apprentice scientists in a preceptor's laboratory and participate in student development and education activities. This program is expected to strengthen the research skills and competitiveness of participants for pursuit of a graduate degree while also stimulating them to have an interest in addressing the health problems that disproportionately affect racial/ethnic minorities and the medically underserved in the United States.

MARC Ancillary Training Activities. In addition to the programs described above, MARC has formed relationships with professional scientific societies to develop innovative programs aimed at increasing the number of underrepresented biomedical scientists. These societies include the American Society for Cell Biology, the American Society for Microbiology, the Society for Advancement of Chicanos and Native Americans in Science, and the Federation of American Societies for Experimental Biology. With MARC support, the societies have sponsored activities that engage students and faculty members in the biomedical sciences, including visiting scientist programs, summer research opportunities, and scholarships enabling attendance at national scientific meetings and conferences.

Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research, as mandated by federal law (Section 487(a)(4) of the Public Health Service Act, as amended). NIGMS also participates in an NIH-wide program providing predoctoral fellowship support for students from groups that have been shown to be underrepresented in the biomedical sciences. These fellowships provide up to 5 years of support for research training leading to the Ph.D. or equivalent research degree; the combined M.D./Ph.D. degree; or other combined professional degree and research doctoral degree in the biomedical or behavioral sciences or in health services research.

The Institutional Research and Academic Career Development Award (IRACDA). IRACDA combines a traditional, mentored postdoctoral research experience with an opportunity to develop teaching skills through mentored assignments at a partner institution. The goals of the program are to provide a resource to motivate the next generation of scientists and to promote linkages between research-intensive institutions and other institutions that can lead to further collaborations in research and teaching.

Bridges to the Future. One special initiative supported by NIGMS is the Bridges to the Future Program, which is co-sponsored by NIGMS and the NIH National Center on Minority Health and Health Disparities. The mission of the Bridges to the Future program is to make available to the biomedical science research enterprise and to the nation the intellectual talents of a diverse biomedical research workforce. It does so by facilitating the transition of students from associate- to baccalaureate-degree granting institutions and from master's to doctoral degree-granting institutions. The program promotes effective inter-institutional partnerships that lead to improvement in the quality, quantity, and diversity of students being trained as the next generation of scientists. Examples of activities supported through the Bridges program include laboratory research experiences, mentoring and academic counseling programs, curriculum enrichment, visiting lectureships, and course development.

Research Supplements to Promote Diversity in Health-Related Research. As part of a revised NIH-wide program formerly known as "Research Supplements for Underrepresented Minorities," principal investigators holding NIGMS research grants may request supplements to improve the diversity of the research workforce by supporting and recruiting students, postdoctoral fellows, and eligible investigators from groups that have been shown to be underrepresented. Any principal investigator at a domestic institution holding an active NIGMS research grant, program project grant, center grant, or cooperative agreement research program, with a reasonable period of research support (usually 2 years or more) remaining at the time of the supplemental award, is eligible to submit a request to NIGMS for an administrative supplement to the grant.

National Research Service Award (NRSA) Institutional Research Training Programs. NIGMS also provides training support through its traditional NRSA training programs. All Institute-supported training grants are required to establish acceptable recruitment plans to encourage the participation of students underrepresented in traditional research training programs. These recruitment efforts are an integral part of the Institute's ongoing research training programs, and their costs cannot be separated from NIGMS's total research training budget.

Native American Research Centers for Health (NARCH). NARCH is a collaborative program with the Indian Health Service to improve and expand health research involving American Indian and Alaska Native tribes and people. This collaboration is designed to enhance and expand the capacity and skills of tribal organizations and Native American researchers to conduct high-quality biomedical and behavioral health research and to apply successfully for competitive research grants.

2.2.1.2 Performance Measures

Continued support for these programs.

2.2.1.3 Outcome Measures

The expected long-term outcome of NIGMS's ongoing training and career development activities is participation by a greater diversity of students and faculty in science. More specific goals and measures are outlined in applicants' funding proposals, and they vary from institution to institution. These outcomes are peer-reviewed when grantees submit renewal applications at the end of their funding period, and they are one consideration in providing continued funding for a program.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Outreach and Technical Assistance

NIGMS is actively engaged in staff outreach visits to diverse institutions to explain new program requirements, review incoming applications, and monitor ongoing programs. In addition, NIGMS staff members make presentations at regional workshops, targeted at institutions not currently funded by NIGMS, to introduce the workshop participants to NIH and NIGMS and familiarize them with the Institute's efforts to increase the diversity of the biomedical science workforce. NIGMS also provides outreach through several web sites designed to provide information on ongoing NIGMS programs and initiatives. In addition to staff outreach efforts, NIGMS provides extramural funding for technical assistance activities performed by third parties, such as professional societies.

3.1.1 Objective One: Provide Technical Assistance to Institutions

Provide institutions with the knowledge and assistance required to take advantage of research and training opportunities for students and faculty underrepresented in the biomedical research workforce.

3.1.1.1 Action Plan

Continue outreach and technical assistance activities.

3.1.1.2 Performance Measures

Continued support for staff visits to institutions, development of workshops for potential applicants, and performance of other communication activities at research conferences and workshops.

3.1.1.3 Outcome Measures

Support for technical assistance is expected to result in the involvement of diverse institutions in activities to develop their ability to successfully compete for NIGMS support and strengthen their own evaluation processes.

3.2 Area of Emphasis Two: Ethical, Legal, and Social Issues in Genetic Research

People of different ethnic and geographic backgrounds may have different alleles of genes that predispose them to complex genetic disorders or influence their reactions to pharmacological treatments. Identifying such genes would be valuable for diagnosis and the development of therapies. However, genetic studies on members of specific populations raise the possibility of discrimination, stigmatization, and stereotyping.

3.2.1 Objective One: Establish Mechanisms to Protect Participants in Genetic Research

NIGMS has taken the lead in efforts to develop approaches that would permit investigators to conduct these important genetic studies while protecting the subjects and the populations from which they come from negative impact.

3.2.1.1 Action Plan

Support community consultations and the development of policies to guide research involving individuals and populations participating in genetic studies related to health disparities.

3.2.1.2 Performance Measures

Continued support for regional meetings and the receipt of input and advice from members of population subgroups.

3.2.1.3 Outcome Measures

The outcome of these efforts will be greater understanding among researchers and subject populations, and the protection of subjects from any negative impacts in future genetic research studies.

The National Institute of Mental Health

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF MENTAL HEALTH

MISSION/VISION STATEMENT

The mission of the National Institute of Mental Health (NIMH) is to reduce the burden of mental illness and behavioral disorders through research on the mind, brain, and behavior. Mental disorders constitute an immense burden on the U.S. population, with major depression now the leading cause of disability in the United States, and schizophrenia, bipolar disorder, and obsessive-compulsive disorder ranked among the 10 leading causes of disability. NIMH also takes the lead in understanding the impact of behavior on human immunodeficiency virus (HIV) transmission and pathogenesis, and in developing effective behavioral preventive interventions. The NIMH conducts a wide range of research, research training, and research capacity development, as well as public information outreach and dissemination, to fulfill its mission.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIMH has a long history of concern and action related to health disparities and ethnic minority groups as well as other underrepresented groups. In 1980, NIMH established the position of Associate Director for Special Populations and subsequently established an Office for Special Populations (OSP) to oversee NIMH activities concerning underrepresented groups, including ethnic minorities. Recently, NIMH, in collaboration with consultants and public comment, developed a 5-year Strategic Plan to address mental health outcome disparities through research that aims to describe, understand, and remedy the disproportionate impact on minority populations of mental disorders and behaviorally influenced physical health conditions such as HIV/Acquired Immunodeficiency Syndrome (AIDS). The research takes into consideration relevant contextual frameworks, including interpersonal, sociocultural, and organizational factors.

Reducing health disparities requires multiple approaches; therefore, the revised NIMH Health Disparities Strategic Plan encompasses three Areas of Emphasis:

1. Research
2. Research Capacity
3. Community Outreach, Information Dissemination, Public Health Education

Additionally, increased emphasis on achieving a more ethnically and racially diverse pool of mental health investigators and providers influences each of the strategic plan’s objectives. A number of benefits will derive from achieving a significant increase in the ethnic and racial diversity of the investigator resource pool. Individuals from ethnic and racial groups underrepresented among the mental health investigator and caregiver community are likely to posses the necessary motivation and persistence needed to more effectively address questions of health disparities and attract participants for research clinical trials. They also may bring to the research task empathetic insight into the distinctive experiences, needs, and strengths of minority populations. A more subtle, but equally important outcome of increased diversity in the active training pool will be the sensitizing impact of a training environment enriched by diversity on the attitudes and insights of non-minority mental health investigators and caregivers.

NATIONAL INSTITUTE OF MENTAL HEALTH

The NIMH Health Disparities Strategic Plan recognizes the importance of increasing minority group member participation in clinical trials to generate sufficient power to separately analyze minority outcomes. Achieving broader participation will require wider community outreach and dissemination of information regarding mental health disparities to break down the formidable barriers of misunderstanding and mistrust about the nature and purpose of mental health research. Although the Areas of Emphasis, objectives, and action plans presented below vary according to the requirements of different groups; such diverse perspectives and approaches will have tremendous applicability to the Nation as a whole. This health disparities strategic plan signifies an important recommitment of NIMH to its long and continuing history of efforts to address and reduce health disparities through a strong portfolio of minority-relevant research, research training, and large-scale clinical trials.

The NIMH 5-year strategic plan for reducing health disparities prioritizes ongoing research, research training/capacity building, and public information outreach and dissemination activities, as well as new initiatives for the coming 5 years. Although NIMH has many other activities underway and planned in the area of health disparities, those represented in this strategic plan currently receive the greatest emphasis. The plan reflects ongoing activities and those projected for startup in fiscal years 2004-2008.

To develop this strategic plan, NIMH Director Thomas Insel formed an internal working group involving staff from all divisions and offices to work on the plan, monitor progress in meeting objectives, and recommend refinements on a yearly basis. In addition, members of the public provided comments to the National Center on Minority Health and Health Disparities that were carefully considered for inclusion in this plan. Outlined below in order of priority are the Areas of Emphasis, their objectives, action plans, and measures that are developed to further improve the effectiveness of NIMH's research portfolio, with the ultimate goal of reducing and eliminating mental health disparities and thereby improving health outcomes for all Americans.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Research to Overcome Mental Health Disparities

NIMH needs both basic science and clinical studies to reduce the burden of mental disorders. Neuroscience offers us the opportunity for advances on each of these disorders, just as molecular and cellular biology offer great hope for cancer, heart disease, and diabetes. As with these other medical illnesses, we recognize that progress in mental disorders requires an understanding of environmental as well as genetic factors. NIMH is uniquely positioned to advance the understanding of gene-environment interactions, given our long history of support for the behavioral sciences. By working with other NIH institutes on major "Roadmap" goals, NIMH is part of a broad, ambitious coalition to ensure that the best biomedical science has a major impact on public health. Through its clinical trials, NIMH provides opportunities for patients and families to participate in treatment research as well as evaluation and prevention studies. The involvement of the many people who participate in our clinical research studies is essential for generating knowledge with public health impact and is greatly appreciated. The President's New Freedom Commission on Mental Health report describes the need to transform mental health care in America. As explained in this historic report, research must ensure that science in the laboratory links to service in the community. NIMH has developed a services research portfolio and large-scale clinical trials that address the problems of identifying and receiving the best, currently available treatments.

1.1.1 Objective One: Measure the Extent of Mental Health Disparities (Continuation of Activities)

As indicated in the Surgeon General's 1999 Report on Mental Health, mental disorders constitute a burden on the U.S. population with $69 billion spent in 1996 for diagnosis and treatment of mental illness. Approximately 28 percent of the U.S. population has a diagnosable mental disorder or substance abuse disorder, with only one-third receiving some type of treatment in a 1-year period. Though there is a paucity of research about the effects of mental illness and mental disorders among ethnic minority groups, it is acknowledged that mental illness is at least as prevalent among ethnic minority groups as in the majority White population. Yet ethnic minorities with mental illnesses and mental disorders appear to be less inclined to seek treatment from the organized mental health system. Those who do not seek treatment or discontinue treatment consistently cite several recurring barriers and impediments to treatment which include costs, language, stigma, fear, distance, and misperceptions by clinicians. Within and among minority populations, access to adequate services is uneven at best and, where data exist, outcomes of illness as well as treatment have been shown to be poorer than in majority populations. The disease burden associated with mental disorders falls disproportionately on ethnic minority populations and women.

1.1.1.1 Action Plan

1. Provide continued support to nationally representative epidemiological studies of mental disorders to compare patterns of mental disorders in major racial/ethnic groups in the United States with those of the majority population.
2. The timeline for this objective is fiscal years 2004 through 2006.
3. The estimated objective completion date is 2006.

1.1.1.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Increased information about patterns of mental disorders and mental illnesses in major racial/cultural groups in the United States in comparison with those of the majority population.
2. Translation of findings into effective and efficient prevention and treatment programs for ethnic minority groups.

1.1.1.3 Outcome Measures

The NIMH will use this procedure to measure and evaluate outcomes of the objective:

1. Conduct an annual In-Process Review (IPR) to measure the progress, achievements, and continued relevance of the objective.

1.1.1.4 Outcomes

Two national surveys have been undertaken, and the preliminary data are being analyzed.

1.1.2 Objective Two: Conduct Basic Behavioral Research on Stress and Coping (Continuation of Activities)

Cultural and ethnic minorities on average face more stressors quantitatively and qualitatively than the majority population. Basic behavioral science research has documented certain cultural and ethnic variations in processes involved in coping with stress, such as cognitive, emotional, and social processes; perception of self; and motivation.

1.1.2.1 Action Plan

1. Provide continued support to nationally representative epidemiological studies of mental disorders and service use.
2. The timeline for this objective is fiscal year 2004 through fiscal year 2006; continues ongoing studies.
3. The estimated objective completion date is undetermined.

1.1.2.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Study the basic psychological processes related to stress, trauma, and coping, with a focus on elucidating the complex processes that contribute to disparities in mental health.
2. Examine cultural factors that foster resiliency or adaptive coping, with an aim of developing new prevention and treatment strategies.

1.1.2.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. The NIMH will conduct an annual IPR to measure the progress, achievements, and continued relevance of the objective.
2. The NIMH will review findings to determine differences in service usage in relation to patterns of coping and adaptation styles among various ethnic groups and determine the reduction of mental health disparities.
3. The NIMH will assess differences in service usage by ethnic minority groups in relation to coping and adaptation styles and ethnicity and in relation to length of residency in the United States.

1.1.2.4 Outcomes

In fiscal year 2004, five basic behavioral science grants were supported that will provide important information regarding basic psychological responses to stress as well as coping styles, including cultural variations that have implications for health and well-being.

1.1.3 Objective Three: Study Macro-Structural Factors in HIV/AIDS and Mental Disorders

The main routes of HIV transmission in the United States, unprotected sexual intercourse and intravenous drug use, are behaviors that are confounded by macro-structural factors that create contexts of powerlessness, disenfranchisement, and HIV risk behavior for racial and ethnic minorities. Macro-structural factors are defined as those sociocultural and environmental factors that might affect health outcomes and disparities, and include factors such as racism, poverty, stigma, unreliable transportation, homelessness, homophobia, violence, and immigration. When women have HIV infection or AIDS, other household members also are likely to have the disease (e.g., infants or children), and the stress of the caretaker role combined with the death and dying process of self and loved ones contribute additional macro-structural factors that generate disparities. Behavioral research is needed to identify, define, and address the impact of macro-structural factors on HIV risk behavior and how they limit the effectiveness of interventions. It will be necessary to discover not only the cultural, racial, and social contexts within which HIV transmission is prevented (or is not prevented), but also to determine the impact of interventions at multiple levels within these communities. Studies should specifically address vulnerable subgroups within minority communities (e.g., youth, women, the incarcerated, the severely mentally ill, the homeless, drug abusers) who are particularly affected by HIV due to a confluence of social, economic, and other factors.

As people with HIV infection are increasingly living longer with improved immune function and better health outcomes due to advances in combination drug treatments, HIV disease has evolved from a progressive, ultimately fatal disease (at least in developed countries) to a chronic condition that can often be managed long term. Thus, the face of the HIV epidemic has changed with the emergence and rapid increase in non-HIV co-morbidities and a decrease in the co-morbidities commonly associated with HIV infection (e.g., Kaposi's sarcoma, *Mycobacterium avium* complex disease, *Pneumocystis carinii* pneumonia).

1.1.3.1 Action Plan

1. Provide continued support to nationally representative epidemiological studies of mental disorders, decision-making, impulsivity, substance abuse, disability, and service utilization.
2. Convene a meeting on some of the macro-structural factors (homelessness and violence) affecting HIV transmission (Summer 2005), release a Request for Applications (RFA) on homeless youth infected with HIV in FY2006, and prepare a monograph on the topic to be published in 2006. At least one new NIMH initiative per year on a single macro-structural factor will be developed and funded through the Office of AIDS Research (OAR) of the NIH. Annual or biennial workshops will be held by NIMH to bring together current grantees and propose new directions.
3. Convene a meeting to address issues related to co-morbidities associated with HIV and other relevant research topics emerging from evolution of HIV to a long-term chronic illness (Summer 2006), release a HIV/hepatitis C virus (HCV) co-infection RFA in FY2007, and prepare a monograph on the topic to be published in 2007. At least one new NIMH initiative per year on neuropsychiatric co-morbidities with HIV disease (e.g., severe mental illness and substance abuse) will be developed and funded through the OAR of the NIH. Annual or biennial workshops will be held by NIMH to bring together current grantees and propose new directions.
4. The timeline for this objective is fiscal year 2002 to 2006. Continue studies through an expanded RFA and develop a new RFA with a fiscal year 2003 release date.
5. The estimated objective completion dates are undetermined.

1.1.3.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Yearly counts of RFAs, Program Announcements (PAs), and Requests for Proposals (RFPs) directly relevant to the action plan,

1.1.3.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Yearly counts of publications, presentations, and conferences related to the action plan; yearly counts of new Research Project Grant (RPG) and K applications submitted and funded on specific macro-structural factors related to HIV transmission.

1.1.3.4 Outcomes

To be determined.

1.1.4 Objective Four: Conduct Pharmacogenetic and Pharmacokinetic Studies

Sex, racial, and ethnic diversity accounts for some of the variability in the body's reaction to medications; that is, population frequencies of certain genes that appear to influence drug metabolism vary by sex, race, and ethnic identity. Within and among racial and ethnic groups, these genes also may be associated with individual differences in drug effectiveness (hypersensitivity or resistance) and drug toxicity. There also are both pharmoacokinetic and pharmacodynamic differences in drug response between men and women. Some of these differences are genetic, but they may also be influenced by differences in metabolism due to levels of endogenous steroids, body fat composition, and other factors. Obtaining information about sex, race, and ethnicity, in addition to factors such as age, gender, family history, etc., is critical in research aimed at developing and testing drug therapies tailored to individual patients.

Genetic differences in drug-metabolizing enzymes represent a significant problem in therapeutics. The presence of variations in the structure of genes within a population may result in substantial interindividual and interethnic variability in the efficacy/toxicity ratios for many clinically important drugs. For example, one variant of the cytochrome P-450 enzyme, CYP2D6, exhibits differences in activity across ethnic groups. CYP2D6 variations change the activity of the enzyme, resulting in slow, extensive, and/or ultra-rapid drug metabolism. Interindividual variations in the capacity of other enzymes to metabolize drugs also are responsible for different responses or adverse effects. Identifying the genes responsible for differential pharmacological responses will aid in predicting an individual's likely response to a medication before it is prescribed. Relatively few studies have examined the role of ethnic differences in determining clinical responsiveness or adverse reactions to medication treatments for mental disorders. NIMH is participating in the genetics database single nucleotide polymorphisms (dbSNP), established by the National Center for Biotechnology Information (NCBI) as a central repository for both single base nucleotide substitutions and short deletion and insertion polymorphisms. SNPs will be helpful for mapping complex traits, such as mental illness. NIMH proposes to stimulate pharmacogenetic research on the fundamental mechanisms underlying individual variation in drug response and susceptibility to adverse drug effects in and between ethnic populations.

1.1.4.1 Action Plan

1. Steps to achieve the objective include new NIMH support to nationally representative pharmacogenetic and pharmacokinetic studies to identify where genetic variations may cause drug response variation among susceptible individuals, families, high-risk populations, and/or ethnic minority groups.
2. The timeline for this objective is as follows: fiscal year 2003, develop and release RFA; fiscal year 2004, review proposals and make awards; fiscal years 2005-2009, data collection; fiscal year 2010, analyze data and write report; fiscal year 2011, NIMH review of report.
3. The estimated objective completion date is September 30, 2011.

1.1.4.2 Performance Measures

To demonstrate accomplishment of the objective, NIMH will develop an RFA to identify and characterize proteins/genes or gene families where genetic variation causes drug response variations in studies of susceptible individuals, families, high-risk populations, and/or ethnic minority groups.

1.1.4.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of the NIMH portfolio to determine whether studies identified and characterized proteins/genes or gene families where genetic variation causes drug response variations in susceptible individuals, families, high-risk populations, and/or ethnic minority groups.

1.1.4.4 Outcomes

In 2003 NIMH and the National Institute of General Medical Sciences (NIGMS) issued RFA MH-04-001, “Pharmacogenomics of Mood and Anxiety Disorders.” The goal of this RFA is to solicit applications to perform high-quality research studies that correlate responses to drugs used to treat mood or anxiety disorders with genetic variation, and create a valuable knowledge base populated with reliable information that links drug response phenotypes to genotypes.

NIMH and the Office of Research on Women’s Health (ORWH) continue to support a Specialized Center for Research (SCOR) that examines the pharmacokinetics, pharmacodynamics, and pharmacogenetics of antidepressants and anti-epileptic drugs during pregnancy and lactation utilizing both clinical and animal data to develop pharmacokinetic/pharmacodynamic models.

1.1.5 Objective Five: Study the Factors That Produce Health Disparities in Treatment Responses, Adherence, Outcomes, and Quality (Continuation of Activities)

Clinical research by NIMH-supported investigators and others has demonstrated the efficacy of various interventions for mental illness. However, unless there is sufficient diversity in the clinical population studied, there can be no reasonable confidence that the results apply to all in the community. Part of the challenge is that minority groups are less likely to enroll in clinical trials of treatment interventions. Of particular interest is whether different groups have less response to commonly used interventions such as pharmacological medications and psychotherapeutic approaches. In addition, research has shown that providers do not always deliver what are considered to be the best interventions for a particular illness. This gap in quality of care has been shown to be particularly problematic in relation to services provided to minority groups. Also, consumers do not always use what are considered to be the best interventions for a particular illness.

1.1.5.1 Action Plan

1. Provide support to a number of large clinical treatment trials that test treatments in the community and incorporate sufficient numbers of minority subjects to permit conclusions about the effectiveness of these treatments. NIMH also has launched a dissemination research program that supports research designed to understand why providers use certain treatments in the community and why consumers choose certain forms of treatment interventions.
2. Sponsor and co-sponsor workshops and conferences focused on improving participation of ethnic minority groups in research protocols.
3. Encourage and facilitate the submission of minority-specific ancillary studies to large-scale clinical trials. These studies will promote innovative lines of scientific inquiry regarding the understanding and treatment of mental disorders in ethnic and racial minority populations. Another new RFA would adapt the principles of NIMH's HIV and AIDS behavioral prevention and adherence interventions for use with ethnic minority groups to research adherence in minority populations with severe mental illness.
4. The timelines for these objective are: fiscal years 2002 to 2006, continue ongoing studies; release new RFAs in fiscal year 2003; in fiscal year 2004, review proposals and make awards; fiscal years 2005-2007, collect data; fiscal year 2008, analyze data and write report; fiscal year 2009, NIMH reviews report.
5. The estimated objective completion date is September 30, 2009.

1.1.5.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Determine strategies for recruitment and retention of minority group members into randomized clinical trials.
2. Determine which are the most relevant, appropriate, and acceptable outcomes regarding symptoms and functioning.
3. Continue to support studies that attempt to learn whether there are, and the reasons for, differences in outcomes for ethnic minority groups when treatment interventions are provided in the community.
4. Determine whether providers use different interventions for various ethnic minority groups and if so, why.
5. Assess the reasons why ethnic minority consumers choose various treatment interventions.
6. Determine the behaviors and principles for care providers that affect the quality of care and treatment outcomes for ethnic minority consumers.
7. Determine the behaviors and principles for ethnic minority consumers on the quality of care and treatment outcomes for ethnic minority consumers.

1.1.5.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of clinical trial databases to determine whether there are recruitment and retention of representative minority group members in randomized clinical trials.
3. Analyses of the NIMH portfolio to determine whether studies identified and characterized the most culturally relevant, appropriate, and acceptable outcomes regarding symptoms and functioning.
4. Analyses of the NIMH portfolio to determine whether studies determined whether there are, and the reasons for, differences in outcomes for minority groups when treatment interventions are provided in the community.
5. Review of NIMH and other research institutes’ studies to determine whether providers use different interventions for various minority groups and if so, why.
6. Review of the completed studies to determine whether researchers learned the reasons why minority consumers choose various treatment interventions.
7. Analysis of studies to determine whether findings indicate the behaviors and principles for care providers that affect the quality of care and treatment outcomes for ethnic minority consumers.
8. Analysis of studies to determine whether findings indicate the behaviors and principles for ethnic minority consumers on the quality of care and treatment outcomes for ethnic minority consumers.
9. Analysis of the findings to determine whether the principles of NIMH’s HIV and AIDS behavioral prevention and adherence interventions can be adapted for use with ethnic minority groups to improve adherence in minority populations with severe mental illness.

1.1.5.4 Outcomes—N/A

1.1.6 Objective Six: Study Suicide/Depression and Other Severe Mental Illnesses in Women, Racial and Ethnic Minority Populations, and Other Health Disparity Groups

As noted in the Surgeon General’s Call to Action to Prevent Suicide (1999), the suicide rates for the general population in the United States remained relatively stable with a small decline over the last 2 decades. However, the rates for specific age, gender, and ethnic groups have changed substantially. Among Native Americans and Alaska Natives, many communities have experienced consistently elevated suicide rates. At increased risk are African American males aged 15-19 years, whose rates of suicide have increased 105 percent between 1980 and 1996.

U.S. suicide rate patterns associated with age, gender, and ethnicity provide profound evidence that culture is associated with suicide risk and protection. Yet there are few theoretical models of the role in culture in risk and protection in suicidality, and this has limited scientific and public health advances in this area. Additionally, mental disorders, including depression, are thought to be underdiagnosed among ethnic minority populations due to differences in cultural beliefs, expression of symptomatology, and help-seeking behaviors. Among Asian Americans, rates of emotional distress appear to be higher than generally believed. The experience of acute and chronic discrimination appears to increase risk of major depression and anxiety for ethnic populations.

Although chronic mental illnesses are comparatively prevalent in the minority and majority populations, limited available evidence points to significant differences in treatment access, the appropriateness of diagnosis and treatment, cultural and family views of mental illness, and, as a function of all of these factors, effectiveness of treatment services and outcomes for minorities. Co-morbid substance abuse disorders as well as homelessness and incarceration may be more prevalent in some ethnic and racial minorities. Reducing the burden of the most severe mental illnesses among minority populations requires better understanding of these factors and use of that knowledge to adapt effective treatment and services.

Chronic, severe mental illness, such as schizophrenia, is also poorly understood in women. The course of illness and treatment response issues to traditional therapies are understudied, in part because of the underrepresentation of women in studies of severe chronic mental illness. Equally poorly addressed are issues related to the risks/benefits of treatments as they relate to pregnancy and childbearing and how such reproductive events may alter the course of the illness itself.

1.1.6.1 Action Plan

1. Provide support to nationally representative epidemiological suicide, depression, and severe mental illness studies to identify which factors cause variations among individuals, families, high-risk populations, and/or ethnic minority groups.
2. Convene a cooperative workshop to address how culture can be considered in making suicide prevention efforts more effective, durable, and safe. Culture pertaining to ethnicity will be the primary focus of this meeting, with culture considered to include self- and community-identity, community norms, and “ways of thinking” and behavioral practices that could affect how an individual engages in behavior linked to life-or-death outcomes.
3. The timeline for this objective is: fiscal year 2003, release RFA; fiscal year 2004, review proposals and make awards; fiscal years 2005-2007, data collection; fiscal year 2008, analyze data and write report; fiscal year 2009, NIMH review of report.
4. The estimated objective completion date is September 30, 2010.

1.1.6.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

a. Expansion of the initiative focused on improving valid and reliable measurement of psychopathology and other culturally relevant variables such as stress that are related to cultural adaptation for diverse ethnic and minority populations.

b. Assembly of expert panels to establish guidelines for research methodology and measurement for research in diverse populations and minority populations such as the need for more naturalistic studies using qualitative methods to better understand the experiences of minorities.

1.1.6.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyze the NIMH portfolio to determine whether valid and reliable measurements of psychopathology and other culturally relevant variables, such as stress, that are related to cultural adaptation for diverse ethnic and minority populations were identified.
3. Analyze reports from expert panels to determine whether guidelines for research methodology and measurement for research in diverse populations and minority populations, such as the need for more naturalistic studies using qualitative methods to better understand the experiences of minorities, are either practical or in development.

1.1.6.4 Outcomes

1.1.7 Objective Seven: Identify Factors That Overcome Health Disparities Related to Health Service Delivery and Use by Ethnic Populations

NIMH-supported researchers have shown that even when controlling for obvious confounding variables—such as health and mental health status, income, education, attitudes towards health, and status of health insurance—there are significant disparities in the use of mental health services across racial and ethnic groups. For instance, minority group members are less likely than people in the majority population to make return visits once in treatment, they are somewhat more likely to stay in treatment in an ethnically oriented program regardless of the race or ethnic background of the clinician, and ethnic minorities are less likely to agree to enroll in clinical trials.

1.1.7.1 Action Plan

1. Provide support for mental health services mixed-methods research with ethnic minority populations.
2. The estimated objective completion date is September 30, 2010.

1.1.7.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Incorporation of research objectives relating to the elimination of disparities in mental health care delivery in all mental health services research PAs and RFAs.

2. Continued support to grants under the Interventions and Practices Research Infrastructure Program (IP-RISP) PAR-00-096. This grant should be directed to support research on how to improve service utilization and care. This initiative would be directed to community and patient organizations, provider groups, community health centers, professional organizations, payers, state mental health departments, policymakers, the media, and other service system settings including jails, social services, and schools.
3. Providing continued technical assistance to the field about strategies for research that will provide policy-relevant and empirically valid mechanisms for eliminating mental health care disparities. This will include the encouragement of research on how individual, sociocultural, and organizational contexts affect access to, use of, and perceptions of mental heath services for ethnic minorities with cross-disciplinary translational approaches.

1.1.7.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of the NIMH portfolio to determine whether new studies focus on practice research topics such as patient/consumer, provider, organizational, and modifiable environmental factors, in an attempt to identify sources of health disparities that are amenable to change.
3. Analyses of the NIMH portfolio to determine whether new studies address research issues such as individual health practices and treatment preferences, provider and patient decision-making, economic considerations, and quality of care in typical non-academic clinical services settings where ethnic and minority patients are served, as a means of better understanding influences on service utilization.
4. Analyses of the NIMH portfolio to determine whether research under the IP-RISP PAR-00-096 produced viable findings on how to improve service utilization and care for ethnic minority populations.
5. Analyses of the NIMH portfolio to determine how individual, sociocultural, and organizational contexts affect access to, use of, and perceptions of mental heath services for racial and ethnic minorities with cross-disciplinary translational approaches.

1.1.7.4 Outcomes

1. NIMH has funded 13 research and career development awards focused on the engagement of minority populations into treatment, which go far beyond the concept of “cultural competence.”
2. NIMH has funded seven research and career development awards focused generally on the mental health service use issues for specific minority populations. Currently funded research focused generally on the mental health service use of rural populations.
3. Numerous publications have resulted from these grants that show the advances made in this area in the last few years.

1.1.8 Objective Eight: Increase Mental Health Research in Rural, Frontier, and Isolated Populations: Determine Disparities in These Populations Compared to Metropolitan Areas

The 2003 President's New Freedom Commission Report on Mental Health and the Surgeon General's 1999 Report on Mental Health document the enormous public health burden of mental illness and co-occurring disorders in the United States. Although inconclusive, research evidence suggests that the prevalence and incidence of mental illness for adults and children are similar for rural and urban/metropolitan populations; co-occurring conditions associated with mental health problems, such as suicide, differ in these areas, with rural suicide rates exceeding urban rates. Nearly 60 million Americans living in rural and frontier communities face additional barriers to receiving effective prevention and treatment services. Access to and availability of mental health specialists, such as psychiatrists, clinical psychologists, and clinical social workers, in most rural, frontier, and isolated communities appears to be a factor that contributes to the burden of mental illness. Low socioeconomic status, geographic isolation, lack of transportation, and cultural differences between consumers and providers in understanding the expressed symptoms of some mental illnesses may further limit the amount and quality of mental health services available in rural, frontier, and isolated populations. Thus, compared to other groups (e.g., urban or suburban consumers) rural, frontier, and isolated residents often enter care later in the course of their illness, enter care with more serious symptoms, and require more intensive and expensive treatment. There is a continuing need for studies to assess and monitor the availability and quality of mental health services for individuals in these non-metropolitan areas. Furthermore, additional studies are needed to develop effective intervention models to address unmet needs and to determine ways in which barriers that impede access to proper levels of care can be eliminated.

1.1.8.1 Action Plan

1. Steps to achieve the objective include continued support of nationally representative studies in rural and frontier populations (contrasted with appropriate comparison groups) that measure the incidence and prevalence of mental disorders, service utilization and outcomes of care, and intervention models designed to enhance access and quality of mental health care.
2. The timeline for this objective is fiscal years 2004 through 2008.
3. The estimated objective completion date is undetermined.

1.1.8.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Release of a new Rural Mental Health and Drug Abuse (NIMH/National Institute on Drug Abuse [NIDA]) PA to study methods of eliminating barriers to mental health care in rural, frontier, and isolated communities.

2. Continue to stimulate submission of grant applications that focus on rural and frontier mental health issues. This will be accomplished through dissemination of the NIMH/NIDA rural PA and the NIMH portfolio of ongoing grants, presentations at professional meetings, and implementation of regional workshops.

1.1.8.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate outcomes of the objective:

1. Conduct an annual IRP to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of the NIMH portfolio to determine how individual, sociocultural, and organizational contexts affect access to, use of, and perceptions of mental health services for racial and ethnic minorities with cross-disciplinary translational approaches.

1.1.8.4 Outcomes (to be determined)

1.1.9 Objective Nine: Determine the Efficacy and Effectiveness of e-Mental Health Care as a Means to Reducing Barriers to Appropriate Care for Rural, Frontier, and Isolated Populations

Telehealth (defined as the use of telecommunications and information technologies to provide access to health information and services across a geographical distance, including (but not limited to) consultation, assessment, intervention, and follow-up programs to ensure maintenance of treatment effects) offers promising alternative methods for overcoming the barriers to delivering an enhanced quality of mental health services to underserved locations and populations (e.g., rural and frontier communities). The technology is increasingly available, and it has the potential to reduce disparities in mental health care service delivery. Telehealth also holds considerable promise as a vehicle for decreasing professional isolation and improving provider quality of life, and in turn, may lead to increased recruitment and retention of professionals in rural and frontier communities. However, there is much to be learned about the efficacy, effectiveness, and efficiencies of providing mental health care through telecommunications, particularly to rural areas.

1.1.9.1 Action Plan

1. Steps to achieve the objective include continued support of nationally representative studies in rural/frontier populations, prisons, and nursing homes, and within hearing-impaired populations. Studies would focus on satisfaction among providers and consumers, and whether mental health care can be delivered as effectively through telecommunications technologies as it can be delivered face-to-face, as determined by the improved mental health of consumers, cost-savings/cost-avoidances for insurers, and increased access to the appropriate level of care.
2. The timeline for this objective is fiscal years 2004 through 2008.

3. The estimated objective completion date is undetermined.

1.1.9.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Conduct technical assistance workshops with telehealth experts and mental health researchers to develop concept papers for subsequent e-mental health studies.
2. Continue to stimulate grant applications that focus on e-mental health through other venues such as dissemination of the NIMH/NIDA rural PA, presentations at professional meetings, and implementation of a periodical regional rural conference.

1.1.9.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate outcomes of the objective:

1. Conduct an annual IRP to measure the progress, achievements, and continued relevance of the objective.
2. Track the number and kinds of e-mental health studies, kinds of research designs employed, and the number of findings published in refereed journals.

1.1.9.4 Outcomes (to be determined)

1.1.10 Objective 10: Encourage Research That Will Expedite the Dissemination, Implementation, and Adoption of Effective Treatment and Prevention Efforts for Homeless Persons with Alcohol, Drug Abuse, or Mental (ADM) Disorders

A growing body of empirical literature has documented that homelessness and inadequate/unstable housing conditions significantly affect persons with alcohol, drug abuse, or mental (ADM) disorders; interfere with effective treatment; and pose significant barriers to achieving optimal outcomes. The challenges posed by ADM disorders are often compounded by other life difficulties (e.g., HIV/AIDS or other serious medical conditions, lack of personal and financial resources, paucity of social support systems, limited availability of housing options, trauma, stigma, etc.), which further compromise treatment outcomes. These multiple factors are often co-occurring, fluctuating, and interactive in complex ways. This complexity has remained an ongoing challenge to the development, implementation, and sustainability of effective, empirically based services, interventions, and prevention efforts for the identified population.

We need health services research to investigate the cultural acceptability, effectiveness, long-term outcome, and sustainability of services, interventions, and preventive and rehabilitative strategies targeted to homeless or unstably housed persons with ADM disorders. Research should address relevant factors from a developmental perspective as well as across systems (health care, parole/correctional, foster care, shelter programs, etc.). This may include the adaptation of pharmacological, psychosocial, behavioral, or environmental approaches—individually or in combination—and should target functional and symptomatic outcomes.

Of particular importance, because of the disproportionate numbers of minority populations who are homeless, are interventions aimed at reducing health and services disparities related to minority status in addition to disparities related to age, gender, and HIV/AIDS status. Also of great interest are studies that address significant questions for homeless persons involved in the criminal justice system and homeless persons with co-occurring disorders.

1.1.10.1 Action Plan

1. NIMH has issued two PAs, both in conjunction with NIDA and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) (http://grants2.nih.gov/grants/guide/pa-files/PA-02-150.html), one of which has a specific focus on severe mental illness and AIDS (http://grants2.nih.gov/grants/guide/pa-files/PA-04-024.html), encouraging health services research to provide policy relevant data.
2. The timeline for this objective is ongoing. There is no anticipated completion date.

1.1.10.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of this objective:

1. Policy relevant information that can be used by states and the federal government for setting up programs that will address the service needs of homeless mentally ill people.
2. Implementation of evidence-based programs by states, counties, and cities that will enable formerly homeless mentally ill people to find and keep housing, avoid substance abuse and high risk behaviors for HIV/AIDS, and receive appropriate mental health treatment.

1.1.11 Objective 11: Increase Research That Will Improve Recognition, Diagnosis, Assessment, and Treatment of Mental Disorders in Ethnic Minority Children and Children Residing in Rural, Remote, and Isolated Areas

The Report of the Surgeon General's Conference on Children's Mental Health, and the Surgeon General's supplement *Mental Health: Culture, Race & Ethnicity* highlight the need for increased accessible, culturally competent, scientifically proven services that are sensitive to youth and family strengths and needs. In addition, the Institute of Medicine (2002) report *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health care* documents that racial and ethnic disparities in health care persist despite considerable progress in expanding health care services and improving the quality of patient care. These reports underscore the need for research that can improve assessment, recognition, and coordination of services for minority children and adolescents with mental illness.

1.1.11.1 Action Plan

1. Steps to achieve the objective include new and continued NIMH support for studies that identify barriers to detection and access to services for mental illness in minority children and adolescents and to determine the extent to which children with mental illness receive services across sectors.
2. Timeline: Fiscal years 2004-2008.
3. Estimated objective completion date: undetermined.

1.1.11.2 Performance Measures

The NIMH will use the following performance measures to demonstrate accomplishment of the objective:

1. Encourage the translation of research findings into effective and efficient prevention and treatment programs for ethnic minority children and adolescents that recognize factors such as age, gender, race, culture, ethnicity, and geographic locale.
2. Encourage research on best practices for early detection of mental health problems in children and adolescents.

1.1.11.3 Outcome Measures

The NIMH will use the following procedures to measure and evaluate outcomes of the objective:

1. NIMH will conduct annual IPR to measure the progress and continued relevance of the objective.
2. The development of effective and efficient prevention and treatment programs for children and adolescents from diverse populations that recognize factors such as age, sex, race, culture, and geographic locale.

1.1.12 Objective 12: Promote Research to Determine if There Is a Unique Genetic Susceptibility to Mental Illness (e.g., Schizophrenia) in Racial and Ethnic Populations (New)

Research has established that there are prominent genetic components to many psychiatric disorders. Current evidence indicates that multiple genes are involved in determining whether full-fledged mental illness will become manifest, although the precise configuration of this multi-genetic template has yet to be determined. It is not unreasonable to suppose that this genetic pattern may vary in different racial and/or ethnic groups. Minority populations are reported to have greater susceptibility to a number of known risk factors and co-morbidities associated with mental illness, including stress, violence, substance abuse, and prenatal/perinatal insults, and there is little information on whether these susceptibilities are primarily genetically or environmentally determined.

1.1.12.1 Action Plan

1. Given the state of our current knowledge, continued NIMH support for genetic research on mental illness in minority populations is critical.
2. Encourage studies that include assessment and analysis of risk factors that may have greater weight in different racial and ethnic groups.
3. The NIMH will continue its efforts to encourage new investigators in psychiatric genetics using diversity supplements.
4. The timeline for this objective is fiscal years 2004 through 2008.
5. The estimated objective completion dates are undetermined.

1.1.12.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Track genetic studies for racial and ethnic composition.
2. Document and continue to encourage banking of genetic information in the NIH repository, so that data on larger numbers of ethnic and racial populations can be amassed for more reliable analysis.

1.1.12.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. The NIMH will conduct an annual IPR to measure the progress, achievements, and continued relevance of the objective.
2. The NIMH portfolio will be examined to determine whether studies on the genetics of mental illness in racially and ethnically distinct populations are adequate, and encourage the research community to focus on groups that continue to be underserved.
3. The NIMH will monitor the quantity of genetic information available in the NIH repository on mental illness in racial and ethnic groups on a regular basis, and encourage the research community to focus on groups that continue to be underserved.

1.1.12.4 Outcomes (to be determined)

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Increasing the Research Capacity of Institutions Conducting Research in Mental Health Disparities

Since its creation in 1946, the NIMH has introduced a variety of innovative funding mechanisms designed to facilitate career development for mental health researchers in general and investigators from minority and other underrepresented groups specifically. These mechanisms range from high school and undergraduate support to specialized programs for pre- and postdoctoral fellows. These mechanisms have been developed because increased numbers of minority and other underrepresented researchers are needed for at least three reasons: (1) their numbers are insufficient to meet the current demands of academia, basic and services research, and the duties of mentorship; (2) the shortfalls projected in the nation's scientific workforce by the year 2050, which include basic biomedical, behavioral, and social science researchers, can be avoided if development of minority and other underrepresented investigators begins today; and (3) there is a need to enrich the scientific knowledge base through increased participation, in every research arena, of racial and ethnic minority investigators, as well as study participants from rural populations and persons of low socioeconomic status. Additionally, both empirical and anecdotal evidence indicates that investigators from these backgrounds often have a particular commitment to research designed to address health care disparities.

2.1.1 Objective One: Improve Partnerships Between Ethnic Minority and Majority Research/Academic Institutions (Continuation of Activities)

The NIH Roadmap initiative highlights an initiative called "Research Teams of the Future," which is based on the observation that the scale and complexity of today's biomedical research problems increasingly demand that scientists move beyond the confines of their own discipline and explore new organizational models for team science. For example, imaging research often requires radiologists, physicists, cell biologists, and computer programmers to work together on integrated teams. Many scientists will continue to pursue individual research projects; however, they will be encouraged to make changes in the way they approach the scientific enterprise. NIH wants to stimulate new ways of combining skills and disciplines in both the physical and biological sciences. In essence, the formation of partnerships between individuals also can be extended to partnerships between institutions. In trying to overcome mental health disparities, partnerships between research-intensive institutions and institutions where the research infrastructure is not fully developed, but research interest in mental health disparities is high, should be encouraged. This PA expired in 2006.

2.1.1.1 Action Plan

1. Fund meritorious applications received under RFA MH-01-009 ("Institutional Research Training Programs: Increasing Diversity").
2. The timeline for this objective is: monitor MH-01-009 to fiscal year 2006; in fiscal year 2007, perform data analysis and report preparation; in fiscal year 2008 report findings to the National Advisory Mental Health Council (NAMHC).
3. The estimated objective completion date is September 30, 2009.

2.1.1.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Continue to fund the grants under RFA MH-01-009 (“Institutional Research Training Programs: Increasing Diversity”).
2. Continue discussions with and technical support of institutions seeking to further expand their current neuroscience and behavioral training programs that address diversity in mental health research.

2.1.1.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Development of expanded neuroscience and behavioral training programs at minority and collaborative institutions as a result of the NIMH initiatives.

2.1.1.4 Outcomes

NIMH has funded three Institutional Training grants (T32) under RFA MH-01-009 “Institutional Research Training Programs: Increasing Diversity.”

2.1.2 Objective Two: Expand Institutional Infrastructure Development Opportunities to Support Training of Minority, Other Underrepresented, and Majority Investigators Who Desire to Conduct Health Disparities Research (Continuation of Activities)

Institutions with strong programs for training minority and other underrepresented investigators need institutional support to encourage and maintain their efforts. Although the NIMH Minority Research Infrastructure Support Program (M-RISP) contributes to building strong infrastructures for research, NIMH will continue to seek additional avenues to enhance research capacity for junior and mid-career minority and other underrepresented researchers.

2.1.2.1 Action Plan

1. NIMH will continue collaborative partnerships to develop and enhance initiatives involving minority and other underrepresented and non-minority mental health researchers who study racial and ethnic minority and other health disparity groups.
2. NIMH will continue to provide supplemental grant support to researchers to add studies of service use and treatment acceptability and promote training and career development for junior investigators interested in research focused on health disparities.
3. The timeline for this objective is: fiscal year 2004, pay supplements; fiscal years 2004-2016, monitor trainees’ progression; fiscal year 2017, perform data analysis and report preparation; fiscal year 2018, report findings to the NAMHC.
4. The estimated objective completion date is September 30, 2019.

2.1.2.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Continued NIMH training support of minority and other underrepresented and non-minority investigators who propose to conduct research to determine why there are disparities within and across racial and ethnic minority groups, rural populations, and socioeconomic groups in access and in the use of mental health and mental health-related services.
2. Continued NIMH grant support to minority and other underrepresented and non-minority investigators who propose to conduct research to determine what the differential patterns of mental health service use are across racial and ethnic minority and non-minority populations, rural populations, and persons of low socioeconomic status.

2.1.2.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of the findings generated by minority and other underrepresented and non-minority investigators supported by NIMH grants.
3. Analysis of the productivity of researchers supported by NIMH Diversity Supplements (grant support) to determine whether training and career awards resulted in the development of senior investigators interested in research focused on health disparities.

2.1.2.4 Outcomes

A new grant called the “Advanced Centers for Mental Health Disparity Research Program” has been developed to advance the mental health research capacity of institutions that conduct health disparity research.

2.1.3 Objective Three: Invigorate Training and Career Development Mechanisms Focused on Minority and Other Underrepresented Investigators to Enhance the Capacity of Diverse Institutions to Conduct Biomedical/Behavioral Research and Research Training (Continuation and New Activities)

The NIMH staff is engaged in ongoing discussions with institutions that are seeking opportunities to further expand their training programs. Negotiations are under way for these institutions to combine resources and build new, creative partnerships with other institutions to enhance research and career development programs, and to encourage further study of mental health disparities. Additionally, despite the continued disproportionate impact of HIV infection upon racial and ethnic minorities (69% of new HIV infections are in communities of color, yet these communities make up less than

25% of the U.S. population), funded minority and other underrepresented investigators and minority-focused scientists remain a very small portion of the total funded HIV investigator pool. The broad objectives of this initiative are to enhance and expand the capacity for NIMH-funded HIV/AIDS research by minority and other underrepresented investigators in HIV prevention research, therapeutics, neuropsychiatry, and basic and clinical neuroAIDS. The organization infrastructure at certain institutions is inadequate to carry out mental health research in the most important HIV research areas of HIV prevention, HIV therapeutics, and neuroAIDS. Expanded support for research infrastructure capacity at these institutions is essential for the development of minority investigators in the HIV and AIDS portfolio.

2.1.3.1 Action Plan

1. NIMH will continue to fund meritorious research infrastructure support programs and increase the chances of trainee success by conducting technical assistance workshops.
2. NIMH will continue to fund meritorious programs for training honors undergraduate and high school students, including those from underrepresented backgrounds, in areas relevant to mental health.
3. NIMH will develop an initiative to support short-term training grants (R25) for individuals at institutions that bring together leaders in clinical interventions, services, and cultural/health disparities research. These short-term training grants would focus on networking and enhancing local capacity or the potential submission of ancillary studies or site participation.
4. NIMH will create an NIMH grantee career development program based on the tracking and analyses of the career/research selection choices and achievements of trainees and investigators funded by NIMH's training, career, and investigator awards.
5. NIMH will conduct a meeting to address HIV research capacity building through the development of minority-focused mentoring programs for HIV mental health research. Additionally, co-sponsorship with existing health disparities AIDS programs at other Institutes and Centers (e.g., Research Centers at Minority Institutions or the National Center for Research Resources [NCRR]) will continue.
6. The timeline for these objectives is: fiscal years 2004-2005, continue to fund and monitor investigators; 2004-2005, obtain the legal authority and develop the grantee career development tracking program; conduct the HIV capacity building meeting during fiscal year 2005 and release and pay the HIV RFA/PA; fiscal years 2004-2006, monitor ongoing progress of the HIV initiative. At least one new NIMH initiative per year on development of investigators from minority and other underrepresented groups will be proposed for funding through the OAR of the NIH.
7. The estimated objective completion date is indeterminate.

2.1.3.2 Performance Measures

The NIMH will use these performance measures to demonstrate accomplishment of the objective:

1. Continued NIMH funding support to capacity development applications to advance health disparity research and support for technical assistance workshops that help faculty develop grant application writing skills and become familiar with the priority science areas in the NIMH research portfolio.
2. Continued NIMH funding support to meritorious Career Opportunities in Research (COR) Education programs to train honors undergraduate students, including those from underrepresented backgrounds, in mental health research fields of training. This PA expired in 2006.

2.1.3.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Annual IPRs to measure the progress, achievements, and continued relevance of the objective.
2. Analyses of the research productivity of investigators funded by research infrastructure development awards to determine the effectiveness of the NIMH financial investment.
3. The creation of an NIMH grantee career development program with the authority and capacity to "track" individual awardees to analyze the career/research selection choices and achievements of trainees and investigators funded by NIMH's training, career, and investigator awards.
4. The number of minority scientists (and minority-focused scientists) who investigate HIV who complete the programs funded through the mentoring RFA.
5. The effectiveness of the mentoring program and the number of new RPG and K applications submitted and funded for these scientists correlated to the sponsoring Institutes and Centers in HIV prevention, HIV therapeutics, and neuroAIDS.

2.1.3.4 Outcomes

NIMH has funded two Short-Term Training grants (R25). One is at a historically Black institution and is to establish summer programs that prepare young underrepresented minority students for a career in neuroscience. The second is to expose underrepresented minority undergraduate students to Ph.D. graduate programs in the biomedical sciences.

2.1.4 Objective Four: Develop and Promote a Mental Health Research Scientist Development Program That Provides a Continuum of Training and Career Development Opportunities to Ensure a Diverse Workforce for the Future (New)

A comprehensive program for the development of independent investigators in mental health has been created to increase the representation of men and women from minority and other underrepresented groups, from low socioeconomic status communities, and from rural populations. This program includes existing programs within the OSP, including the NIMH COR and M-RISP. In collaboration with the training branches of the extramural scientific divisions, the Research Scientist Development Program (RSDP) uses existing NIMH training, career development, and research mechanisms to train and sustain the career development of investigators from underrepresented groups. The RSDP develops interactions with the NIMH Intramural Research Program to provide additional venues for training underrepresented individuals in mental health research, including those opportunities in the continuum of career development programs. The RSDP assists the NIMH Division of Extramural Activities in identifying investigators with the expertise, experience, and academic status appropriate for service on NIMH standing and ad hoc review committees. The RSDP engages, collaborates, and partners with universities and colleges and scientific, educational, and professional organizations to promote research and career development opportunities in mental health research and to identify and assist individuals from minority and other underrepresented groups, persons of low socioeconomic status, and members of rural populations who are underrepresented in biomedical and behavioral science.

2.1.4.1 Action Plan

1. Coordinate efforts with the extramural and intramural research training branches to identify, engage, and inform potential applicants at all career levels about the continuum of research training and career development mechanisms identified with the RSDP.
2. Further develop the partnership with the NIMH Intramural Research Training and Fellowship Office to integrate intramural training programs with the RSDP to provide appropriate career stage opportunities for students seeking mental health research careers.
3. Continue the development of linkages between NIMH National Research Service Award (NRSA) training programs and the NIMH Intramural Research Program with the M-RISP, NIMH T32 Graduate Training Programs, and NIMH COR programs to enable students and investigators at various institutions to continue their progress in developing independent research careers.
4. Continue efforts to enhance the diversity of NIMH standing and ad hoc review committees and advisory groups.
5. Facilitate and support the development of research mentoring networks formed by senior investigators from underrepresented groups and communities.
6. The timeline for this objective is 2004-2008 continue to fund and monitor training programs and analyze outcomes on an annual basis.

2.1.4.2 Performance Measures

1. Development of publications, web-based resources, and similar resources that provide specific information about NIMH-sponsored grant programs and the preparation of grant applications.
2. Development of partnerships with national organizations to inform and educate individuals and organizations about the research career options delineated by the RSDP in both formal and informal settings.
3. The identification of investigators from underrepresented groups who are appropriately qualified to serve on NIMH peer review committees and advisory groups.
4. The development of research mentoring networks supported by established investigators from underrepresented groups and communities.

2.1.4.3 Outcome Measures

1. The application rate and success of submissions for training, career development, and research grant awards by faculty at minority institutions and applicants from underrepresented groups.
2. The success of programs developed in collaboration with the extramural divisions designed to stimulate increased training and research grant application submissions from students and investigators from underrepresented groups.
3. Increased diversity on NIMH peer review and advisory groups through greater representation by racial and ethnic minorities and women.

2.1.4.4 Outcomes

The data are incomplete for a valid and reliable analysis of this new objective.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One

3.1.1 Objective One: Develop and Disseminate Research-Based Mental Health and Mental Disorders Information

Approximately half of Americans with mental illness do not seek help. Lack of accurate information about mental illness and treatment services, as well as stigma and fear, are significant barriers that prevent many people with mental illness and mental disorders from seeking professional help. For racial and ethnic minorities, those obstacles can be further compounded by cultural traditions, religious beliefs, coping styles, language, mistrust, unreliable transportation, and clinician bias, all of which can be viewed as major contributors to health disparities. NIMH has approached the reduction of stigma and the differences in health outcomes between groups through a public education campaign on the causes, signs, symptoms, treatments, and prevention of mental disorders. However, to ensure the best use of research-based treatments in real-world practice settings requires educational efforts that should not only target individuals with mental disorders, but also their support networks, first-line responders, service providers, advocacy and professional organizations, health care companies/payers, educators, policymakers, and local, state, and national government agencies.

3.1.1.1 Action Plan

1. NIMH will continue to promote its mental health information and outreach initiatives. Specific initiatives include the “Outreach Partnership Program” and the “Men and Depression Campaign.” In addition to specific initiatives, NIMH has various avenues of information dissemination including its “Dialogues” web site, Alliance for Research Progress meeting, consultations with

organization representatives, NAMHC meetings, and information dissemination booths at various conferences and meetings.

2. The Outreach Partnership Program was launched in March 2000 and is designed to help bridge mental health research and clinical practice by disseminating the latest research findings; informing the public about mental disorders, alcoholism, and drug abuse; and ultimately reducing the stigma and discrimination associated with mental illnesses. The initiative establishes "Outreach Partners" in every state, the District of Columbia, and Puerto Rico to enhance interactions with state mental health agencies and deliver science-based mental health information to individuals and local communities. NIMH will continue to collaborate with the "Outreach Partners" and encourage them to focus on racial and ethnic minority groups using various communication and outreach strategies to educate people about mental illnesses. Minority outreach to communities within their states is a requirement of the contractual agreement with each Partner. National and local organizations, including those with missions focused on racial and ethnic minorities, are being invited to join the Outreach Partnership Program as National Partners and Local Partners, respectively. NIMH currently partners with NIDA and seeks to expand support of the Outreach Partners Program to other relevant Department of Health and Human Services Agencies, such as NIAAA and the Substance Abuse and Mental Health Services Administration (SAMHSA). A formal evaluation of the effectiveness of the program and ways to improve outreach activities is planned for FY2005. The estimated objective completion date is indeterminate.
3. Continue to plan and conduct "*Dialogues*" with a focus on specific minority communities. See http://www.nimh.nih.gov/Outreach/dialoguesforums.cfm. Present up-to-date scientific findings and significant research that is of importance to minority communities. Include "grantsmanship" workshops to encourage members of racial and ethnic minority groups to become researchers. Provide access to NIMH publications at an Information Fair. Conduct regional outreach to service providers, educators, local government, advocacy organizations, Members of Congress, and other policymakers to encourage their participation. All five previous *Dialogues* held since 1999 have specifically addressed the mental health needs and concerns of a minority population.
4. Continue to develop broad-spectrum and culturally sensitive materials about mental health and mental disorders. Plan and conduct interactive meetings with voluntary and professional organizations, and specifically target racial and ethnic minority organizations.
5. Maintain an NIMH web site to allow worldwide access to information on mental disorders and NIMH research.

3.1.1.2 Performance Measures

These performance measures will demonstrate accomplishment of the objective:

a. Outreach Partnership Program.
   1. NIMH support for the Program.
   2. Evaluate Outreach Partner outreach activities targeted to minority communities through yearly reporting requirements.

   3. Evaluate how widely the NIMH Update is distributed and what groups received the Update.
   4. Complete formal evaluation of the Program.

b. In 2005 and 2007, conduct *Dialogues* in areas of the United States with significant racial or ethnic minority populations with mental health needs.
c. Continue to update and evaluate the current stock of dissemination materials and publications to determine opportunities or specific needs for new documents.
d. Web site development will continue to support multicultural objectives and maintain a culturally sensitive composition.
e. The current and future public education campaigns will target specific minority populations in addition to the general public.

3.1.1.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

a. Outreach Partnership Program.
   1. Increased involvement by other Department of Health and Human Services agencies in the program.
   2. Continued or increased minority outreach by our Outreach Partners.
   3. Increased number of national and local minority-related organizations joining the Outreach Partnership Program.
   4. Outreach Partners as well as national and local partners increase the dissemination of the NIMH Update to increase the number of individuals and organizations that receive the mental health-related news and resource updates.
   5. Implement changes and improvements identified through the formal program evaluation.
b. Evaluation will be conducted to assess learning and satisfaction with the dialogue meetings and their programs. Different ethnic and racial minority groups will have received up-to-date research findings about mental illness and co-occurring disorders.
c. Evaluation will be conducted to assess learning and satisfaction by the advocate and professional groups attending the meetings and programs. Racial and ethnic minority advocacy groups and professional associations will have received special outreach resources and information useful to their constituency groups.
d. Web site information will continue to be culturally relevant and useful to minority populations.
e. The current and future public education campaigns will have culturally relevant materials that reach the target minority populations.

3.1.2 Objective Two: Outreach for Clinical Trial Participation to Increase Representation in Clinical Trials and Obtain Generalizable Results

NATIONAL INSTITUTE OF MENTAL HEALTH

For decades, NIH has sponsored research on how various illnesses and their treatments affect groups differently with respect to race, sex, and age. Although the Institute has long emphasized the importance of including women and members of minority groups in its intramural and extramural clinical trials, NIH made the inclusion an official requirement in 1995. However, efforts to recruit members of minority groups have often been hampered by reasons ranging from mistrust of research motives to logistical problems (e.g., childcare and transportation). In the NIMH experience, minority recruitment into clinical trials has been impeded for these same reasons.

3.1.2.1 Action Plan

1. The NIMH Office of Communications will continue to provide public relations expertise directed towards the recruitment of participants/patients, particularly for several nationwide treatment-effectiveness studies.
2. Outreach Partnership Program: Outreach Partners are required to provide support for clinical trial recruitment. When recruitment assistance is needed, Outreach Partners will be called upon to reach out to the communities and organizations in their state for assistance in informing state and local communities about the opportunities to join the clinical trial.
3. The estimated objective completion date is indeterminate.

3.1.2.2 Performance Measures

These performance measures will demonstrate accomplishment of the objective:

1. Continued NIMH funding support and encouragement to its Office of Communications to provide public relations expertise designed to significantly increase the participation level of ethnic minorities in research studies and those funded by NIMH.
2. Outreach Partners reach out to their communities and local organizations to inform them about clinical trials in their state or region when a clinical trial is open, or will soon be open, for recruitment.

3.1.2.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Data analyses to determine the level of increase in ethnic minority participation in research studies and those funded by NIMH, as a result of activities by the Office of Communications.
2. Development and dissemination of a PAR to establish minority outreach clinical trials programs at medical schools throughout the United States and its territories.
3. Data analyses to determine the level of increase in ethnic minority participation in research studies and those funded by NIMH as a result of activities by the Outreach Partners and the Outreach Partnership Program.

3.1.3 Objective Three

Educate communities, service providers, state and local governments, and businesses about health disparities and the costs associated with lack of treatment, reduced access to treatment, and underawareness of the importance of culture in treatment-seeking behavior.

3.1.3.1 Action Plan

1. Provide resources, research findings, and government-related information to Outreach Partnership Program members about health disparities and the costs associated with lack of treatment, reduced access to treatment, and underawareness of the importance of culture in treatment-seeking behavior. Monitor the request and usage of appropriate NIMH publications. Establish a network of national partners to receive and help disseminate mental health disparities research information at the national level.
2. The Office of Communications will continue to develop and disseminate materials that summarize research findings related to health disparities.
3. Plan and conduct biannual "dialogues" with a focus on specific minority communities. See http://www.nimh.nih.gov/Outreach/dialoguesforums.cfm. Incorporate up-to-date scientific findings and significant research about the costs of health disparities and the importance of culturally appropriate treatments to businesses, governments, health care providers, and communities. Provide information about barriers to access.
4. Plan and conduct interactive meetings with voluntary and professional organizations, and specifically target racial and ethnic minority organizations. Incorporate up-to-date scientific findings and significant research about the costs of health disparities and the importance of culturally appropriate treatments to businesses, governments, health care providers, and communities. Provide information about barriers to access, and provide relevant NIMH publications.

3.1.3.2 Performance Measures

These performance measures will demonstrate accomplishment of the objective:

1. Outreach Partners, national partners and local partners actively disseminate health disparities materials and resources to their communities and local organizations throughout the nation.
2. Continue to update and evaluate current stock of dissemination materials and publications to determine opportunities or specific needs for new documents.
3. In 2005 and 2007, conduct dialogues in areas of the United States with significant racial or ethnic minority populations with mental health needs. Minority attendance will be assessed.
4. Participation by established groups of mental health advocates representing racial and ethnic minority groups in NIMH priority setting will increase, as measured by attendance at annual consultation meetings, such as the National Alliance for Research Progress.

3.1.3.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

a. Data analyses to determine the level of distribution of health disparities-related information by members of the Outreach Partnership Program.
    1. Analyses of efforts by the Outreach Partners to target various groups including health care professionals with information on the importance of eliminating health disparities.
    2. Analyses of the productivity of the national and local partners to contribute to the generation of policy, plans, and procedures that enhance the link between mental health research and services within the various states, the District of Columbia, and Puerto Rico, to reduce health disparities.

b. The Office of Communications will continue to develop and disseminate materials on issues of health disparities.

c. Evaluation will be conducted to assess learning and satisfaction with the dialogue meetings and their programs. Different ethnic and racial minority groups will have received up-to-date research findings about mental health and disorders and co-occurring disorders.

3.1.4 Objective Four

Outreach to ethnic minority communities to seek input for priority setting. NIMH will continue to seek advice from minority communities throughout the United States to inform its research planning and funding decisions.

NIMH has a variety of ways to seek and obtain input on its strategic planning process. For example, NIMH hosts various meetings across the United States designed to inform the public of cutting-edge mental health research and to gather input from the community about public health needs. NIMH also receives input from its Outreach Partnership Program members.

3.1.4.1 Action Plan

1. Plan and conduct biannual “dialogues” with a focus on specific minority communities. See http://www.nimh.nih.gov/Outreach/dialoguesforums.cfm. Conduct significant consultations and visits with minority communities prior to the meetings to ensure topics are critical to participants.
2. Plan and conduct interactive meetings with voluntary and professional organizations, specifically targeting racial and ethnic minority organizations.
3. Outreach Partners are encouraged to provide information to NIMH throughout the year on its research objectives. This information can be from their organization or as a “pass through” from other state organizations, state or local government agencies, or local communities. Minority organizations and communities are encouraged to work with NIMH partners or become partners to provide information directly to NIMH.

3.1.4.2 Performance Measures

These performance measures will demonstrate accomplishment of the objective:

1. In 2005 and 2007, conduct dialogues in areas of the United States with significant racial or ethnic minority populations with mental health needs. Minority attendance will be assessed.
2. Participation by established groups of mental health advocates representing racial and ethnic minority groups in NIMH priority setting will be increased, as measured by attendance at annual consultation meetings, such as the National Alliance for Research Progress.
3. Information provided from partners in the Outreach Partnership Program will be compiled and presented to appropriate Institute staff in a timely fashion.

3.1.4.3 Outcome Measures

The NIMH will use these procedures to measure and evaluate the outcomes of the objective:

1. Evaluation will be conducted to assess satisfaction with opportunities to provide feedback. Additional opportunities will be provided through email and listservs. Racial and ethnic minority members of the public will have received special outreach and opportunities to communicate their needs directly to NIMH for priority setting.
2. Evaluation will be conducted to assess satisfaction with opportunities to provide feedback. Additional opportunities will be provided through email and listservs.
3. Evaluation will be conducted to assess satisfaction with opportunities to provide feedback. Information provided to appropriate Institute staff will be evaluated and tracked to determine the type of outcomes that arise from the input from partners.

The National Institute of Neurological Disorders and Stroke

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

MISSION/VISION STATEMENT

The mission of the National Institute of Neurological Disorders and Stroke (NINDS) is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world. To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NINDS is the lead agency for basic and clinical research focused on the brain, spinal cord, and peripheral nerves; their development, degeneration, and regeneration; and their disorders and diseases. The NINDS has scientific interests in neurological disorders as diverse as stroke, epilepsy, multiple sclerosis, head and spinal cord injuries, Alzheimer’s disease and other dementias, Parkinson’s disease, neurofibromatosis, muscular dystrophy, neuroAIDS, amyotrophic lateral sclerosis, and Huntington disease. Many neurological and neuromuscular disorders are chronic disorders, characterized by progressive decline in cognitive, sensory, or motor function over a long period, resulting in disability, suffering, and long-term care at tremendous cost to the patient, family, and society. A number of neurological disorders are disproportionately more common in certain racial and ethnic groups. For example, the incidence of stroke is disproportionately high in the African American population, occurs at younger ages, and the mortality rate is nearly 80 percent greater than in Caucasians. Epilepsy and certain types of traumatic brain injury, as well as human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS) and diabetes, both of which have associated neurological complications, are other examples of disorders where certain racial/ethnic populations are at increased risk.

The NINDS has initiated a comprehensive health disparities planning process to define research priorities and approaches for reducing the burden of neurological disease in those populations where the burden is highest. Because substantial and persistent disparities are observed in diverse populations, the plan emphasizes reducing disparities in populations historically at increased risk for diseases and disorders of the nervous system. We further hope to achieve reductions in health disparities through efforts to diversify the workforce leading to the recruitment of the most talented researchers from all groups; to improve the education and training environment; and to help ensure a balanced perspective in the determination of research priorities in 10 primary areas of focus. These areas include research on stroke, the neurological complications of HIV/AIDS, epilepsy, neurological complications of diabetes, treatment and management of pain, injury to the developing brain, and the cognitive and emotional health of children. Other areas include expanding research capacities in diverse populations, enhanced training among academic institutions and researchers, improving access to and dissemination of research information to the public, and promoting adherence to inclusion policies to promote diversity in our clinical research enterprise.

The NINDS has developed collaborative partnerships and networks throughout the nation and world to investigate health problems and conduct research on neurological diseases and disorders. Our planning process identified effective approaches to encourage resource sharing and collaboration to diversify student and faculty populations and thus increase the participation of individuals who are currently underrepresented in NINDS mission-related programs and research activities. We will continue to identify innovative strategies to strengthen the inclusion of all groups in clinical studies and to develop more effective methods to promote culturally appropriate prevention, treatment, and other intervention studies in medically underserved populations. In addition, we will continue to provide leadership and training to attract and retain investigators committed to research on health disparities, and to develop strategies for educational outreach to foster improved dissemination of research-based information to at-risk communities.

1.0 AREAS OF EMPHASIS IN RESEARCH

The NINDS is the lead agency for basic and clinical research focused on the brain, spinal cord, and peripheral nerves; their development, degeneration, and regeneration; and their disorders and diseases.

In 2001, the NINDS initiated a comprehensive health disparities planning process to define research priorities and approaches for reducing the burden of neurological disease in minority populations. The NINDS Strategic Plan on Minority Health Disparities was developed in consultation and collaboration with intramural and extramural researchers and other federal agencies. The goals of the Plan are to achieve reductions in health disparities through targeted investments in research infrastructure and funding of 10 primary areas of focus.

1.1 Area of Emphasis One: Stroke

Stroke is the third leading cause of death in the United States, killing approximately 150,000 Americans every year. More than 700,000 new or recurrent strokes occur each year, leaving approximately 4 million Americans living with neurological deficits due to stroke. The risk for suffering a stroke and the associated mortality increase with age; thus, the frequency of stroke is expected to increase substantially with the aging of the American population.

The risk of stroke also varies by race and ethnicity. The incidence of stroke is disproportionately high in the African American population, occurs at a younger age, and the mortality rate is nearly 80 percent greater than in Caucasians. In Hispanic Americans, the incidence of subarachnoid hemorrhage is approximately two and a half times that of Caucasian Americans, and the death rate is significantly higher at younger ages. The burden of stroke in these populations is substantial and its impact on the U.S. health care system is likely to increase because ethnic and racial minorities are the fastest-growing segments of the population in several states; by the year 2020, it is anticipated that minorities will outnumber Caucasian Americans in many states.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Ongoing Programs

The NINDS is supporting studies on the epidemiology, etiology, pathophysiology, and secondary prevention of stroke in diverse populations. These include prevention/primary intervention studies focused on the evaluation of risk factors and stroke incidence in diverse communities. The NINDS also funds secondary/tertiary intervention studies, including a small pilot trial on subcortical strokes, also known as lacunar infarcts, in Mexican American subjects. An exciting project being funded by NINDS is the Reasons for Geographic and Racial Differences in Stroke (REGARDS), a 5-year study that addresses the wide range of hypothesized causes of excess stroke mortality in the southeastern United States among African Americans. Approximately 30,000 African Americans and Caucasians from the Stroke Buckle—an area within the Stroke Belt with exceptionally high rates of stroke—and elsewhere in the nation will be enrolled in the study and followed for 3 years for onset of new stroke events. The resulting information will be useful for designing interventions to reduce excess stroke mortality.

Currently funded projects include the following:

– 1K23NS049463-01	The Effect of Socioeconomic Status on Outcome After Stroke
– 1K23NS050161-02	Stroke Genetics in a Multi-Ethnic Community
– 5K23NS042912-05	Inflammation and Infection as Risk Factors in Stroke
– 5K23RR016186-06	The Genetic Basis of Intracranial Aneurysms
– 5K24NS002241-04	Echocardiographic Stroke Predictors in a Tri-Ethnic Community
– 5R01NS029993-14	Stroke Incidence and Risk Factors in a Tri-Ethnic Region
– 5R01NS030678-13	Hemorrhagic and Ischemic Stroke Among Blacks and Whites
– 5R01NS036286-07	Aortic Cardiovascular Disease and Silent Brain Infarcts
– 5R01NS036695-09	Genetic and Environment Risk Factors for Hemorrhagic Stroke
– 5R01NS038916-08	Stroke Surveillance an a Bi-Ethnic Community
– 5R01NS039486-02	Stroke, M.I., and Antiphospholipid Antibodies
– 5R01NS040807-05	Family Study of Stroke Risk and Carotid Atherosclerosis
– 5R01NS045012-04	Genetics of Early Onset-Stroke
– 5R01NS045789-02	Psychosocial Impact of Stroke on Family Caregivers
– 5U01NS038529-07	Secondary Prevention of Small Subcortical Strokes (Sps3)
– 5U01NS039143-05	Warfarin Vs Aspirin in Reduced Ejection Fraction—STAT
– 5U01NS041588-05	Etiology of Geographic and Racial Differences in Stroke
– 5U01NS042804-03	Silent Cerebral Infarct Multi-Center Clinical Trial
– 5U01NS042940-04	Silent Cerebral Infarct Multi-Center Clinical Trial—SCC
– 5U01NS043975-05	Warfarin Vs Aspirin in Reduced Ejection Fraction—CLIN
– 5U01NS048069-02	Alaska Native Stroke Registry
– 5Z01NS002863-15	Epidemiology of the Developmental Disabilities
– 5P01NS020020-23	Mechanisms of Regulation of Cerebral Blood Flow
– 5R01NS034949-12	Predictors of Spontaneous Cerebral AVM Hemorrhage
– 5R01NS045948-03	Aspirin Prophylaxis in Sickle Cell Disease

– 5R01NS046717-03	Cognitive and Neuroimaging Study in Sickle Cell Disease
– 5Z01NS002856-15	Hibernation—A New Approach to Stroke Therapy
– 5Z01NS002924-11	Protective Mechanisms in Cerebral Ischemia

1.1.1 Objective One: To Establish the Magnitude of the Disparity and the Nature of the Contributing Factors

Recent Programs and Progress to Date

(a) Workshop on Racial/Ethnic Disparities in Stroke

In November 2002, the NINDS convened experts in stroke, epidemiology, and health disparities research to focus on the disparate burden of stroke among racially diverse populations. The workshop reviewed the current knowledge on stroke disparities, examined potential determinants for these disparities (especially for stroke in young individuals), and proposed strategies and outcome measures for addressing these health disparities.

The panel provided the NINDS with recommendations for advancing stroke disparities research. Some of these recommendations include: (1) expanding population-based studies to measure temporal trends in stroke incidence, prevalence rates, and outcomes in racial and ethnic subgroups; (2) investigating the interrelationships between race and ethnicity, risk factors, and stroke mechanisms; (3) understanding the effects of how inadequate medical insurance, the primary care physician, and acculturation patterns affect access to health care; (4) expanding clinical trials to include epidemiological and health service components; (5) evaluating the barriers to adherence of stroke prevention strategies; and (6) increasing the pool of minority and other underrepresented investigators.

The report from this workshop is available at:
http://www.ninds.nih.gov/news_and_events/proceedings/stroke_disparities2002.htm

1.1.1.1 Action Plan

Proposed New Directions:

(a) Stroke and Cerebrovascular Disease Prevention-Intervention Research Program

In FY2003, the NINDS, in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Research Resources (NCRR), funded a cooperative agreement with Morehouse School of Medicine for a Stroke Prevention/Intervention Research Program (SPIRP). One goal of the agreement is to augment and strengthen the research capabilities to reduce the burden of stroke in populations historically at increased risk from this disease. Phase 1 began July 1, 2003, with pilot studies and infrastructure development activities. Phase 2 is scheduled to begin in 2007.

The primary goals of the Stroke and Cerebrovascular Disease Prevention/Intervention Research Program are to:

1. Develop sustainable, replicable, and culturally appropriate prevention and/or intervention research programs targeted to racially diverse populations designed to decrease the incidence and prevalence of stroke;
2. Strengthen basic, clinical, and translational research capacity at institutions of higher education committed to addressing health disparities related to stroke;
3. Enhance opportunities for multidisciplinary research collaborations between institutions of higher education and institutions with established programs in stroke research; and
4. Increase the role of research in maintaining a vigorous and stimulating academic milieu that will inspire students and fellows to pursue careers in research on stroke and other vascular diseases.

(b) Stroke Disparities Research Program in a Washington, DC Minority Community.

The NINDS will establish a stroke research-care program in a hospital serving a diverse population in the Washington, DC area, modeled on a successful program at Suburban Hospital in Bethesda, Maryland. In September 2003, a contract was awarded to Washington Hospital Center, which serves a predominantly minority community in the Washington, DC area, to provide support for NINDS stroke researchers. In August 2004, the clinical care and research activities of the program were initiated. The program is using cutting-edge brain imaging technology to serve the clinical needs of acute stroke patients and providing NINDS investigators a unique platform for developing new therapies to treat and prevent strokes based on better understanding of the evolving cerebral injury in stroke. In addition, this program could eventually serve as a base from which to conduct studies of the epidemiology of stroke, barriers to acute stroke care, and quality of care within the specific at-risk communities being served by the hospital. This information could be used to tailor stroke prevention and intervention programs, including stroke awareness/education campaigns, to those communities, thereby reducing the burden of disease.

1.1.1.2 Performance Measures

Performance measures for the SPIRP project include the establishment of a research infrastructure and administrative activities, the submission and funding of high-quality applications for program-based research projects, and the recruitment of diverse individuals involved in SPIRP center activities.

1.1.1.3 Outcome Measures

Based on the SPIRP program model at Morehouse School of Medicine, the NINDS will consider developing and piloting similar programs in the extramural community in other priority research areas for NINDS in health disparities.

The goal of the Washington Hospital Center program is to have a well-established research and acute care program in the minority communities of Washington, DC, and to improve time-to-acute stroke care in these communities.

1.2 Area of Emphasis Two: HIV-Associated Neurological Disease

HIV infection/AIDS is a leading cause of death for young adults, and approximately 375,000 have died from the disease in the United States. It is estimated that 650,000 to 900,000 Americans are infected with HIV, 15 to 30 percent of whom will develop some type of neurological disorder in the course of their illness.

AIDS affects certain racial and ethnic groups disproportionately. Although minorities constitute approximately 30 percent of the total population, they account for nearly 70 percent of all AIDS cases. Although the number of new (incident) cases is decreasing in some populations, it is increasing among African Americans, especially homosexual men. Of reported cases in women and children, more than 75 percent are minorities. Despite the reality of these data, the natural history of this infection in minorities has not been well established. For example, the interaction between co-morbid conditions/pre-existing ones and HIV infection has not been documented, although it is well known that members of minority groups tend to have been exposed to or carry a higher number of infectious agents when compared to Caucasians. This knowledge has immediate and direct repercussions in the diagnosis, prognosis, and treatment of minority patients infected with HIV.

Ongoing Programs

The NINDS is supporting studies on the epidemiology, etiology, pathophysiology, and secondary prevention of NeuroAIDS in diverse populations. In addition, the NINDS is supporting programs to enhance the availability of racially/ethnically diverse tissue resources as well as multiple clinical trials to develop effective HIV treatments. Two studies focusing on the prevention and treatment of NeuroAIDS include Specialized Neuroscience Research Programs (SNRP) at the University of Puerto Rico and the University of Hawaii. The program at the University of Puerto Rico Medical School has established a cohort of women and children to determine the major host and viral factors responsible for disease pathogenesis. A second program, at the University of Hawaii, is studying the prevalence and incidence of dementia in HIV seropositive individuals 50 years of age or older compared with younger HIV seropositive individuals.

Other programs funded by NINDS include: (1) the National NeuroAIDS Tissue Consortium (NNTC), a national resource for the provision of well-characterized tissues and fluids from HIV-infected patients to NeuroAIDS investigators; and (2) the Neurological AIDS Research Consortium (NARC), which supports investigations on a range of epidemiological and pathophysiological studies of the disease, as well as studies focused on secondary and tertiary interventions.

Currently funded projects include the following:

– 5R24NS045491-09	Texas Repository for AIDS Neuropathogenesis Research
– 5R24MH059724-09	The Manhattan HIV Brain Bank (NNTC)
– 5R24MH059745-09	California NeuroAIDS Tissue Network (NNTC)
– 5R24NS038841-09	National Neurological AIDS Bank
– 5U01NS032228-11	Neurologic Aids Research Consortium
– 5K23NS043091-05	Epidermal Innervation as an Outcome Measure

1.2.1 Objective One: To Establish the Magnitude of the Disparity and the Nature of the Contributing Factors

Programs and Progress to Date

(a) Planning Panel on NeuroAIDS in Minority Populations

In July 2001, the NINDS convened experts in NeuroAIDS to identify what additional policies and programs the NINDS can implement to address the issue of health disparities with respect to the neurological complications of HIV/AIDS. The meeting report from the NINDS Health Disparities Planning Panel on NeuroAIDS in at-risk populations can be found at: http://www.ninds.nih.gov/news_and_events/proceedings/NeuroAIDS_2001.htm

The Panel developed recommendations and priorities in the areas of Research, Research Capacity, and Outreach. The highest priority has been assigned to research activities to understand the natural history and clinical course of neurological complications of HIV/AIDS among minorities. Examples of these include:

- Incidence and prevalence of the array of neurological manifestations, and associated risk factors;
- Disease progression (or conversely, disease stabilization) and associated risk factors, e.g., genetics, co-infection; and
- Treatment: array of therapies, adherence to recommended therapies, and response to therapies.

The panel noted that as a prelude to progress in this area, it might be necessary to develop screening and assessment tools for identifying the neurological complications of AIDS in diverse groups.

1.2.1.1 Action Plan

Proposed New Directions in HIV-Associated Neurological Disease

(a) Epidemiological Studies of neuroAIDS in At-Risk Populations

Based on the planning panel on NeuroAIDS, the NINDS continues to encourage studies that will address the research priority areas. One cost-effective strategy for such studies would be to utilize existing HIV/AIDS cohorts that are well characterized. These studies may involve specific subgroup analyses or may require enhancement of the cohorts to ensure sufficient sample sizes for meaningful analyses. Foreign cohorts that reflect the racial/ethnic diversity within the United States also may be considered because treatment is often less prevalent in developing countries, providing information on the natural history of neurological complications among minority populations.

The studies could also accommodate activities to facilitate natural history/clinical course studies, notably the normalization of neuropsychological instruments to minority populations.

Neuropsychological testing has been developed with little or no participation of minority populations, and norms established for the Western world have been used without adjustments to racial/ethnic subgroups. These tests serve as a measure of HIV neurological involvement and are used to monitor NeuroAIDS treatment success. The fairness of using such instruments with minorities has been questioned, and their accuracy in measuring mild cognitive impairment in these populations is controversial. The NINDS will encourage the development of culturally sensitive neuropsychological instruments and/or normative data in defined communities or neighborhoods with representative populations.

1.2.1.2 Performance Measures

Performance measures include encouraging studies of neuroAIDS in underserved populations, particularly in priority areas identified at the July 2001 planning panel.

1.2.1.3 Outcome Measures

Outcome measures include gaining a better understanding of the natural history of neuroAIDS in certain subgroups, particularly through studies utilizing existing cohorts of patients.

1.3 Area of Emphasis Three: Epilepsy and Status Epilepticus

Epilepsy is characterized by recurrent unprovoked seizures. Status epilepticus, a serious condition characterized by acute continuous or repetitive seizures, is a major medical and neurological emergency in the United States, killing more than 50,000 Americans each year. Approximately 260,000 new or recurrent cases of status epilepticus occur each year, and approximately 8 percent of patients in coma manifest non-convulsive status epilepticus. The elderly have the highest incidence of status epilepticus, which is also associated with increased mortality. Thus, the frequency of status epilepticus and its mortality is expected to increase significantly with the aging of the American population.

The incidence of status epilepticus is disproportionately higher in African Americans across the entire age spectrum. In the elderly, it is more than four times the incidence in the general population. Moreover, recent findings suggest that there is a significantly higher genetic predisposition for

African Americans to develop status epilepticus in comparison to members of non-minority populations.

According to studies, the incidence of epilepsy in the African American community in Harlem is 50 percent higher than in the Caucasian population. This disparity has been attributed to socioeconomic differences and other factors including nutrition, exposure to violence, reduced health infrastructure, and altered access to medical care. However, at a Health Maintenance Organization (HMO) in Houston, incident cases of epilepsy seemed higher in Hispanic and African American children. Recruitment from the same HMO would appear to control for access to care and socioeconomic status. Similarly, in Atlanta, African American children have a higher lifetime prevalence compared to Caucasian children under the age of 10. The lifetime prevalence in these studies is probably closest to demonstrating real differences in incidence. In the elderly, the incidence of all seizures by age 70 was about 25 percent in the African American community of Harlem compared to 10 percent in Caucasians. Age-specific mortality attributable to seizures/epilepsy and overall mortality are also considerably higher in African American than in Caucasian populations. The potential roles of genetics or specific gene-environment interactions in the incidence of epilepsy have not been determined.

Ongoing Programs

The NINDS is supporting studies in a number of areas related to health disparities in epilepsy. Examples include a multi-center study of idiopathic generalized epilepsy, to identify the loci involved in the expression of idiopathic generalized epilepsy and investigate their interactions, testing the differences in specific candidate loci between Caucasians and non-Caucasians; and a population-based study at the Medical College of Virginia Epilepsy Research Center to investigate status epilepticus in populations at increased risk.

Currently funded projects include the following:

–	1K23NS046086-03	Is Cerebral Malaria a Risk Factor for Epilepsy?
–	2R01NS027941-17A1	A Multicenter Study of Idiopathic Generalized Epilepsy
–	1R21NS055353-01	Epidemiology and Burden of Neurocysticercosis in Burkina Faso
–	5P50NS016308-26	Epilepsy Clinical Research Program
–		

1.3.1 Objective One: To Establish the Magnitude of the Disparity in Epilepsy and Status Epilepticus: Occurrence and Treatment, and the Nature of Contributing Factors

Recent Programs and Progress to Date

(a) Planning Panel for National Workshop on Minorities and Epilepsy

A panel of experts was convened on November 13, 2002, to define research priorities and approaches for addressing epilepsy and status epilepticus in minority populations. The panel examined the current state of knowledge regarding disparities in the areas of: epidemiology, clinical management and outcomes, the role of stigma, and economics, and also for specific populations including Native Americans, women, and urban (inner-city) residents. The overall conclusion was that more information on disparities in epilepsy and status epilepticus is needed before proper interventions or campaigns can be developed. Research is needed generally to improve knowledge about the epidemiology, issues in treatment and clinical management, outcomes, and barriers such as stigma. In addition, a conceptual framework is needed on which further studies would be designed.

A summary of the Health Disparities in Epilepsy Planning Panel can be found at:
http://www.ninds.nih.gov/news_and_events/proceedings/epilepsy_panel_2002.htm

(b) Program Announcement (PA): Reducing Disparities in the Treatment of Epilepsy
(*http://grants.nih.gov/grants/guide/pa-files/PAS-03-164.html*)

The findings from the Epilepsy Planning Panel were used to develop a set of research priorities and approaches for addressing epilepsy and status epilepticus in minority populations, and a PA with set-aside funds, entitled “Reducing Disparities in the Treatment of Epilepsy” was released in August 2003 and expired in September 2006. This announcement solicited applications to address the key gaps in knowledge relating to epidemiology, clinical management or treatment, and the role of perceptions in prevention/intervention efforts.

1.3.1.1 Action Plan

Proposed New Directions in Epilepsy and Status Epilepticus

(a) Epilepsy and Status Epilepticus in Diverse Populations

The NINDS will encourage research focused on the frequency of epilepsy and status epilepticus, risk factors, clinical manifestations, natural history, and prognosis in diverse minority populations. Research on specific populations will be encouraged, for example, in defined communities or neighborhoods with representative diverse populations. Research also will be sought on barriers to appropriate clinical management of the disease experienced by minority populations.

(b) Secondary Epilepsy in Racial/Ethnic Minorities

Research indicates that African Americans and Hispanics are at increased risk for stroke (especially at younger ages), while Native and African Americans are at higher risk for brain injury (due to accidents, firearms, low birth weight). Both conditions are known to be associated with epilepsy. The NINDS will encourage research on factors related to differential risk for secondary epilepsy, prognosis, and intractable seizures.

(c) Pathophysiology of Epilepsy and Status Epilepticus in Minorities

The NINDS will promote studies to identify factors essential to the understanding of the basic mechanisms underlying these conditions in different racial/ethnic groups. These factors include, but are not limited to, cerebral vascular disease, genetics, sickle cell anemia, and alcoholism.

1.3.1.2 Performance Measures

A short-term performance measure is the receipt of applications and funding of high-quality applications in the area of reducing disparities in the treatment of epilepsy. Funding of new studies in the priority areas mentioned above is an additional, longer-range measure of performance.

1.3.1.3 Outcome Measures

Outcome measures include gaining a better understanding of the frequency of epilepsy and status epilepticus and their risk factors, clinical manifestations, natural history, and prognosis in diverse populations, as well as the increased risk of secondary epilepsy in different racial/ethnic groups. The outcome of studies to identify factors essential to the understanding of the basic mechanisms underlying these conditions in various racial/ethnic groups will also be used to measure progress of this objective.

1.4 Area of Emphasis Four: Neurological Complications of Diabetes

Diabetes is the seventh leading cause of death in the United States, affecting nearly 16 million Americans. Compared to that in Caucasians, the prevalence of diabetes in Hispanic Americans and in African Americans is approximately 50 percent and 70 percent higher, respectively. Among Native Americans and Alaska Natives, the prevalence of diabetes is more than twice that of Caucasian Americans, being the highest in the world among the Pima tribe. Thus, the burden of diabetic complications, including sensori-motor peripheral neuropathy, is disproportional in minority populations. Also, there is evidence that lower extremity amputations, which to some extent reflect neuropathology, occur more frequently among diabetics who are members of minority groups.

Current Institute activities related to health disparities in diabetes-related neuropathy include a clinical-epidemiological study of the disorder in a Native American population.

– 5R01NS036797-10	Neuropathy Study Among Hispanic and American Indian Populations

1.4.1 Objective One: To Establish the Magnitude of the Disparity and the Nature of the Contributing Factors and Outcomes

During the development of the NINDS Strategic Plan on Minority Health Disparities, the extramural neuroscience community identified the neurological complications of diabetes as an area of disease focus. The magnitude and disparity of these neurological complications were based on the disparity of diabetes in at-risk populations.

Recent Programs and Progress to Date

(a) PA – Race/Ethnic Disparities in the Incidence of Diabetes Complications.

NINDS, in collaboration several other NIH Institutes, released a PA in 2002 seeking research projects to understand racial/ethnic disparities in the development of the microvascular (nephropathy, retinopathy, and neuropathy), and macrovascular (cardiovascular disease and stroke) complications of diabetes.

1.4.1.1 Action Plan

Proposed New Directions in Neurological Complications of Diabetes

(a) Race/Ethnic Disparities in the Incidence of Diabetes Complications

The NINDS will continue to co-fund research programs with the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK) that are focused on sensori-motor neuropathy, its frequency, natural history, and outcomes, including lower extremity amputation.

(b) Diabetic Neuropathy in the National Health and Nutrition Examination Survey (NHANES)

In the ongoing NHANES survey, the National Center for Health Statistics (NCHS), recently began using a simple measure of neuropathy, and is enrolling 5,000 new cases per year. These cross-sectional evaluations are uniquely suited for studying major outcomes related to neuropathy (ulcer, amputation, mortality). In 3 or 4 years, that sample (15,000 to 20,000) will be large enough to generate normative data by age, race, and sex. Thus, the NINDS could potentially use an inter-agency agreement to collaborate with the NCHS to include more precise measures of neuropathy to be used in the examination protocol.

(c) Analysis of Existing Diabetic Studies Toward Neurological Endpoints

Extensive cohorts of diabetic patients exist and are well characterized in the scientific literature. The NINDS will explore the possibility of supporting the analysis of existing data sets to further elucidate the frequency of sensori-motor neuropathy and the nature of its predictors, prognostic factors, and interventions to prevent or delay the development of neuropathy.

(d) Minority Cohorts in Established Diabetes Protocols

Longitudinal studies of diabetes are currently under way, some with substantial minority representation. The NINDS will encourage these protocols to use innovative methods to recruit and retain research participants, to differentiate the types of neuropathy occurring with diabetes, to monitor the progression of disease, and to define outcomes of the neuropathy itself.

1.4.1.2 Performance Measures

Near-term performance measures for these activities include stimulating research in the target areas. The NINDS has made initial exploration of a possible collaboration with private research agencies to conduct an epidemiological study of neurological complications of diabetes among Native Americans.

1.4.1.3 Outcome Measures

A major goal of this objective is to advance our knowledge of the neurological complications of diabetes, particularly a better understanding of the causes and progression of neuropathy as well as the development of effective therapies. The results of longitudinal studies, some with significant minority representation, will give us a better insight into the progression of the disease and the outcomes of the neuropathic complications.

1.5 Area of Emphasis Five: Health Disparities in Treatment and Management of Chronic Pain Disorders

Chronic pain disorders, such as migraine headaches, may be more prevalent in certain populations or present special problems when considering therapeutic approaches. Further, recent studies indicate inadequate treatment for pain in diverse populations, and ethnic differences in the perception of pain. To stimulate research, NINDS, as one of the lead Institutes for the Pain Research Consortium at NIH, will direct research efforts to identify treatment and management strategies for chronic pain conditions in diverse populations. This initiative is of particular interest to NINDS, and potentially to members of the NIH Pain Research Consortium and the NIH intramural community, as well as to potential partners in the pharmaceutical and biotechnology industries.

Currently funded projects include the following:

1K01NS055094-01	Ethnic Differences in Acute Pain and Analgesic Response
5K01NS046582-03	Race, Psychiatric Disorders, and Headache
5R01NS042754-05	Ethnic Differences in Responses to Painful Stimuli

5R01NS045186-04 NPY Regulation of Peripheral Human Nociceptors and Pain

1.5.1 Objective One: To Develop Treatment and Management Strategies for Chronic Pain in Diverse Populations

Recent Programs and Progress to Date

(a) NIH Pain Consortium First Annual Symposium—Advances in Pain Research.

The NINDS, in collaboration with several other NIH Institutes, supported a symposium on pain research in April 2006. The symposium focused on advances in pain research, including the genetics, neuronal mechanisms, imaging, cognitive and emotional aspects, and treatment of pain. The symposium also focused on individual differences in pain and analgesia by gender and ethnicity.

1.5.1.1 Action Plan

Proposed New Directions in Chronic Pain

1. The NINDS will focus on studies to identify racial/ethnic differences in pain perception and processing and to identify and assess barriers influencing effective chronic pain management and treatment in different racial/ethnic groups. In this effort, we will determine the nature and extent of disparities in the delivery of pain treatment in target populations and in specific disease states.
2. The NINDS will focus on studies to identify new diagnostic tools for different pain mechanisms and objective measures of analgesic drug action. Key elements in this effort will be research to understand differences in response to analgesic drugs in diverse populations; encouraging development of a quantitative sensory testing battery for pain patients; and encouraging development of imaging markers of analgesia and analgesic mechanisms.

1.5.1.2 Performance Measures

Performance measures for these activities include organizing and holding a future workshop on Health Disparities in Chronic Pain and Its Management, and stimulating interest in the research community in the identified target areas.

1.5.1.3 Outcome Measures

Outcome measures include a better understanding of the racial/ethnic differences in pain perception and processing, identification of barriers influencing effective chronic pain management and treatment in various populations, and development of chronic pain management strategies for diverse populations.

1.6 Area of Emphasis Six: Injury to the Developing Brain

Injury to the pre- and postnatal brain is a leading cause of death and morbidity in children, especially injury induced by adverse fetal/perinatal environments and trauma. In the Child Health USA 1999 publication, the Department of Health and Human Services Health Resources and Services Administration (HRSA) reported that the infant mortality rate and the low birth weight and very low birth weight (VLBW) rates are twice as high in African American infants as in Caucasian infants. VLBW infants are at the highest risk for physical developmental disabilities (learning and behavioral problems, motor disabilities/cerebral palsy, and mental retardation) and death. In addition, certain types of traumatic injury in infancy appear to be more frequent in minority populations. However, the information available is insufficient to adequately identify the causes of these injuries and the subpopulations of infants at greatest risk of sustaining these injuries.

Current institute activities related to health disparities include a toxicogenomic study of neural tube defects in Guatemala.

1F31NS053282-01	A Toxicogenomic Approach to Human Neural Tube Defects

1.6.1 Objective One: To Study the Effects of Biological and Environmental Factors in the Immediate and Long-Term Outcomes of Age-Dependent Brain Injury

Recent Programs and Progress to Date

(a) Working Group Meeting: Cognitive and Emotional Health in At-Risk Children

A panel of experts was convened on July 23, 2001, to define research priorities and approaches for addressing the cognitive and emotional health of minority children. The panel examined the current state of knowledge regarding the impact of biological, environmental, and sociological factors on the immediate and long-term outcomes of the developing brain. The panel recommended the following:

- The establishment of multidisciplinary working groups to help frame research questions and gather pilot data.
- Develop new assessment tools that would be sensitive to the following factors: culture, socioeconomic status, gender, rural versus urban location, language, and literacy.
- Identification and implementation of the use of (appropriate) biological markers.
- Conduct of longitudinal multi-site studies.
- Provision of access to multiple intervention strategies that are preventive, remedial, culturally relevant, and therapeutically effective.
- Establishment of a board of advisors to provide oversight for legal, political, and ethical issues.
- Establishment of educational opportunities to increase cultural diversity of future health professionals, researchers, and their staff.

- Funding of basic neuroscience research to study the effects of post-traumatic stress on the brain, the changes that occur in the brain with puberty (and early onset of puberty), and the impact of environmental contaminants on brain function.
- Encouragement of multi-NIH Institutes' initiatives and multi-agency initiatives.

1.6.1.1 Action Plan

(a) Research on Developmental Brain Injury

The NINDS will continue to encourage studies for additional analysis on existing data pertinent to injury of the developing brain from birth until late infancy. Diversity research supplements may be used to recruit additional participants to existing studies to increase the statistical power of on-going studies, and to make the results generalizable to diverse populations.

1.6.1.2 Performance Measures

Measures of performance will focus on the submission and funding of high-quality applications in the targeted areas.

1.6.1.3 Outcome Measures

Longer term outcome measures include recruiting more diverse patients into existing studies to better understand developmental brain injury in these populations, and identification of the key factors affecting the frequency of perinatal, neonatal, and infant brain injury.

1.7 Area of Emphasis Seven: Health Disparities in Cognitive and Emotional Health of Children

Children in urban centers are at increased risk for adverse health outcomes due to chronic exposure to negative environmental factors including toxic substances, violent neighborhoods, and impoverished educational facilities. A large percentage of these children have had documented exposures to toxins (e.g., lead), and yet they have not received adequate follow-up care despite well-known impairments linked to such exposures.

In urban children, there is an issue of added vulnerability: it is well documented that a large percentage of minority mothers, especially African American women, give birth to low and very low birth weight babies, often associated with premature labor. These conditions are often associated with injury to the developing brain, which will likely be compounded by the insult of environmental toxins.

Neglect and domestic and community violence are also important factors challenging the normal cognitive and emotional development of urban minority children. Symptoms of anxiety and stress similar to those associated with Post Traumatic Stress Disorder have been diagnosed with increasing frequency in these children.

1.7.1 Objective One: To Assess the Complex and Multifaceted Issues Associated With Disparities in Cognitive and Emotional Health of Children

Recent Programs and Progress to Date

(a) Workshop on the Cognitive and Emotional Health of Minority Children.

In July 2001, this workshop of national experts discussed the concept of "normal" cognitive and emotional development in children, and how to assess the defined "normality." This group also focused on environmental and pharmacological effects, as well as the result of neglect and other adverse conditions on the cognitive and emotional health of children, resulting in recommendations on how to promote the normal development of all urban children. The report from the *Health Disparities Working Group Meeting: Cognitive and Emotional Health in Minority Children* can be found at:
http://www.ninds.nih.gov/news_and_events/proceedings/MH_Meeting_Summary72301.htm

The working group concluded that the overarching need is for the support of research on the development of neutral and/or culturally sensitive assessment tools, community-based research, and multi-site longitudinal studies. Specific recommendations include:

1. Encourage the establishment of multidisciplinary working groups to help frame research questions and gather pilot data.
2. Develop new assessment tools that would be sensitive to the following factors: culture, socioeconomic status, gender, rural versus urban location, language, and literacy.
3. Identify and implement the use of (appropriate) biological markers.
4. Conduct longitudinal multi-site studies.
5. Develop, implement, and provide access to multiple intervention strategies that are preventive, remedial, culturally relevant, and therapeutically effective.
6. Establish educational opportunities to increase cultural diversity of future health professionals, researchers, and their staff.
7. Fund basic neuroscience research to study the effects of post-traumatic stress on the brain, the changes that occur in the brain with puberty (and early onset of puberty), and the impact of environmental contaminants on brain function.
8. Encourage multi-NIH Institutes' initiatives and multi-agency initiatives (including SAMHSA, HRSA).

(b) New York Academy of Sciences Conference "Roots of Mental Illness in Children"

In March 2003, the NINDS co-funded a New York Academy of Sciences conference with the National Institute of Mental Health (NIMH) to build bridges between animal research and clinical approaches for studying mental health and disorders in children and adolescents. The conference focused on the common symptoms or dimensions observed in several childhood disorders that can help us conceptualize special features of behavioral and neural development which, together with the impact of environmental factors, confer susceptibility or resilience to cognitive and emotional dysfunction during early stages of development.

(c) PA on Methodology and Measurement in the Behavioral and Social Sciences

In March 2002, the NINDS joined the NIH Office of Behavioral and Social Sciences Research (OBSSR) and 14 other NIH Institutes in releasing a PA (PA-02-072) that solicits research grant applications on methodology and measurements in the behavioral and social sciences. In this PA, the participating Institutes and Centers particularly encouraged research that addresses methodology and measurement issues in diverse populations, including instrument design, calibration, and refinement to study culture and self-identification of race-ethnicity, as well as health disparities.

(d) Prospective Study of Chronic Kidney Disease in Children

In November 2002, the NINDS partnered with the NIDDK and NICHD to release an RFA (RFA-DK-03-012) to conduct a prospective epidemiological study of children with chronic kidney disease. The cohort of 600 children with mild to impaired kidney function will be recruited from a diverse population sample. The primary goals of the study are to determine the risk factors for decline in renal function and the incidence of, and risk factors for, impaired neurocognitive development and function.

1.7.1.1 Action Plan

1. The NINDS will encourage studies assessing factors (prenatal, perinatal, environmental) influencing the cognitive and emotional development in children from populations at the highest risk. The focus of these studies will be to characterize the relationship between health disparities and normal and dysfunctional cognitive development and function, including issues of prevalence, severity of condition, risk factors, and cognitive patterns that lead to life-long health problems in these groups.
2. The NINDS will also explore funding research on the long-term effects of “early experiences” (*in utero*, perinatal) on brain development and function. The goals of these studies would be to begin a community-based longitudinal study of the health of children from at-risk groups and to develop collaborative partnerships with federal agencies to join in the development and support of the study.
3. The NINDS will encourage grantees to expand their ongoing cognitive neuroscience programs and explore new research projects that characterize the relationship between health disparities and the normal and dysfunctional cognitive and emotional development of at-risk children.

1.7.1.2 Performance Measures

Performance measures include encouraging grantees to pursue research in the targeted areas, leading to the submission of high-quality applications. Performance measures will focus on the establishment of the necessary structure to support the above lines of research: programs to encourage grantees to expand and explore new research in these areas, and collaborative partnerships.

1.7.1.3 Outcome Measures

Gaining a better understanding of the cognitive and emotional health of minority children, through studies on a wide range of aspects of mental health and neurocognitive impairment, will demonstrate success of this objective.

Expansion of cognitive neuroscience programs at grantee institutions, particularly programs that that characterize the relationship between health disparities and the normal and dysfunctional cognitive and emotional development of at-risk children, will be viewed as successful measures of progress.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

The biomedical research enterprise of the United States has consistently produced novel research discoveries that have lead to effective medical therapies. The success of this enterprise derives largely from the diversity of the research teams and the types of institutions doing the work. Historically Black Colleges and Universities, Hispanic-Serving Institutions, Tribal Colleges and Universities, Alaska Native Serving Institutions and Asian American/Pacific Islander Serving Institutions, as defined in the Higher Education Act, represent valuable resources to the NIH biomedical research enterprise. These institutions have a history and tradition of educating and training diverse scientists and have the potential to empower minority communities to improve their health status through participation in health research. The Research Capacity programs are primarily race neutral and predicated on the Institution of Higher Education and not the individual.

To meet the increasing demand for medical therapies in the future, the biomedical research enterprise must increase the diversity of America’s scientific workforce and continue to build and maintain state-of-the-art research environments at institutions participating in biomedical research. The NINDS will continue its strategic plan to promote a diverse scientific and technology workforce and will provide programmatic assistance to research institutions to develop and sustain basic, translational, and clinical neuroscience research programs.

2.1 Area of Emphasis One: Research Capacity Building and Enhanced Training Among Institutions and Researchers

The NINDS—in collaboration with the NCRR, NIMH, NIDA, OAR, and NHLBI—co-sponsors the Specialized Neuroscience Research Programs (SNRPs). This is a national network of research programs consisting of 75 neuroscience investigators and 65 affiliated neuroscience research collaborations. These programs offer assistance to diverse institutions to develop and sustain basic, translational, and clinical neuroscience research programs. Support for this initiative is recognition of the contributions this segment of the extramural community has made to advancing scientific understanding, educating and preparing minority researchers and health professionals, and delivering research benefits to underserved communities.

The programs are designed to achieve the following goals:

- To assist in infrastructure development leading to well-established, state-of-the-art neuroscience research programs;
- To foster innovative and effective partnerships and collaboration between institutions and established neuroscience laboratories at federal and non-federal research institutions;
- To create, support, and maintain a stimulating academic and intellectual milieu to inspire and prepare students and fellows to pursue research careers in neuroscience; and
- To provide support to develop and sustain competitively funded neuroscience research projects and programs.

Ongoing Programs (Research Capacity Building):

(a) SNRP U-54 Series RFA-NS-01-009 and RFA-NS-99-007

These grants are designed to enhance the quality and productivity of neuroscience research and capabilities of faculty, students, and fellows at M.D. and/or Ph.D. granting institutions by supporting the development and/or enhancement of basic, clinical, and translational research projects and programs at these institutions and increasing the number of neuroscience students and postdoctoral fellows from minority and other underrepresented groups. SNRP grants have been active at the following institutions:

U54NS039405	University of Puerto Rico—Rio Piedras
U54NS039406	University of Hawaii
U54NS039407	Howard University
U54NS039408	Universidad Central del Caribe
U54NS039409	University of Texas at San Antonio
U54NS041071	Meharry Medical College
U54NS041069	University of Alaska at Fairbanks
U54NS041073	Hunter College

U54NS46798	Morehouse School of Medicine—SPIRP
U54NS034194	Morehouse School of Medicine
U54NS043011	University of Puerto Rico Medical Science
U54NS043049	University of Hawaii

(b) S11: Collaborative Neurological Sciences (CNS) Award (PAR-05-149)

The Collaborative Neurological Sciences Award (S11) encourages thematic research investigations to strengthen biomedical and behavioral programs at minority-serving institutions. The award supports a research partnership for faculty to collaborate with grantees from leading neuroscience research laboratories on specific research themes. The nature of the collaborations will include joint research efforts and publications, shared research instrumentation and resources, exchange of research techniques, and other scientific activities to enhance the research capabilities of applicants to successfully compete for independent research funding during the performance period of the award.

Some of the institutions that have participated in this funding mechanism include:

- Morehouse School of Medicine
- University of Hawaii, Manoa
- University of the District of Columbia
- University of Puerto Rico, Medical Science Campus
- Universidad Central del Caribe
- Lehman College, Bronx, New York

2.1.1 Objective One: Implementation of Basic, Translational, and Clinical Neuroscience Research Programs to Advance and Promote our Health Disparities Research Agenda

2.1.1.1 Action Plan

Due to rapidly changing demographics in the United States and the large economic impact, a greater understanding of the unique social, biological, and economic determinants of disease among the disparate race/ethnic groups in this country and throughout the world is imperative. To accomplish this goal, the “best and the brightest” from every segment of the country will be needed. In this regard, one of the components of the NINDS Five-Year Strategic Plan is to promote diversity by focusing on “Research Capacity Building and Enhanced Training Among Institutions and Researchers to Foster an Improved Health Status and Reduce the Burden of Neurological Disease Experienced by All Americans.”

2.1.1.2 Performance Measures

Long-term performance measures for the SNRPs include scientific publications, scientific presentations at national and international meetings, improved research infrastructure, recruitment of new faculty, and the submission and funding of high-quality applications for program-based research projects.

2.1.1.3 Outcome Measures

An important outcome measure for this objective is to strengthen research capacities at institutions of higher learning as defined in the Higher Education Act including increasing the number of diverse, disadvantaged, and disabled students and fellows involved in SNRP center activities. An additional outcome measure is to encourage diverse high school students to pursue higher education opportunities, particularly looking toward careers in neuroscience.

2.1.2 Objective Two: Identify and Support the Next Generation of Basic, Clinical, and Translational Neuroscientists From a Diverse Range Of Groups

2.1.2.1 Action Plan

(a) Research Education Grants for Neuroscience Scholars Programs Through National Scientific Societies

These programs are designed to enhance collaboration with scientific societies to identify and support the next generation of basic, clinical, and translational neuroscientists; to stimulate communications between all segments of the research community interested in advancing neurologic health care; and to promote improved outreach to communities at increased risk for diseases and disorders of the nervous system. These programs enable the grantee organization to provide research and research-related experiences to undergraduate, graduate, and medical students, postdoctoral fellows, and other junior scientists from underrepresented groups to broaden their skills and enhance their career development opportunities.

To achieve success in this initiative, the NINDS is partnering with scientific societies to develop innovative programs to attract and retain the most talented individuals from all groups for future training and leadership positions in our extramural research community.

The Neuroscience Scholars Program (an R25) sponsors travel to the Annual Society for Neuroscience meeting; 42 travel fellows were supported during the 2005-2006 budget year. These fellows are accomplished graduate and postdoctoral students who are developed through mentoring, short courses, and other scientific enrichment activities to achieve leadership positions and promote diversity in neuroscience.

Diversity Research Training Opportunities

The NINDS funds a wide range of programs including research supplements, training, and fellowship programs to expand the pool of applicants and increase exposure of diverse students at the high school, undergraduate, graduate, and medical school levels to careers in biomedical research. A diverse medical and scientific workforce provides a wide array of ideas and approaches to scientific problems that are critical to the advancement of knowledge.

In an effort to address disparities, NINDS has implemented several programs to increase the number of disabled, disadvantaged, and underrepresented individuals in neuroscience. These include the following: Predoctoral Fellowship Award to Promote Diversity in Health-Related Research (F31), Career Development Award to Promote Diversity in Neuroscience Research (K01), and Research Supplements to Promote Diversity in Health Related Research. These programs support the recruitment, training, and research of specific individuals at all levels within the biomedical research workforce.

Research Supplements to Promote Diversity in Health-Related Research (PA-05-015)

This program is designed to address the need for a diversified workforce by increasing the number of individuals from minority and other underrepresented groups, individuals with disabilities, and individuals from disadvantaged backgrounds actively participating in biomedical research. As such, funding support is intended to attract and bolster research and research training experiences to better prepare these individuals for a productive career in the neurosciences. The program provides support for individuals throughout the continuum from high school to the faculty level.

Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research (PA-06-0481)

The NINDS will provide support for research training leading to the Ph.D. or equivalent research degree; the combined M.D./Ph.D. degree; or other combined professional doctorate/research Ph.D. degrees in the biomedical or behavioral sciences. These fellowships are for well-qualified students from diverse groups found by the institution to be underrepresented in the biomedical and behavioral sciences in the United States.

K01 - Career Development Award to Promote Diversity in Neuroscience Research (PAR-05-071)

The objective of the Career Development Award to Promote Diversity in Neuroscience Research is to promote diversity among faculty-level neuroscience investigators who are competitively funded to conduct independent research. Eligible organizations include domestic for-profit or non-profit organizations; public or private institutions such as universities, colleges, hospitals, and medical, dental, or nursing schools; or other institutions of higher education involved in neurological research. Eligible principal investigators include those individuals making the transition to an independent scientific career at the senior postdoctoral and junior faculty stages who come from groups that have been shown to be underrepresented in neuroscience research.

2.1.2.2 Performance Measures

Near-term performance measures include increasing the number of scientific societies with Neuroscience Scholars Programs. The training and career programs should lead to increased recruitment, mentoring, training, and retention of diverse individuals in the scientific and technology workforce. Longer-term performance measures include increasing the number of stipends awarded and the number of education projects within these programs.

2.1.3.3 Outcome Measures

Increasing the diversity of the basic, clinical, and translational neuroscience research workforce at all levels of the career ladder would demonstrate a successful outcome of this objective.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

NINDS outreach activities focus on the dissemination of up-to-date health and research-related information to diverse communities and to health professionals and organizations. The information provided is broad-ranging, including printed and electronic materials and brochures; professional exhibits at scientific meetings, conferences, and workshops; and other direct communications with the extramural and intramural community. A second area of emphasis focuses on promoting diversity in clinical studies. The NINDS has had excellent success in its compliance with NIH policies to include women and minorities in clinical research. Enrollment data and tracking of these groups and their subpopulations are updated annually.

3.1 Area of Emphasis One: Dissemination of Public Information and Outreach

3.1.1 Objective One

To further disseminate information on stroke, including preventive measures, warning signs, and the urgency of immediate care to diverse populations, at a grassroots level.

NINDS has supported several outreach activities to improve the recruitment and retention of neuroscientists from diverse backgrounds. NINDS research and training opportunities and health information have been disseminated throughout the diversity extramural research community, through the sponsorship of scientific booth and public speaking activities. These activities also have addressed the White House Executive Orders on Minority Initiatives to increase access to and participation of minority populations, institutions, and organizations in biomedical research.

3.1.1.1 Action Plan

(a) National Public Education Campaign on Stroke: Know Stroke in the Community: An NIH/CDC Partnership.

This initiative is intended to expand on NINDS's well established *Know Stroke, Know the Signs, Act in Time* public education campaign, with culturally appropriate materials and programs specifically targeted to racial and ethnic communities who are at a higher stroke risk. The materials have information about stroke awareness, stroke prevention and the importance of time in acute stroke care.

- Know Stroke in the Community, launched in May 2004, is a public education campaign run by the NINDS-Office of Communications and Public Liaison (OCPL) that teaches people to recognize the signs of stroke and emphasizes the need to act quickly. African Americans, Hispanics, and individuals living in the "Stroke Belt" of the United States are at a higher risk for certain kinds of stroke and experience higher mortality rates. *Know Stroke* identifies and enlists "Stroke Champions," respected members of the community, to educate about the signs and symptoms of stroke. The program is currently running in 10 cities—Atlanta (GA), Houston (TX), Richmond (VA), Chicago (IL), Birmingham (AL), New Orleans (LA), Boston (MA), Cleveland (OH), St. Louis (MO), and Jacksonville (FL)—and has recruited 105 Stroke Champions who have delivered the *Know Stroke* message to more than 116,500 individuals. NINDS communicates regularly with enlisted Stroke Champions to ensure the continued success of the program. The *Know Stroke* brochures are publicly available on the Internet in both English and Spanish.
- In August 2005, the NINDS and the National Council of La Raza launched a stroke educational video that targets Hispanic populations. NINDS and National Council of La Raza are distributing the video, entitled "*Ataque cerebral: concozca los síntomas y actúe a tiempo*," as well as other educational materials, to more than 200 community lay health educators who work within NCLR's network of affiliates. NCLR is also in the process of implementing a pilot *Know Stroke* program in El Paso, Texas, and Washington, DC, which will include extensive training of community members to act as lay health educators.
- The NINDS has developed two 60-second radio public service announcements, one of which features a testimonial by a stroke survivor in Baltimore, whose stroke was recognized by a coworker, and thanks to immediate treatment, has made a full recovery. The NINDS partnered with the Radio One LIFE Campaign to broadcast the public service announcements for 2 weeks in May, National Stroke Awareness Month. Radio One is the seventh largest broadcasting company in the United States and is the largest company to primarily target African Americans, with 66 stations in 22 markets, reaching 13 million adults each week. The radio spots also will be sent out nationwide for public service airplay in the summer of 2007.
- The NINDS is working with the local news media in each of the five *Know Stroke* communities to place newspaper articles and to book stroke experts on television and radio public affairs

programs. Spanish-speaking doctors have been identified in each market to broaden the outreach to Hispanic audiences.

- NINDS and CDC jointly produced a brochure called “What You Need to Know About Stroke” that is targeted at African American audiences. The brochure was researched in focus groups before and after production. Research indicated an interest in prevention messages and real-life stories. Both of these suggestions were incorporated into the final product, which received widespread praise in subsequent focus group testing. The groups also suggested development of a small wallet card that allows them to track stroke risk factors after doctor’s visits. The card also contains the warning signs of stroke.
- Health Fairs are a very successful venue for the distribution of the NINDS’ English and Spanish health education materials. The Know Stroke Champions are identifying local opportunities for stroke education events, including outreach at African American churches, clinics, and other potential partnerships that fit the particular needs of each community. Additionally, NINDS has sent a variety of Spanish publications to several events that target Hispanics, including the Share the Health Expo, the National Association of Hispanic Journalists, the National Hispanic Medical Association and Radio Unica health fairs.
- The NINDS continues to play an active role in the Stroke Belt Consortium, has distributed patient education kits to communities throughout the south, and is invited annually to present its latest educational programs at the national Stroke Belt Consortium meeting.

(b) Workshops

The Annual Specialized Neuroscience Research Programs National Conference provides a forum for students, faculty, and professionals in the community to share their latest research, address the unique challenges of minority-serving institutions in science, form networks of mentors and colleagues, and gain access to educational and career opportunities. In 2006, the conference held a Health Disparities Workshop as a pre-conference event named *Arctic Peoples and Beyond: Decreasing Health Disparities Through Basic and Clinical Research.* The goal of the workshop was to determine new research questions, recommendations, and ideas that could impact future NINDS funding directions related to health disparities. During the scientific conference, both basic and clinical scientists from the NINDS supported U-54s, and experts from outside the SNRP community presented their research on areas of health disparities such as stroke and substance abuse. More than 160 attendees, including NINDS Director Dr. Story Landis, invited scientific speakers, and federal attendees (NINDS program staff and other NIH co-funding SNRP partners) participated in the conference.

3.1.1.2 Performance Measures

Performance measures include conducting outreach through local media channels and distribution of printed materials at health fairs and national meetings. Information dissemination to communities at the highest risk for stroke and an understanding of stroke risk factors and warning signs among these groups are important goals.

3.1.1.3 Outcome Measures

Outcome measures include raising awareness about stroke signs and symptoms and increasing the numbers of patients in these communities who seek treatment for stroke.

3.1.2 Objective Two: Development of New Communications Outlets

3.1.2.1 Action Plan

(a) Increase efforts to translate NINDS publications into Spanish, and provide links to Spanish-language publications and web sites on the NINDS home page.

- NINDS has translated the Know Stroke brochure, posters, and bookmarks into Spanish. NINDS is now in discussion with the National Council of La Raza to develop additional Spanish stroke and Parkinson’s disease materials, which could be used by the nationwide “Promotores de salud” program.
- In addition, the NINDS has translated into Spanish 13 fact sheets and two Hope Through Research brochures on several neurological disorders. These publications also will be available online.

(b) Develop an email list service/interest group of individuals serving or representing diverse, at-risk communities and organizations to assist in efforts to reach their communities.

3.1.2.2 Performance Measures

Measures of performance on this goal include number of NINDS publications translated into Spanish, establishment of links to Spanish-language publications and web sites on the NINDS homepage, and establishment of an email listserv.

3.1.2.3 Outcome Measures

Increased awareness about neurological disease—its causes, symptoms, and ways to get treatment—in minority and Spanish-speaking communities is an important outcome of this objective.

3.2 Area of Emphasis Two: Inclusion Policies/Activities for Minorities in Clinical Research

Ongoing Programs

The NINDS supports a clinical trial in stroke and several observational studies directed at specific ethnic populations in the areas of stroke, epilepsy, neurological complications of HIV/AIDS, neurological complications of systemic lupus erythematosus, and pain. These clinical research projects present specific opportunities for diverse groups to be involved as participants in research.

3.2.1 Objective One: Establish a National Network on Minority Health Disparities Prevention/Intervention Research in Neurological Disease

3.2.1.1 Action Plan

(a) Establish a prevention/intervention research network throughout the extramural community

The NINDS is considering establishing a prevention/intervention research network throughout the extramural community. The goal is to foster stronger linkages between investigators at minority and majority institutions with community-based organizations to promote racial and ethnic diversity in clinical studies. This network could be initiated through the existing SNRPs, by encouraging more clinically relevant activities as part of the SNRP programs.

3.2.1.2 Performance Measures

The key near-term performance measure is the number of extramural research organizations that would be part of the network. Longer-term performance measures would focus on productivity of the network and on successful collaborations between institutions and community-based organizations to promote diversity in clinical studies.

3.2.1.3 Outcome Measures

An increase in recruitment and retention of diverse populations in clinical studies is the main outcome measure of this objective.

The National Institute of Nursing Research

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE OF NURSING RESEARCH

MISSION/VISION STATEMENT

The National Institute of Nursing Research (NINR) supports clinical and basic research to establish a scientific basis for the care of individuals across a life span—management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, promotion of quality of life for those with chronic illness, and care for individuals at the end of life. NINR's research emphasizes the special needs of minority and underserved populations, the population groups that experience health disparities. This unique combination in one Institute enables NINR to provide leadership in its initiatives to benefit the special needs of at-risk and underserved populations, and to address health disparities. These efforts are crucial in the creation of scientific advances and their translation into cost-effective quality health care for all individuals.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Reducing and eliminating health disparities was a vital component of the NINR Strategic Plan for the 21st Century. Several activities were conducted to obtain input to improve the focus of the plan. Presentations at the NINR National Advisory Council meetings invited comment and input from members from the community. The State of the Science meetings, National Nursing Research Roundtable meetings, NINR Research Themes meeting, and NINR annual retreat provided forums for public comments. Early in the plan, a substantial contribution came from the State of the Science Meeting on Community-Partnered Interventions in Nursing Research to Reduce Health Disparities. A Program Announcement (PA) was issued for research on community-partnered interventions to reduce health disparities (PA 02-134). The NINR convened a Research Themes meeting to identify cross-cutting themes for NINR. One theme was to identify effective strategies to reduce health disparities. NINR has added the NINR Roadmap activities to its strategic plan. The Roadmap includes efforts to address health disparities. It proposes collaboration in research, with interdisciplinary teams working together on all aspects of a research area, and increasing outreach to minority and community members to participate in the design of research relevant to each group. The Roadmap proposes developing research networks such as the Resource Centers on Minority Aging Research formed by the National Institute on Aging and the NINR.

These objectives will be continued for the Strategic Plan 2004-2008. Research initiatives and the development of research capacity among minority and vulnerable population groups will be continued. The NINR research themes and objectives will influence initiatives and new research that will accelerate the reduction and elimination of health disparities. The focus of NINR's research areas of opportunity on health promotion activities and chronic illness management will continue to provide opportunities in culturally sensitive research to understand disparities and improve the applicability of research findings in treatment, care, and health behavior protocols. The NINR's leadership in research in community-partnered interventions provides opportunities for building community capacity and involves minority and vulnerable populations in research. Community-partnered research will contribute to improving the public trust in NINR and the National Institutes of Health (NIH). NINR's strategy for research training and infrastructure development focuses on enhancing the development of students and nurse researchers through training, and developing research infrastructure in schools of nursing. NINR has a specific emphasis on preparing minority nurse researchers. This focus on expanding research training and research capacity enables NINR to provide leadership in strengthening and sustaining the conduct of nursing research to reduce health disparities.

The NINR Strategic Plan includes community outreach activities to obtain input and recommendations from minority nurse leaders and professional associations. The NINR works with the National Coalition of Ethnic Minority Nurse Associations (NCEMNA) to elicit recommendations for new and continuing activities. In the period 2004-2008, these activities will be extended to working with the Association to increase public trust in the NIH and NINR and to promote participatory research efforts among minority and vulnerable populations.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One

Intervention research; research to determine underlying causes of racial and ethnic variations in responses to health and disease; and health promotion research for minority men, women, and children.

There are several disease areas and health conditions that differently affect minority and vulnerable populations. Preterm delivery and low birth weight disproportionately affect minority populations. Learning how to reduce this disparity requires an understanding of how adverse societal and behavioral backgrounds among lower socioeconomic status population groups interact to increase women's susceptibility to premature births. Early onset of cardiovascular disease, complications, and fatality from stroke all affect African American men to a greater degree compared to men from other population groups. The rates of type 2 diabetes are high among American Indians, African Americans, Hispanic Americans, and Asians/Pacific Islanders. There is evidence that complications occur more frequently among individuals with diabetes in these populations. The reasons for these differences are not well known, but may be due to differences in availability of, and discontinuity in, health care and quality of health services. This hypothesis generates research related to sociocultural, environmental, and behavioral mechanisms, and to biological/technological factors that contribute to successful and ongoing self-management of diseases in specific minority populations. The NINR intends to continue supporting research on the underlying causes of racial and ethnic variations in health. For the 2004-2008 Strategic Plan period, the NINR will include research on those causes of disease that afflict vulnerable populations of lower socioeconomic status and from rural regions. The focus will be on diseases for which the burden is highest for these vulnerable population groups.

The relative priority of this Area of Emphasis among NINR's other Areas of Emphasis in health disparities is high.

These areas of emphasis are based on recommendations from conferences and professional organizations of the past 4 years. Such conferences include the National Nursing Research Roundtable Meetings of the past 4 years, the NINR Themes Meeting of 2003, the National Advisory Council Recommendations from the past 4 years, and the NCEMNA Conferences of 2001 and 2003. Minorities from the communities participated in such events and contributed recommendations for research.

1.1.1 Objective One

Solicit, review and support research on reducing preterm birth and low birth weight in minority families, including research to address how adverse societal, behavioral, and environmental conditions alter gene expression to increase the susceptibility for premature birth in high-risk racial and ethnic groups.

A Program Announcement (PA) was issued in December 2003 (PA-04-027) and will remain active through 2006, or for half the time of the Strategic Plan period 2004-2008. This Program PA solicits applications for research to reduce preterm birth and low birth weight in minority families. The objective is to fund collaborative multidisciplinary biobehavioral research that can elucidate the mechanisms underlying disparities in pregnancy outcomes as well as interventions to reduce such disparities. Another PA (PA-02-102, active through 2005) solicits research on the role of gene-environmental interactions underlying premature birth.

1.1.1.1 Action Plan

Conduct the scientific review, selection, and funding of applications submitted to the above PAs. Monitor and track the research for progress and findings. Reissue the announcements as needed.

1.1.1.2 Performance Measures

- The number of applications submitted for review.
- The number of applications submitted by minority investigators.
- The number of applications funded.
- The number of applications using community-partnered interventions.
- The success rate in subject recruitment and retention.
- The number of projects progressing as proposed.

1.1.1.3 Outcome Measures

- The knowledge, science advances, and number of publications.
- The number of findings that suggest further research is needed.
- The number of interventions that could be tested in clinical trials.
- The number of interventions tested and ready for translation.

1.1.2 Objective Two

Solicit, review, and support research focused on health for minority populations with specific focus on health promotion.

A PA on health promotion among racial and ethnic minority males was issued in 2003 (PA-03-170) and will remain active through 2006. The purpose is to stimulate and expand research leading to an understanding of the factors influencing the health-promoting behaviors of racial and ethnic minority males across the life cycle, and to test culturally and linguistically appropriate interventions for health promotion in these populations. A PA was issued in 2003 for research on the role of gene-environmental interactions underlying premature birth (PA-02-102), and will remain active through 2005 and stimulate research in the FY2004-2008 plan period.

1.1.2.1 Action Plan

Conduct the scientific review, selection, and funding of applications submitted to the PAs. Monitor and track the research progress. Monitor and track subject recruitment and retention in the research. Reissue the announcements as needed.

1.1.2.2 Performance Measures

- The number of applications submitted for review.
- The number of applications submitted by minority investigators.
- The number of applications funded.
- The number of applications using community-partnered interventions.
- The success rate in subject recruitment and retention.
- The number of projects progressing as proposed.

1.1.2.3 Outcome Measures

- The knowledge, science advances, and number of publications.
- The number of findings that suggest further research is needed.
- The number of interventions that could be tested in clinical trials.
- The number of interventions tested, and ready for translation.

1.1.3 Objective Three

Solicit, review, and support research to understand racial and ethnic disparities in the development of diabetes complications, and factors that contribute to successful self-management of diabetes among minorities.

A PA on race/ethnic disparities in the incidence of diabetes complications was issued in 2002 (PA-02-165) and will remain active through 2006.

The objective of the research is to understand racial and ethnic disparities in the development of micro- and macrovascular complications of diabetes, with knowledge contributions from epidemiologic, metabolic, and genetic studies. Related to this is a PA for research on self-management of diabetes and other chronic diseases in minority populations (PA-00-113). It solicited research related to sociocultural, environmental, and behavioral mechanisms and biological/technological factors that contribute to successful and ongoing self-management of chronic diseases among minority populations.

1.1.3.1 Action Plan

Conduct the review, selection, and funding of applications submitted to the above Program PAs. Continue to monitor currently ongoing projects from this objective and to track progress of findings. Monitor and track subject recruitment and retention in the research. Reissue the announcements as needed.

1.1.3.2 Performance Measures

- The number of applications submitted for review.
- The number of applications submitted by minority investigators.
- The number of applications funded.
- The number of applications using community-partnered interventions.
- The success rate in subject recruitment and retention.
- The number of projects progressing as proposed.

1.1.3.3 Outcome Measures

- The knowledge, science advances, and number of publications.
- The number of findings that suggest further research is needed.
- The number of findings that could be tested in clinical trials.
- The number of interventions tested, and ready for translation.

1.2 Area of Emphasis Two

Social and cultural knowledge/fact finding, intervention, and feasibility studies that incorporate social and cultural dimensions of health and principles of cultural competency.

Social science research has illuminated many basic social and cultural structures and process that influence health and shape perceptions of and responses to health problems. Social and cultural factors influence health by affecting exposure and vulnerability to disease, risk-taking behaviors, and effectiveness of health promotion efforts. Several sociodemographic constructs such as race, ethnicity, and socioeconomic status are used in the study of the etiology of health and disease. The meanings of these constructs depend on the cultural, geographical, and historical contexts, and are of significance in designing interventions for health promotion and effective care. Social science research is needed to explore the implications of social stratification from socioeconomic status, social class, race, and ethnicity. Research is needed to clarify the social integration of individuals. Studies to improve the conceptualization of culture and to identify relevant cultural phenomena are a prerequisite to culturally appropriate intervention studies. Research on the etiology of health and illness will lead to an understanding of health and disease as a social phenomenon associated with social ties and influences. Research to test culturally sensitive communication models for children and elderly people, and for communicating across cultures, will guide the development and testing of culturally competent care.

The NINR collaborates with the all the components of NIH on these programs. The relative priority of this Area of Emphasis among NINR's other Areas of Emphasis in health disparities is moderate.

These areas of emphasis are based on recommendations from Conferences and professional organizations of the past 4 years. Such Conferences include the National Nursing Research Roundtable Meetings of the past 4 years, the NINR Themes Meeting of 2003, the National Advisory Council Recommendations from the past 4 years, and the NCEMNA Conferences of 2001 and 2003. Minorities from the communities participated in such events and contributed recommendations for research.

1.2.1 Objective One

A PA to examine social and cultural dimensions of health was issued in 2001 (PA-02-043) and may remain active in the strategic plan period 2004-2008. The research will elucidate basic social and cultural factors in the etiology and consequences of health and illness, link basic research to practice for improving prevention and treatment, and explore ethical issues in social and cultural research. Three PAs with purposes related to this objective have been issued beginning in this 2004-2008 strategic plan period (PA-04-057; RFA-CA-05-013; PA-04-053). They will include research for improving care for dying children and their families, research to reduce barriers to symptom management and palliative care, and research that will conduct feasibility studies or developmental projects in complementary approaches to cancer care. In all of them, the research will address specific issues of vulnerable children of lower socioeconomic status populations, communication issues, and issues of cultural sensitivity. They will remain active for 1 or more years from 2004 to 2007.

1.2.1.1 Action Plan

Conduct the scientific review, selection, and funding of applications submitted to the above PAs. Continue to monitor current projects and to track research progress. Monitor and track subject recruitment and retention in the research. Reissue the announcements as needed.

1.2.1.2 Performance Measures

- The number of applications submitted for review.
- The number of applications submitted by minority investigators.
- The number of applications funded.
- The number of applications using community-partnered interventions
- The success rate in subject recruitment and retention.
- The number of projects progressing as proposed.

1.2.1.3 Outcome Measures

- The knowledge, science advances, and number of publications.
- The number of findings that suggest further research is needed.
- The number of findings that could be tested in clinical trials.
- The number of interventions discovered, tested, and ready for translation.

1.3 Area of Emphasis Three

To focus on reducing health disparities through partnerships with target communities in all phases of research.

Specific conditions such as cancer, cardiovascular disease, infant mortality, diabetes, lack of immunization, and human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) affect racial and ethnically diverse minority communities at rates several times higher than the national averages. Since the release of the Secretary’s Task Force report on Black and Minority Health in 1986, many initiatives have been implemented to address health disparities noted among racial and minority populations. Although research on health disparities has contributed much information for reducing these disparities, they still persist. Community-partnered research enhances the validity of the research by incorporating the knowledge of the subject communities. It bridges cultural gaps that may exist between community and investigators; incorporates cultural, social, and economic factors that influence health; facilitates the design of culturally appropriate and sensitive interventions and measures; and provides resources in the community for health care and behavior changes. Community-partnered interventions will engage community members and build their knowledge and participatory resources for identifying and addressing health issues, and for building trust in mainstream medical care and health care based on funded research. The approach will increase the sustainability of follow-up health care and health behavior.

The relative priority of this Area of Emphasis among NINR's other Areas of Emphasis in health disparities is high.

This program was based on recommendations from an NINR Conference entitled: "Community-Partnered Interventions in Nursing Research to Reduce Health Disparities," November 5-6, 2001, and on recommendations from community participants in the National Nursing Research Roundtable Meetings of the past 4 years, the NINR Themes Meeting of 2003, the National Advisory Council Recommendations from the past 4 years, and the NCEMNA Conferences of 2001 and 2003. Minorities from the communities participated in such events and contributed recommendations for research.

1.3.1 Objective One

A Program Announcement for community-partnered interventions to reduce health disparities was issued in 2002 and will continue into this Strategic Plan period (PA-02-134). The objective of this announcement is to support research to demonstrate that community-partnered interventions are effective in promoting successful recruitment and retention of minority populations in culturally sensitive research.

1.3.1.1 Action Plan

Continue to monitor current projects and track research progress. Monitor and track subject recruitment and retention in the research and the degree of community participation achieved in each study.

1.3.1.2 Performance Measures

- The number of applications submitted for review.
- The number of applications submitted by minority investigators.
- The number of applications funded.
- The number of applications using community-partnered interventions.
- The success rate in subject recruitment and retention.
- The number of community groups representing minority and vulnerable populations engaged in the research.
- The number of projects progressing as proposed.

1.3.1.3 Outcome Measures

- The knowledge, science advances, and number of publications.

- The number of science advances or protocols specifically demonstrated for minority populations.
- The number of findings that suggest further research is needed.
- The number of findings that could be tested in clinical trials.
- The number of interventions discovered, tested, and ready for translation.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One

To enhance research opportunities for and to improve the diversity of qualified doctorally prepared nurse investigators; to create effective nurse researcher role models for underrepresented students; and to build capacity for health research through partnership between nursing faculty at a variety of diverse academic institutions.

There is underrepresentation of racial /ethnic minority populations in biomedical and behavioral research in the Nation. There are ongoing trans-NIH research training programs. NINR has instituted an approach to foster the participation of diverse institutions in addressing the training needs of nurse investigators, including those from underrepresented groups, through mentoring from various academic institutions. To foster the development of nursing researchers, faculty, and students at diverse institutions, NINR has collaborated in funding Nursing Partnership Centers on Health Disparities. The purpose of these Centers is to develop partnerships between researchers, faculty, and students at these institutions and institutions with established health disparity research programs. This will expand the cadre of nurse researchers involved in minority health or health disparities research, and it will expand the development of research infrastructure and research capacity of nurse investigators, including those from underrepresented groups, at diverse schools of nursing. NINR also uses the NIH PA (PA-05-015) entitled, “Research Supplement to Promote Diversity in Health Related Research” to attract a diverse cadre of individuals to the sciences and to careers in biomedical, behavioral, clinical, and social science research.

The relative priority of this Area of Emphasis among NINR’s other Areas of Emphasis in health disparities is high. It is a priority area of development in research because the national nursing shortage is affecting the development of the research workforce in nursing science.

These areas of emphasis are based on recommendations from Conferences and professional organizations of the past 4 years. Such Conferences include the National Nursing Research Roundtable Meetings of the past 4 years, the NINR Themes Meeting of 2003, the National Advisory Council Recommendations from the past 4 years, and the NCEMNA Conferences of 2001 and 2003. Minorities from the communities participated in such events and contributed recommendations for research.

2.1.1 Objective One

To enhance research opportunities for and to improve the diversity of qualified doctorally prepared nurse investigators.

NINR has had a long-standing interest in increasing the number of minority investigators in nursing research. This career development award (RFA NR-04-003) is an approach to strengthen the participation of a variety of diverse institutions to nursing research. NINR recognizes that that the paucity of qualified minority nurse investigators in academic research settings has a created a shortage of role models for minority students. This announcement seeks to address this problem by enhancing the research capabilities of nurse faculty members, including those from underrepresented groups.

2.1.1.1 Action Plan

Continue to monitor ongoing projects from this objective to track progress. Monitor and track the progress of the awardees. Re-issue the Request for Applications (RFA) to encourage more applicants as other applicants complete and exit the program.

2.1.1.2 Performance Measures

- The number of applications submitted for review.
- The number of research studies in health disparities completed by minority awardees.
- The number of career development applications funded.
- The number of minority faculty and students who received research experience.
- The success rate in subject recruitment and retention.
- The number of projects progressing as proposed.

2.1.1.3 Outcome Measures

- The knowledge, science advances, and number of publications from the research conducted.
- The number of minority nurse scientists who completed the training.
- The number of minority nurse scientists who submitted subsequent applications for research funding.
- The number of publications from the research conducted during training.
- The number of subsequently funded applications.

2.1.2 Objective Two

To support the development of research capacity for nursing research in health disparities through collaboration with institutions that have established health disparity research programs.

This objective expands an initiative to build capacity through partnerships between nurse researchers, faculty, and students at various institutions and nurse researchers and faculty at institutions experienced in health disparities research. An RFA was issued (RFA-NR-02-004) to solicit applications to develop nursing partnership centers. This initiative is expected to expand the number of nurse researchers working in health disparities research, increase the number of health disparity research projects, and accelerate the career development of nurse investigators, including those from underrepresented backgrounds.

2.1.2.1 Action Plan

Monitor and assess the projects from this objective, and track the research capacity building. Monitor and track the career progress of the minority and other underrepresented faculty and students engaged in research. Assess the extent to which institutional support was garnered to continue the capacity development.

2.1.2.2 Performance Measures

- The number of partnership centers achieving capacity development as proposed.
- The number of pilot studies on topics related to the elimination of health disparities.
- The number of projects progressing as proposed.
- The number of pilot studies completed successfully.
- The number of minority faculty and students who received research experience.
- The success rate in subject recruitment and retention.

2.1.2.3 Outcome Measures

- The degree to which each partnership center achieved sustainable/substantial research capacity building.
- The number of pilot studies that were completed successfully.
- The number of subsequent applications for research support that were prepared and submitted to NIH and other funding sources.
- The number of applications funded.
- The knowledge, science advances, and number of publications from the research conducted under this grant.
- The number of minority nurse scientists who conducted studies.
- The number of findings that suggest further research is needed.
- The number of findings that could be tested in clinical trials.
- The number of interventions discovered, tested, and ready for translation.

2.1.3 Objective Three

To use diversity supplements to fund research projects to attract a diverse cadre of individuals to the sciences and to careers in biomedical, behavioral, clinical, and social science research and nursing science.

This program began in 1989 and addresses the need to increase the number of minority and other underrepresented scientists participating in biomedical research and the health related sciences (PA-01-079). There are serious health care disparities among minority groups in this country. In expanding research projects by using diversity supplements for students at the high school, undergraduate, graduate, and postgraduate levels, it is anticipated that the applicant pool of diverse individuals entering and remaining in health-related research careers will increase. This strategy will be active in 2004 and may be extended into the subsequent years of the strategic plan.

2.1.3.1 Action Plan

Continue to monitor ongoing projects from this objective. Monitor and track the progress of the awardees. Re-issue the PA as necessary and feasible, to encourage more applicants as other applicants complete and exit the program.

2.1.3.2 Performance Measures

- The number of applications submitted for funding.
- The number of minority students supported in the program.
- The number of minority students who received research experiences.
- The number of students with sustained participation in research.

2.1.3.3 Outcome Measures

- The knowledge, science, and research development in which the minority students participated.
- The number of minority students who completed the training.
- The number of minority students who actively participated in the preparation of publications from the research in which they participated.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Community Outreach

NINR will promote increased community participation and input into research strategies and activities to eliminate and reduce health disparities among minority and vulnerable populations. Increased community participation requires active outreach to the communities to increase the public trust of mainstream medical care and of the NINR among minorities and vulnerable populations. Public trust in the NINR is needed to improve the participation of minorities and vulnerable populations in research so that research findings may be generalized and translated into practice. NINR is proactive in reaching out to minority and vulnerable populations. NINR's Program Director and Staff attend annual meetings sponsored by the National Black Nurses Association (NBNA), and the National Association of Hispanic Nurses (NAHN), to promote nursing research and recruit minorities into nursing research careers. The NINR Director attends the annual meeting of the National Alaska Native American Indian Nurses Association, and will be the keynote speaker at the next annual meeting in this Strategic Plan period. The NINR will continue to work in collaboration with members of the National Coalition of Ethnic Minority Nurses Association, Inc., to obtain input and recommendations for the advancement of minority health research and career development for minority nurses. The NINR will continue its efforts to maintain involvement with minority nursing organizations, enhance communication and dissemination activities, and continue sponsorship of special programs and initiatives. It will work to increase the public trust among minorities in the 2004-2008 strategic plan period.

The relative priority of this Area of Emphasis among NINR's other Areas of Emphasis in health disparities is moderate.

This program was based on recommendations from various professional groups with active interests in promoting the health of minority groups.

3.1.1 Objective One

Sponsor periodic meetings to obtain input from the nurse community on the NINR strategic plan on health disparities.

Hold planned periodic meetings with representatives of minority nurse researchers and the National Nursing Research Roundtable with Institute and community participants. The community input is sought to identify effective approaches and new strategies to reduce health disparities, to change lifestyle behaviors for better health among minority and vulnerable populations; and for new directions for future research and strategic planning. The strategies will include a focus on building public trust in NINR and NIH among these populations.

3.1.1.1 Action Plan

For all three events: review the current NINR research areas of emphasis relative to the national emergent needs; develop a list of relevant community participants to be invited to the meetings; conduct the meetings; record the proceedings; and publish the summaries and recommendations. Incorporate the recommendations into future initiatives.

3.1.1.2 Performance Measures

- The number of new targeted initiatives emerging from the meetings.

3.1.1.3 Outcome Measures

From the meetings:

- The number of new initiatives for health disparities research generated.
- The number of projects subsequently funded.
- The increase in the number of participants from the community.
- The indications of increased public trust of the NINR.

3.1.2 Objective Two

Working with the National Coalition of Ethnic Minority Nurse Associations Inc. (NCEMNA), and its individual member associations to increase the public trust of NINR.

This is a collaborative biennial effort including leaders from the community of minority nurses to provide input to NINR future directions and planning.

3.1.2.1 Action Plan

Work with the associations to choose a conference theme to increase public trust and participation in research by minority and vulnerable populations.

3.1.2.2 Performance Measures

- The number of national minority nurse associations participating.
- The number of minority nurses attending.
- The number of action plans suggested to increase public trust and participation in research by minority and vulnerable populations.

3.1.2.3 Outcome Measures

- The number of action plans that the Associations recommend.
- The number of action plans that were feasible to implement.
- The indicators of public trust and knowledge of NINR among these communities.
- The number of indicators that potentially could contribute to a decrease in health disparities.

The National Institute on Aging

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE ON AGING

MISSION/VISION STATEMENT

The National Institute on Aging (NIA) leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life for all citizens. Millions of Americans are leading healthier lives based, in part, on discoveries from aging research.

In 1974, Congress granted authority to form the NIA to provide leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. Subsequent amendments to this legislation designated the NIA as the primary federal agency on Alzheimer's disease (AD) research. The mission of the NIA is to improve the health of older Americans by supporting and conducting research on the processes of aging, on age-related diseases, and on the special health problems and needs of the aged. The NIA also trains and develops research scientists, provides research resources, and disseminates information on health and research advances relevant to aging, aging populations, and older persons.

NIA findings, along with evidence from a number of clinical trials and studies, suggest more strongly than ever that age-related disease, degenerative conditions, and disability can be delayed or even prevented through specific interventions. Studies of disability rates in the United States show that the percentage of both Blacks and non-Blacks without disability rose dramatically from 1982 through 1999, suggesting important improvements in everyday function across the population. The challenge now is to advance and even accelerate the trend in declining disability and to reduce rates of disease amid a steep rise in the number and proportion of older people.

Currently, there are almost 34 million Americans aged 65 and over, almost 13 percent of all Americans. About 75 million Americans were born in the years 1946-1964, the baby-boom generation. The first baby-boomers will turn age 65 in 2011. From 2010 to 2030, the population of older adults aged 65 to 84 is expected to increase to 80 million, while the population aged 85 and over will increase to 4.8 million. This segment of the population is most at risk for disease and disability. Their ranks are expected to grow from 4.3 million in 2000 to at least 19.4 million in 2050. Further, the racial and ethnic makeup of the older population is also expected to increase with approximately 14 million older Hispanics, 8.6 million older Africans/African-Americans, and 5.8 million older adults from other racial and ethnic groups of the population.

These demographic factors combined threaten to increase the burden of age-related diseases and conditions on individuals, families, and society. Unless new understandings and interventions are developed and implemented to reduce disease and disability, the costs, in both human and financial terms, could be extraordinary.

Aging research is well poised to build upon the work of recent years to improve the lives of older Americans and their families. Toward that end, NIA's overall program is wide ranging and includes research on: the biochemical, genetic, and physiological mechanisms of aging in humans and animal models; the structure and function of the aging nervous system; social and behavioral aspects of aging processes and the place of older people in society; and the pathophysiology, diagnosis, treatment, and prevention of age-related diseases, degenerative conditions, and disabilities.

It has been 20 years since the federal government's health establishment asked a national task force, with substantial leadership from the NIA, to find ways to "exert leadership, influence and initiative to close the existing gap" in the rates of illness and mortality borne by Blacks and other minorities. In that time, much has changed in aging research and the lives of older adults. Among racial and ethnic groups, life expectancy has increased.

However, aging research continues to document the existence of persistent health differentials among older members of various racial and ethnic groups in the United States. Although life expectancy may be increasing, gaps continue; life expectancy at birth, in 2000, averaged 77.4 years for Caucasians and 71.7 for Black Americans. Although disability rates are declining, older Black Americans have higher rates of disability in activities of daily living and experience a gap of 5 percent reporting no disability, with 75 percent of Blacks age 65 and older saying they have no disability compared with 80 percent of older Caucasians (Note: NLTCS, Manton, PNAS May 22, 2001). To reiterate, current population projections suggest that by 2050, the total number of non-Hispanic Whites aged 65 and over will double, the number of Blacks aged 65 and over will triple, and the number of Hispanic elders will increase 11-fold (IOM, CPOP, Understanding Racial and Ethnic Differences in Health in Late Life, 2004).

In response to the deep-rooted and disturbing health disparities among older members of different racial and ethnic groups, the effort to support and conduct research aimed at reducing and eventually eliminating these differences has been institutionalized and invigorated. Several major initiatives have been undertaken by the NIA, along with the National Institutes of Health (NIH). In 2000, the NIA completed a self-assessment of its portfolio of research and training in minority aging from 1993 through 1998. The self-assessment, under the leadership of Dr. James Jackson of the Institute for Social Research at the University of Michigan, culminated in eight principal recommendations for action for improving the health status of minority elders and enhancing the participation of scientists from minorities underrepresented in aging research. The recommendations were part of the background and context for the inaugural NIA Strategic Plan to Address Health Disparities (online at www.nia.nih.gov). That plan, with annual reviews and updates since its inception, features more than 90 actions and initiatives that the NIA can take to advance knowledge and understanding of diseases and conditions affecting minority elders by supporting efforts in three domains: research, research infrastructure, and public information, outreach, and education. The 2004-2008 version of the NIA Strategic Plan to Address Health Disparities is an abridged and restructured plan that includes goals, objectives, initiatives, action plans, performance measures, and outcomes in four broad multilevel areas of emphasis in aging research; five areas of emphasis in research capacity; and seven smaller, different areas of emphasis in community outreach, information dissemination, and public health education.

NATIONAL INSTITUTE ON AGING

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIA maintains a year-round scientific planning process that draws upon interactions with scientists throughout the world, members of Congress, the Institute's National Advisory Council on Aging (NACA) and other advisory committees, constituency groups, and the public. The interactions stimulate internal consideration of potential new research strategies and provide a broad perspective for refining plans. Emphasis is given to novel proposals and collaborative projects that promise to stimulate activities with other research organizations.

The NIA Strategic Plan to Address Health Disparities is the product of collaboration, review, and comment by members of the NACA, selected members of the scientific community in aging, staff of the NIA, and the general public, as part of the National Center for Minority Health and Health Disparities (NCMHD) review process. Regular management and oversight of the plan is the responsibility of the Assistant to the Director for Special Populations and the Minority Aging Work Group. The Work Group is comprised of senior-level scientists and staff representing the major programs and organizations of the NIA. The group meets monthly and presents progress, at least annually, to the NACA.

The NIA uses a deliberative process for coding research projects as minority health and health disparity research. The process for coding projects is consistent with the NIH process and accounts for the inclusion of minorities in research activities in five categories: basic research; clinical research; infrastructure; research training and career development; and outreach. For purposes of this report, minority health issues are considered to be a subset of health disparities issues. Minorities are defined by statute as American Indians/Alaska Natives (including Eskimos and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics (i.e., individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or any other Spanish-speaking country). Health disparities populations are minority populations, low socioeconomic status (low-SES) populations, and rural populations. Additional search terms used to identify relevant aging and health disparities projects and activities are: homeless, low income, Medicaid, medical indigency, medically underserved population, migrant, public assistance, rural area, social class, social mobility, social status, and urban poverty area.

As a part of the NIA's continuing effort to improve the health of minority, disadvantaged and underrepresented groups as well as to encourage research careers for members of underrepresented, disadvantaged, and disabled population groups, we continue to build upon a set of recommendations from the 2000 Review of Minority Aging Research that remains relevant and foundational to the current plan. The ad hoc committee's recommendations included:

1. Eliminate health disparities among ethnic and racial populations.
2. Improve definitions of race, culture, ethnicity, and SES.
3. Implement longitudinal and life course studies.
4. Integrate biology, genomics, and genetics of aging with studies in special populations

5. Refine methods and strategies for minority aging research.
6. Improve recruitment and retention of minority subjects in research.
7. Strengthen and clarify the policy on inclusion of minorities in clinical research.
8. Build capacity and enhance training and information dissemination for minority populations.

The 2004-2008 version of the Strategic Plan to Address Health Disparities, like other strategic plans of the NIA, reflects both Institute-initiated research efforts (that is, research and other activities initiated or solicited by the NIA) and the larger, flexible and often unanticipated investigator-initiated, merit-reviewed, competitively selected research efforts (i.e., research projects proposed by investigators to address topics consistent with the Institute's mission and not requiring or in response to a special initiative). There exists a dynamic and complementary exchange of scientific thought between initiatives initiated by the Institute and those initiated by investigators. Most of the NIA budget is allocated to investigator-initiated research.

The goals of the 2004-2008 Health Disparities Strategic Plan appropriately highlight the critical importance of reducing and ultimately eliminating health disparities; however, it is not clear to what extent its objectives can be achieved over the next decade, even with the most optimistic assumptions for improving health among minorities. What science will be able to do in the next decade is to address and answer questions about causes of health disparities among older adults. The immediate goal will be to identify research needs, such as the need to understand the racial gap in life expectancy, and promote appropriate research and training activities in response to these needs. A longer-term goal will be to apply the outcomes of research to measures that will reduce and ultimately eliminate racial disparities in health.

The goal of eliminating the racial gap in life expectancy is a major national priority. The time it will take to reduce the overall gap will depend on the speed of reduction of the leading cause-specific mortality differences, which will require intensified efforts in both prevention and treatment (Wang, Remington and Kindig, 1999). The NIA, in collaboration with its staff and consultants, have identified selected priority initiatives consistent with the NIA mission and reflective of the more expansive, web-based, NIA Strategic Plan to Address Health Disparities.

Public Comments

In 2004, the NIA asked the National Academies to organize a 2-day meeting, bringing together leaders from a variety of disciplines and professional orientations, to summarize the current state of the science and to identify future directions in attempts to advance progress in the area of minority health and health disparities research. The meeting of public and private stakeholders was fortuitous for NIA and provides additional "public" comment and context for the Strategic Plan. The Institute of Medicine (IOM) committee indicated that to advance the field, research is needed to "partition differences in morbidity and mortality in older populations to determine how much can be attributed to particular diseases and conditions and in turn how much of the differences in diseases and conditions can be assigned to major risk factors." Additionally, three main themes emerged from the meeting. They are consistent with the direction of current initiatives and provide a few new avenues for exploration. The themes, in their entirety, are presented below. Final recommendations for future direction are pending.

- The roots of health differences have to be examined across the life course, taking a longitudinal view and integrated account of the effects of such factors as SES, behavior risk factors, and prejudice and discrimination, as well as the effects across cohorts and periods of selection processes and social policy.
- All factors should be investigated in terms of their links to stress and biopsychosocial mechanisms that lead to impaired health.
- Interventions designed to reduce health differences should be evaluated, along with determining the role of health care quality in racial and ethnic differences, which may range from possible geographic variability to differences in patient compliance and the use of alternative therapies.

The themes presented by the IOM and reflected in initiatives in the 2004-2008 Strategic Plan are consistent with themes and specific suggestions that emerged from public comments to the NCMHD on the NIH Strategic Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006. In reviewing the “Public Comments” report from the NCMHD, NIA staff was pleased to see comments from its constituency included in the area of pain health disparities. Applications are encouraged in this area, and issues of pain perception, detection, and treatment in dementia are an integral part of the emphasis in AD and caregiving. Additionally, NIA continues to work with its Centers programs and various institutions to build strong partnerships in redressing health disparities. NIA’s Behavioral and Social Research Program is actively engaged in advancing the role of health economists in aging research and in addressing health disparities. In most areas of public comment, NIA is able to document progress but, assuredly, more will be done.

The NIA is working with other NIH Institutes and Centers to develop an overall strategy that in total will address the diseases and conditions that challenge older men and women.

The NIA plan is not meant to address all health disparities but rather is a plan to address health disparities within the context of the congressionally mandated mission of the NIA.

1.0 AREAS OF EMPHASIS IN RESEARCH

Health disparities are associated with a broad, complex, and interrelated array of factors. Risk factors, diagnosis, progression, response to treatment, caregiving, and overall quality of life may each be affected by aspects such as race, ethnicity, gender, SES, age, education, occupation, and as yet unknown lifetime and lifestyle differences. The underlying causes of such relationships require in-depth research. Understanding differences and interactions is critical for developing behavioral and public health interventions to reduce burdens of illness and increase quality of life for older persons and older populations.

NATIONAL INSTITUTE ON AGING

Aging research supported by the NIA targets diseases and conditions that contribute significantly to mortality or disability in old age. A major focus of NIA research is AD, a devastating neurodegenerative disease that robs people of memory and other intellectual abilities, leading to loss of social and occupational function and ultimately to complete dependence on others. A number of research groups have examined differences in AD prevalence among racial and ethnic groups, and it appears from some studies that the risk is higher for African Americans and Hispanic Americans than it is for Caucasians, though not all studies provide similar results. Other important causes of disease and disability among racial and ethnic minorities may include cardiovascular disease and cancer, the two leading causes of death in older people; bone, muscle, and joint disorders, such as osteoporosis and osteoarthritis, that contribute to pain and loss of mobility; vision, hearing, and other sensory disorders that can isolate older people; and numerous other age-related conditions that deprive individuals of their independence. This section of the plan includes eight priority initiatives.

1.1 Area of Emphasis One: Alzheimer's Disease, Neuroscience of Aging, and Normal Cognitive Functioning

1.1.1 Objective One: Epidemiology of Alzheimer's Disease

Assess the importance of different genetic risk factors such as APOE4 in diverse and minority population groups of African Americans, Hispanics, Japanese Americans, and Caucasians, as well as non-genetic and protective factors such as SES, early life environment, nutrition, education, and health, to include effects of concurrent illnesses such as cardiovascular disease and stroke.

1.1.1.1 Action Plan

Epidemiology of Alzheimer's Disease: Research in the epidemiology of age-related dementia, including AD, is focused on whether there is a different risk for dementia and AD in particular ethnic groups and whether the course of disease is different in different groups. From the public health perspective, these questions assume great importance as the demographics of the U.S. population change. Not only will there be over fourfold more persons over the age of 85 in the year 2050, but the percentage of the population over the age of 65 that is non-Caucasian will increase from 16 percent to 34 percent. Methodological effects on assessment of cognition in aging and dementia prevalence, such as cultural and educational bias in assessment, are being addressed. A number of grants are directed toward comparing the prevalence and incidence of AD in African American, Hispanic, Japanese American, and Caucasian populations, including genetic epidemiology studies to assess the importance of different genetic risk factors such as APOE4 in these populations. Non-genetic and protective factors such as SES, early life environment, nutrition, education, and health are being studied, as are effects of concurrent illnesses such as cardiovascular disease and stroke.

1.1.1.2 Performance Measures

The basic performance measure for epidemiologic studies of AD is participation level achieved in regard to the various ethnic and racial minority individuals selected for inclusion.

1.1.1.3 Outcome Measures

The basic outcome measures for epidemiologic studies of AD are:

1. Estimates of mortality and morbidity (namely, prevalence and incidence); and
2. Survival with the condition, and assessments of potential risk factors and protective factors (expressed statistically in terms of odds ratios or hazard ratios).

The outcome measures would be the basis for comparisons between different ethnic/racial groups within studies or between studies.

1.1.2 Objective Two: Cognition in the Context of Culture and Environment

Build a base of research data to better understand the effects of behavioral, social, cultural, and technological context on the cognitive functioning and life performance of aging persons

1.1.2.1 Action Plan

To address the recommendation of the National Academy of Sciences to undertake a research initiative to “understand the effects of behavioral, social, cultural and technological context on the cognitive functioning and life performance of aging persons,” the NIA organized and held a workshop titled “Cognition in Context” in 2002. A diverse group of NIA grantees and other investigators was brought together to discuss a number of issues, including how differences in sociocultural context may bring about systematic variation in cognitive function and performance. The NIA has stimulated, independently of issuing a formal solicitation, research in the area of cognition in context and has received several applications on this topic.

Additionally, the relation of disparities in health, SES, and access to community and institutional support is known in general, relative to cognition. The breakout of the contexts of disparity relative to such primary aspects of cognitive function as speed of information processing, perceptual speed, working memory, or inhibition is not well investigated within a reciprocity perspective or via an individual differences perspective. Similarly, higher levels of cognitive function, such as everyday functioning, occupational functioning, strategy development, problem solving, or decision making, are not well studied relative to the reciprocal relations between the contexts and pathways of disparities. The action taken is to promote research grants and investigator interactions that focus on the nature of the potentially epigenetic and reciprocal relations and the points in the life span where pre-emptive and rehabilitative interventions may be most effective.

1.1.2.2 Performance Measures

Receipt of new applications in this area and published papers on the topic.

- Solicit grants that focus on the objectives and action plan.
- Develop exploratory workshops to explore actions relative to objectives.
- Encourage networks of researchers that are focused on objectives.
- Encourage research consortiums focused on objectives.
- Develop Program Announcements (PAs) pertinent to the objectives and action plan.

1.1.2.3 Outcome Measures

Increased knowledge about the role of culture and ethnicity in cognitive performance with age.

1.1.3 Objective Three: Health Disparities in Normal Cognitive Aging and Alzheimer's Disease

Stimulate research on risk and preventive factors for cognitive health in older persons in order to determine, in part, whether a new, comprehensive study of factors to preserve or gain cognitive and emotional health in adults should be launched.

1.1.3.1 Action Plan

A trans-NIH initiative, the Cognitive and Emotional Health Project, has been launched that is sponsored by the NIA, the National Institute of Mental Health (NIMH), and the National Institute of Neurological Disorders and Stroke (NINDS). A database has been constructed that includes information on large longitudinal and epidemiological studies funded by the three Institutes. It catalogs the type of information collected in the identified studies including ethnic, racial, geographic, SES, educational, and health information. An advisory workshop, "Cognitive and Emotional Health: The Healthy Brain Project," was held in the summer of 2001. A related advisory workshop, "Racial and Cultural Effects on Measurement of Cognition," was held in the fall of 2001. A committee of extramural and intramural experts was assembled in 2003 and is currently conducting a Critical Evaluation Study of the extant human research literature on factors for maintaining cognitive and emotional function in older age. The report of this committee should provide information on valid and reliable factors and gaps in the knowledge, and should identify opportunities for ancillary studies and analytic studies of secondary data.

1.1.3.2 Performance Measures

Analysis of results that would point to differences or similarities in factors for cognitive and emotional health in minority groups compared to Caucasians.

1.1.3.3 Outcome Measures

- Identification of existing studies with oversampling of minorities for opportunities for secondary data analyses of factors for cognitive and emotional health maintenance in diverse racial and ethnic groups.
- Identification of existing studies that could incorporate add-on studies with diverse minority cohorts.

1.1.4 Objective Four: National Alzheimer's Coordinating Center (NACC)

Using National Alzheimer's Coordinating Center (NACC) resources, begin to identify potential biomarkers that will help to diagnose AD, permit characterization of disease course, monitor response to treatment in diverse ethnic and racial groups, and perform clinicopatholgical correlations.

1.1.4.1 Action Plan

At present there are virtually no clinical and pathological data on ethnic heterogeneity due to the limited numbers of racial and ethnically diverse patients seen at any one Center. Using larger data sets developed by the NACC and autopsies at individual Centers will allow characterization of the rarer and mixed phenotypes, as well as genetic and ethnic differences that would not be possible with the smaller numbers of subjects in individual Centers. It will allow research on normal aging using control subjects and also on the transition from normal aging to mild cognitive impairment to AD. By pooling patient information and autopsies from racially and ethnically diverse groups and many Centers, it will also be possible to begin to identify potential biomarkers that will help to diagnose AD, permit characterization of disease course, monitor response to treatment in diverse groups, and perform clinicopathological correlations. With the establishment of the NACC, data about enrollments in all of the Alzheimer's Disease Centers (ADCs) are collected in a central database. The data collected by NACC provide a very good description of the types of patients seen at each of the ADCs. They are able, for example, to break down the entire 60,000-plus participants by site, diagnosis, ethnic background, gender, and study participation. The NACC also is set up to fund cooperative studies involving a number of Centers, including studies involving minority issues. One of the projects with substantial accomplishments directly supported by NACC is on ethnic differences in age of onset. This collaborative project evaluated and compared disease onset in five Hispanic communities. The assessment was performed by five NIA-sponsored ADCs with experience evaluating Spanish-speaking individuals. This study indicated that Latinos, the largest and fastest growing minority group in the mainland United States, appear to have an earlier age of AD symptom onset compared to non-Latino Whites with a comparable educational level. Although the factors responsible for this remain to be identified, the observation has a potential impact both on the burden of dementia care carried by this population group and on the dementia-related diagnostic and educational efforts directed towards Latinos.

1.1.4.2 Performance Measures

Numbers of minorities enrolled in NACC, and collaborative research projects.

1.1.4.3 Outcome Measures

Understanding of the development and progression of AD in health disparities populations.

1.1.5 Objective Five: Development of Standardized Measures of Cognitive Change in Normal Aging and AD in Different Ethnic Groups

Examine, substantively and over time, in 2004-2008, the characterization of executive function; recommend the best currently available tests to tap executive function; and consider adaptations of commonly used tests for use in multiple ethnic groups**.**

1.1.5.1 Action Plan

A conference was held in 2001, “Racial and Cultural Effects on Measurement of Cognition,” to discuss the feasibility of and whether there was a need for development of standardized measures of cognitive function in multiple ethnic groups. Several recommendations were generated by the participants including: creation of a document that provides guidelines for important issues in designing cognitive tests and adapting them to different cultures; expansion of the compendium of existing tests that were compiled for the workshop; further research to characterize the domain of executive function; work on developing new and refining current executive function tests; consideration of development of a brief cognitive battery for use by clinicians; provision of support for secondary data analysis; including appropriate measures of education and ethnicity in large studies to accompany the cognitive measures of choice; and establishing normative data for age and culture. The NIA has acted on a number of the workshop recommendations. The compendium of cognitive tests adapted for minority groups was expanded. Several steps have been taken to characterize executive function and to consider new or refined test development. NIA held a workshop in January 2003, “Research Needs in the Evaluation of Executive Functions from Cognitive Aging to Dementia,” and co-organized a trans-NIH workshop in June 2003, “Executive Functions: Current Knowledge and Future Research Opportunities.” A steering committee was established by NIA in 2004 to further examine the characterization of executive function, to recommend the best currently available tests to tap executive function, and to consider adaptations of commonly used tests.

Opportunities for secondary data analytic studies are being explored and compiled through the trans-NIH Cognitive and Emotional Health Project. Research efforts of several NIA-funded investigators have resulted in the establishment of new measures and norms aimed at different ethnic groups. Racial comparisons on intelligence tests, neuropsychological tests, cognitive tests, and dementia batteries generally have shown that despite equating the groups on variables such as years of education and SES, African Americans score lower on these measures. Furthermore, as a result of the use of these types of tests, African Americans who are cognitively normal are more likely to be misdiagnosed as impaired compared to Whites. Matching groups on years of education does not mean that a similar quality of education was received or achieved by each group. The ability to assess quality of education with objective measures could help distinguish true cognitive differences from spurious ones. Dr. Jennifer Manly and colleagues at Columbia University determined in a recent study that African American elders scored significantly lower than Whites on measures of word list learning, word list memory, figure memory, abstract reasoning, language fluency, and visuospatial skill although both groups were matched on number of years of education. After reassessing the findings using an estimate of quality of education, the effect of race was greatly reduced. This work suggests that the use of years of education to define the level of educational experience is inadequate, and that race-specific norms based on corrections for years of education may be less adequate than norms that correct for quality of education. From this work, it is clear that by accounting for just one indicator of educational quality, racial differences on cognitive test performance were significantly reduced, if not eliminated. This approach not only illuminates factors that can account for ethnic group differences on cognitive tests but will help guide the development of new cognitive tests and measures that are culture fair.

There is a need for instruments that are developed for and normed with different native languages and ethnic origins in mind. This is essential to allow valid assessment across groups and to make research and treatment studies applicable across groups. Dr. Dan Mungas successfully pursues his program of developing state-of-the-art assessment instruments that can identify, quantify, and compare cognitive deficits of older adults who are English-speaking Caucasians, African Americans, Hispanics, and Spanish-speaking Hispanics. Important new additions to his work are executive function and day-to-day function components that will increase the utility for predicting and detecting dementia. It is expected that Dr. Mungas' battery, the Spanish English Neuropsychological Assessment Scales (SENAS), will be the first instrument with demonstrated equivalence for the assessment of cognitive impairment and decline in Hispanic, African American, and non-Hispanic Caucasian English speakers as well as Hispanic Spanish speakers.

Dr. Malcolm Dick of the University of California, Irvine has established a collaborative project with the Korean Health Education, Information, and Research Center (KHEIR), a health-related care and information center to the Korean communities of Los Angeles and Orange County. Since 2000, Dr. Dick has trained 10 KHEIR staff in the administration and scoring of the Cross-Cultural Neuropsychological Battery (CCNB).

Dr. Galen Buckwalter is funded by NIA to develop, validate, and establish norms for a telephone interview assessment of cognitive performance in older adults. Half of the enrollment will be minorities, and the normative component of the study will analyze data with respect to minorities, education, and income.

1.1.5.2 Performance Measures

- Receipt of new applications
- Published papers in the area of measurement of cognitive performance in diverse racial and ethnic groups

1.1.5.3 Outcome Measures

Development of strategies to accurately assess cognitive performance in minority elders and to, more accurately than in 2004, diagnose AD in minority elders.

1.1.6 Objective Six: Influence of Disparities on Cognitive Processes

Develop longitudinal perspectives to estimate the influences of disparities on cognitive processes.

Develop new, redirect, and/or utilize existing longitudinal studies to investigate the life span effects of disparities in health, SES, community and institutional access, and disabilities on changes in cognitive function across the life span.

1.1.6.1 Action Plan

Classic longitudinal studies such as the Seattle Longitudinal Study have provided insight into the relative rates of improvement, maintenance, and decline of basic cognitive processes frequently referred to collectively as crystallized (experience related) and fluid (ability to acquire new knowledge) intelligences. In addition to understanding relative rates of improvement, maintenance, and decline, such studies have provided awareness of strong cohort and time-of-measurement effects that influence cross-sectional and longitudinal/individual differences in estimates of cognitive function. The cohort effects that have become apparent in such research (e.g., generational differences in skills) represent environmental and societal interventions that can be evaluated in post hoc fashion There is an absence from such studies of the clear influence of disparities, SES, institutional access, or disabilities on the trajectories of cognitive development, maintenance, and decline. The opportunity exists with significantly improved analysis capabilities and approaches (e.g., imputation techniques, mapping constructs from one study to the next), plus the insight of several years of longitudinal analyses, to examine the influences of the onset, duration, depth, and reversal of disparities; SES; disabilities; and community access on the improvement, maintenance, and decline of cognitive abilities.

1.1.6.2 Performance Measures

- Examine existing grants as potential platforms for achieving objectives and engage investigators in examining potential for achieving objectives.
- Solicit new grants that focus on the objectives and action plan.

- Develop exploratory workshops to explore the pathways for reaching the objectives.
- Develop PAs pertinent to objectives and action plan.

1.1.6.3 Outcome Measures

- Knowledge relevant to the objectives and advancement of the field in aging research.
- Research and review articles published relative to promotion of objectives and action plan.
- Meeting recommendations relative to promotion of objectives and action plan.

1.1.7 Objective Seven: Honolulu-Asia Aging Study (HAAS)

Determine how environmental, neurophysiologic, neuropsychologic, cardiovascular, and genetic factors interact in the development and clinical course of neurologic diseases of old age including AD and vascular dementia (VaD).

1.1.7.1 Action Plan

The HAAS began in 1991 as a continuation of the Honolulu Heart program (HHP), a prospective population-based longitudinal study of Japanese American men born between 1900 and 1919 and living in Oahu, Hawaii, when the study began in 1967. Participants were seen at three mid-life examinations (1965-68, 1968-70, 1971-74), and at three exams in late life (1991-93, 1994-96, and 1997-99). Physical measurements and demographic and medical information were collected at each examination. Starting from 1991, global cognitive function was measured and cases of dementia ascertained. In addition, a magnetic resonance imaging (MRI) sub-study on 575 men was performed in 1995-1996. Further, an autopsy study has been ongoing since 1991; currently, more than 300 men have come to autopsy. The goals of the study are to determine how environmental, neurophysiologic, neuropsychologic, cardiovascular, and genetic factors interact in the development and clinical course of neurologic diseases of old age including AD and VaD. This knowledge will allow a better understanding of the causes of AD and VaD and provide a basis for the development of future prevention and treatment strategies.

Two more rounds of follow-up examinations on the nearly 1,500 survivors were conducted under a grant award administered by the Neuroscience and Neuropsychology of Aging Program at NIA to the Principal Investigator Dr. Lon White. The Kuakini Medical Center will establish a permanent archive for the growing amount of biologic material generated from the study under an administrative supplement to the grant. This initiative stems from a commitment by the NIA and the investigators to maintain the invaluable materials for their future contribution to science. NIA intramural research program (IRP) investigators continue to collaborate with investigators in Hawaii. Since HAAS has measures of brain aging in late life and measures of risk factors in middle age, follow-up observations made in the first series of analyses on blood pressure and cognitive function suggested the addition of several ancillary studies including assays of mid-life levels of inflammation (C-reactive protein, CRP), assays of late life sex hormones, genotypes of polymorphisms regulating cytokines, assays of cerebrospinal fluid for biomarkers of AD and levels of metals, and analysis of the hippocampus imaged on MRI.

1.1.7.2 Performance Measures

- Establishment of biomaterials bank containing all biologic materials generated from this study.
- Continuation of autopsy study as the cohort continues to age.
- Publication of data focused on study's main objectives, the causes of AD and VaD.
- Utilization of this cohort and set for other important age-related research questions, such as understanding the interrelationships among hormones (estradiol and testosterone) and the effect of dementia on this interrelationship.

1.1.7.3 Outcome Measures

Knowledge that will permit a better understanding of the causes of AD and VaD and provide a basis for the development of future prevention and treatment strategies

- Dissemination of study findings with particular emphasis on findings related to AD and VaD risk factors in Asian Americans.
- Implementation of a successful data and biomaterials sharing plan to ensure that this valuable minority health resource is accessible to as diverse a group of investigators as possible.

1.1.8 Objective Eight: Alzheimer's Disease and Caregiving

Expand the number of grants examining strategies for improving patient care within and across population groups and alleviating caregiver burden for minority and underserved providers.

1.1.8.1 Action Plan

Family caregivers of persons with AD are at risk for negative psychosocial and health consequences of chronic stress. The extent of this risk will vary from one individual to another and also may vary from one group to another, depending on the special strengths and problems experienced by members of a particular group. The long-term effects of caregiving, nursing home placement, and patient death are being compared in White, African American, and Hispanic caregivers, each compared to appropriate non-caregiving controls. The results of this research will show the proximal and longitudinal effects of the stress of continued caregiving and the long-term effects of caregiver adjustment to nursing home placement or death of the patient, and will identify variables that predict individual differences in caregiver adjustment, with special emphasis on strengths and problems of racially and ethnically diverse families and the long-term course of caregiving stress that they experience. To this end, NIA is funding a large clinical trial on Resources for Alzheimer's Caregiver Health (REACH). The study population consists of equal proportions of Hispanic, African, and White Americans. Results are expected in 2005.

1.1.8.2 Performance Measures

- Identification of variables that predict individual differences in caregiver adjustment, with special emphasis on strengths and problems of African American and Hispanic families and the long-term course of caregiving stress that they experience.
- Identify and translate practical ways of intervening in alleviating stressors for diverse populations.
- Develop a workshop to determine the next scientific steps at the conclusion of the REACH project.
- If recommend by the workshop, an initiative will be written to address these next steps in caregiving in diverse populations.

1.1.8.3 Outcome Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Knowledge of the longitudinal effects of the stress of continued caregiving.
- Test strategies with intervention research for alleviating the stress of continued caregiving.
- Number of documented strategies in peer-reviewed literature from NIA-supported studies for alleviating caregiver burden and distress across diverse groups and conditions of health disparity.
- Create a catalogue of risk factors associated with caregiver stress for AD and recommend interventions to reduce stressors.
- Translate outcomes from REACH into a practical guide for use in community settings such as Areas' Agencies on Aging or the Alzheimer's Association.

1.2 Area of Emphasis Two: Reducing Age-Related Disease, Degenerative Conditions, and Disability

1.2.1 Objective One: Menopause

Investigated cross-sectional ethnic differences in levels of reproductive hormones in midlife women and longitudinal changes associated with the menopause transition in five diverse racial/ethnic groups of women.

1.2.1.1 Action Plan

Most studies of menopause are limited in generalizability, for they are based on clinic-derived samples or restricted to Caucasian (non-Hispanic) populations. Funded initially in 1994 and renewed in 2004 by NIA, the National Institute for Nursing Research (NINR), and the Office of Research on Women's Health (ORWH), the *Study of Women's Health Across the Nation* (SWAN) is a 15-year, multiethnic, community-based study of the natural history of menopause and the change in ovarian function. SWAN is collecting longitudinal biological, psychological, cultural, and lifestyle data on 3,150 women of five ethnic/racial groups, initially aged 42-52 years of age and premenopausal at baseline. SWAN is comprised of seven clinical field sites, a central reproductive hormone laboratory, a coordinating center, and a repository of DNA and biological specimens for use by SWAN and the extramural community. The targeted enrollment of 1,450 Caucasian, 900 African-American, 300 Hispanic American, 250 Chinese, and 250 Japanese women (n = 3150) was completed in 1997.

SWAN will contribute substantive new knowledge on the menopause transition through its prospective design, multi-ethnic/racial composition, representation of defined populations, and comprehensive measurement and power. SWAN's four overarching aims are to: (1) collect and analyze data on demographics, health and social characteristics, race/ethnicity, reproductive history, pre-existing illness, physical activity, and health practices as potential predictor variables; (2) elucidate factors that differentiate symptomatic from asymptomatic women during the menopausal transition; (3) identify and utilize appropriate markers of the ovarian-hypothalamo-pituitary axis and relate these markers to the menstrual cycle and menopause-related changes, and (4) elucidate factors that differentiate women most susceptible to long-term pathophysiological consequences of ovarian hormone deficiency from those who are protected. Additional research objectives focus on psychiatric and psychosocial domains, sexuality and sexual function, changes in bone mass, body composition, and risk factors for diabetes, osteoporosis, hypertension, and cardiovascular disease and medication use (including estrogen use).

1.2.1.2 Performance Measures

- Annual progress reports detailing participant retention; implementation of new follow-up visits; progress in data collection entry, cleaning, and quality control; and publication progress
- Workshop: Improved Methods for Assessing Hot Flashes

1.2.1.3 Outcome Measures

- Scientific findings that shed light on racial/ethnic differences in: (1) the endocrinological changes of the menopause transition; (2) risk factors for menopause-related symptoms; and (3) markers and predictors of the inception and duration of the menopause and the final menstrual period.
- Evidence showing that memory loss is not an inherent outcome of the menopause transition.

1.2.2 Objective Two: Understanding Physical Function, Disability, and the Disability Decline in Racial and Ethnic Minority Populations

To better understand the progression and decline in disabilities in older racial and ethnic minority population groups

NATIONAL INSTITUTE ON AGING

1.2.2.1 Action Plan

The NIA supports epidemiological research on the onset and progression of physical disabilities in a number of population groups, but additional efforts need to be made to include older minority and diverse populations. Additionally, NIA has supported longitudinal studies, such as the National Long-Term Care Survey, the Longitudinal Study of Aging, and the Health and Retirement Study, which have shown a decline in disability among older adults. These studies have shown overall declines, but little is known about the changes in disability rates by race and ethnicity. Although the data available in this area have expanded, there are limited data on the underlying factors leading to impairments, functional limitations, and disability in different minority groups. NIA is currently supporting studies in several specific minority subgroups of the U.S. aging population and also is supporting national samples of older adults that contain minority oversamples to better enhance analyses. Results of these studies will provide important information on the optimal timing of interventions to effectively alter the course of disability due to diabetes, osteoarthritis, and other diseases. It is anticipated that results from these studies will lead to novel strategies for improving the active life expectancy of older minority individuals. NIA will support grants, conferences, and workshops aimed at understanding how physical function and disability differ by racial and ethnic group and how the disability decline differs by racial and ethnic group. NIA also will support work that encourages the comparison of trends observed in different groups and those observed using different data sources.

1.2.2.2 Performance Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Number of projects exploring cross-group racial and ethnic group differences.
- Number of grants funded using meta-analysis to explore differences in functional limitations in racial and ethnic groups using different data sources.

1.2.2.3 Outcome Measures

- Knowledge of the processes underlying the development of disabilities in various minority groups.
- Identification of correlates of functional limitations and disability in different minority populations.
- Identification and translation of practical ways of intervening to reduce the course of disability in minority populations.
- Quantify changes in disability rates by race and ethnicity.
- Number of publications in peer-reviewed literature from NIA-supported studies that address disability and functional limitations in minority groups.

1.2.3 Objective Three: Dynamics of Health, Aging, and Body Composition (Health ABC)

Investigate the hypothesis that change in body composition (i.e., loss of muscle and bone integrity) is a common pathway through which weight-related health conditions and behavioral factors contribute to functional decline and loss of independence in older persons.

1.2.3.1 Action Plan

Health ABC was initiated and developed by principal investigators from NIA's IRP. This study has refined recruitment and retention strategies; developed, tested, and applied novel methodologies to assess weight-related health conditions, functional capacity, impairment status, and subclinical pathology; and expanded scientific opportunities, particularly in the areas of molecular and genetic markers. A longitudinal cohort was recruited consisting of 3,075 men and women, aged 70-79 at baseline, for yearly clinic examinations; 45 percent of the women and 33 percent of the men were African American. At baseline, all cohort members reported no difficulty walking one-quarter mile or up 10 steps. The major outcome of the study was persistent difficulty performing either of these two activities over two consecutive 6-month follow-ups. Each year, the clinic examination has included a core of measurements on body composition, strength, and function, with additional measurements for specific ancillary studies or to complement other measurements in the study. Some of these unique studies have included measurement of knee osteoarthritis with MRI; the Cognitive Vitality Substudy, which focused on maintenance of cognitive function with aging; and an energy expenditure study in which doubly labeled water and resting metabolic rate were used to assess level of physical activity. In addition, the study has collected data and adjudicated major incident health events including cardiovascular events, cancers, fractures, dementia, diabetes, and other illnesses related to hospitalizations. The study has employed a variety of methods to ensure timely progression in the planning of the study from its inception. Retention in the study has been excellent, with 99 percent of enrollees accounted for.

This clinical research study will contribute to knowledge of risk factors for sarcopenia (loss of muscle mass and strength) in healthier old people and the functional consequences of body composition changes. In addition, Health ABC has characterized the major weight-related health conditions that might mediate changes in body composition, including diabetes and glucose tolerance, coronary heart disease and stroke, pulmonary disease, osteoporosis, osteoarthritis, and depression. Measures of strength and performance are included, as well as information on physical activity and other health habits.

The Health ABC examinations have collected a wealth of measurements in the yearly examinations. Measures have been added to complement those originally planned, and repeated measurements have been made for most of the measures of particular relevance and importance. Longitudinal events are now available, and there is active analysis of both baseline data and longitudinal outcomes. The Health ABC investigators now are preparing the continuation of the project in which the cohort will be followed for 3 additional years. During this time, cohort members will undergo two full clinical examinations, semi-annual phone surveys, a final iteration of the cognitive vitality substudy, and continuous review and adjudication of death and disease events.

1.2.3.2 Performance Measures

- Broadened perspective in the geriatric and gerontology scientific community on biomedical contributors to independence, function, and frailty among Whites and non-Whites as well as the interaction of frailty with co-morbidity.
- Knowledge of risk factors for sarcopenia (loss of muscle mass and strength) in healthier old people and the functional consequences of body composition changes.

1.2.3.3 Outcome Measures

- Identification and validation of covariates of cognitive and physical functional decline.
- Identification of biomarkers for decline in physical function.
- Dissemination of study findings and implementation of findings in state-of-the-art clinical care and/or further clinical research.

1.2.4 Objective Four: Cancer, Aging, Race, and Ethnicity

Fund research to advance knowledge in NIA's efforts to discover age-related differences in the biologic properties and clinical aspects of prostate cancer among different race/ethnicity populations

1.2.4.1 Action Plan

Prostate cancer is a major age-related malignancy. Seventy-one percent of prostate cancer incidence and 92 percent of prostate cancer deaths occur in the age group 65 years and older. Older men of all racial and ethnic backgrounds are at risk for prostate cancer; however, the burden of this malignancy varies according to age, race, and ethnicity. Among diverse male population groups in the United States, African Americans and Caucasians have the highest prostate cancer incidence and higher mortality rates. By contrast, American males of Asian and Hispanic descent and American Indians and Alaska Natives have lower incidence and mortality rates than African Americans and Caucasians.

Epidemiologic data describe these differences to a limited extent, but there is a dearth of information on why rates vary so dramatically according to age, race, and ethnicity. Factors accounting for disparities among the diverse population groups and the impact of this malignancy concomitant with aging are unknown.

The Aging, Race, and Ethnicity in Prostate Cancer Request for Applications (RFA) (AG02-003) issued in 2001 supports research leading to better prevention, diagnosis, prognosis, and treatment. The Biology of Aging Program is currently funding three applications in response to this RFA. They are: Mark Rubin – Prostate Cancer Harbinger Genes (R01 AG21404), Michael Ittmann – Cytokines and FGF in Prostate Cancer Progression (R01 AG21383), and Rajvir Dahiya – DNA Methylation in Aging, Race and Prostate Cancer (R01 AG21418). Research funding will continue to FY2006 for Rubin and Dahiya, until FY2005 for Ittmann.

Dr. Ittmann's research hypothesis is "that increased expression of fibroblast growth factors (FGFs) and IL-6 by normal tissue in the peripheral zone of the prostate acts as a stimulus to prostate cancer progression by providing critical growth and survival signals to prostate cancer cells, and that individual variation in the control of expression of these progression factors may lead to differences in the incidence of prostate cancer…[Furthermore,] a polymorphism of the IL-6 promoter has been described in which the allele that is associated with increased IL-6 transcription is significantly more common in African Americans." Dr. Ittmann will test the hypothesis using benign prostate tissues from men with and without prostate cancer to determine if there are differences in increasing age by race.

Dr. Dahiya's research goal is to identify and characterize the epigenetic alterations that are involved in aging and race-related prostate cancer. The hypothesis is that there will be differences in aging and race-related DNA methylation status of frequently deleted genes. Using prostate cancer samples from African American and Caucasian men, DNA methyltransferase, DNA demethylase, histone deacetylase, mRNA, and protein expression will be analyzed in different age groups to determine their role in regulation of DNA hypermethylation. This could lead to better management of prostate cancer using DNA methylated genes as diagnostic or prognostic biomarkers.

Dr. Rubin's research seeks to determine the earliest overexpressed genes in the development of prostate neoplasia, the frequency of harbinger genes in a cross-sectional study on the aging prostate, and the optimal harbinger genes to assess risk from prostate needle biopsies

1.2.4.2 Performance Measures

- Research is ongoing as described in the Action Plan above.
- Number of grants funded.

1.2.4.3 Outcome Measures

- Knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Analyses of existing databases applicable and relevant to addressing treatment of older prostate cancer patients with emphasis on older ethnic populations.
- Clinical determinants of age- and ethnicity-associated differences in prostate cancer treatment efficacy and effectiveness for such outcomes as survival, treatment complications, side effects of treatment, and functional status.

1.2.5 Objective Five: Normal Aging in the Baltimore Longitudinal Study on Aging

Measure changes in biological and behavioral processes as people of diversity age; relate these measures to one another; and distinguish universal aging processes from those associated with disease and particular environmental effects.

1.2.5.1 Action Plan

The Baltimore Longitudinal Study on Aging (BLSA)

The BLSA's new design is almost completed; enrollment of new participants in the study will start in fall 2004. The criteria for the definition of healthy status are much more solid and accurate, allowing NIA scientists to return to the original intent of the study of 'normal aging." A goal is to make every possible effort to have participants in the study in a much larger range of SES and at least 30 percent from minority groups (focusing on Hispanic Americans). In this population, investigators plan to perform an in-depth study on factors affecting insulin resistance (diet, body composition, inflammation, depression, stress, and cortisol response) and consequences of insulin resistance (sarcopenia, mitochondrial DNA damage, and oxidative stress). The hypothesis is that the causes of the metabolic syndrome are different in different SES strata. The study involves the use of MRI spectroscopy to study muscle metabolism and mitochondrial energetic metabolism.

Health and Disease Status in the BLSA—The Prostate Gland

The BLSA prostate aging and disease study has both retrospective and prospective arms involving repeated assessments of anatomical, physiological, hormonal, and behavioral aspects of age-associated changes in prostate size. The retrospective arm of the study examines the sex steroid and prostate-specific antigen (PSA) levels from frozen sera stored during the three most recent visits and visits closest to 10, 15, 20, and 25 years before study initiation for active and inactive participants over the age of 40. The prospective arm involves male BLSA participants over the age of 30 and will continue for at least 10 years. Our previous work suggests that prostate cancer develops over a period of at least 10 years in most men, and that PSA can stratify men at risk as long as 20 to 30 years prior to diagnosis. During the regularly scheduled BLSA visits, the eligible participants will: (1) complete an objective symptom score analysis quantifying obstructive and irritative voiding symptoms; (2) undergo digital rectal prostatic examinations (DRE) and prostate massage by an urologist; (3) have blood drawn for assays of PSA and other prostate markers and proteomics; (4) undergo uroflow examination and sonographic determination of residual urine volume; and (5) undergo pelvic MRI. Men over age 40 who have given permission for autopsy will have the prostate gland examined pathologically after death.

Over the past year, we have explored the role of dietary factors in BLSA men. Three studies have been reported.

1. Animal studies suggest that energy restriction reduces the growth of tumors, including prostate tumors. However, results from epidemiological studies of energy intake and prostate cancer risk have not been consistent. To examine the association of total energy intake and macronutrient contributors to energy with prostate cancer risk, we studied 444 men who completed at least one food frequency questionnaire (FFQ). At their earliest FFQ completion, the men were 45 to 92 years old. Total prostate cancer cases (n = 68) consisted of men who were diagnosed with cancer before their FFQ completion (n = 46) and men who were diagnosed with cancer after their FFQ completion (n = 22). Total energy intake was positively associated with prostate cancer. Compared to the lowest quintile of energy intake, the OR for the highest quintile was 3.79 (95% CI: 1.52-9.48, p-trend 0.002). Energy-adjusted intake of protein, fat, and carbohydrate were not statistically significantly associated with prostate cancer risk. This study suggests a higher risk of prostate cancer with increased energy intake.

2. Vitamin C (ascorbic acid) is a water-soluble antioxidant that is hypothesized to prevent carcinogenesis by scavenging free radicals and protecting DNA from oxidative damage. *In vitro* studies have demonstrated that vitamin C inhibits the growth of both androgen-independent and androgen-dependent prostate cancer cells. Although several cohort studies have examined the association between dietary intake of vitamin C and prostate cancer risk, only one study has investigated the association for plasma vitamin C. In this study, we hypothesized that high prediagnostic plasma vitamin C concentrations would be associated with a reduced risk of prostate cancer in men. Plasma vitamin C (ascorbic acid) concentrations were measured previously in blood samples drawn between 1987 and 1990. Plasma vitamin C concentrations were studied from 489 men with 57 subsequently diagnosed with prostate cancer an average of 4.8 years after the blood draw (range 0.1 to 12.5 years). No inverse association was found between serum vitamin C and prostate cancer for the entire sample. We concluded that plasma vitamin C concentrations within the normal range are not protective against prostate cancer in adult men, although there may be an age-related difference in risk associated with vitamin C.

3. We examined the association between prostate cancer and calcium and other nutrients thought to influence the synthesis of 1,25-dihydroxyvitamin D [1,25(OH)2D]. The analyses included 457 men who were 46 to 92 years old at the time of completion of an FFQ. Among them, 69 men were diagnosed with prostate cancer during their lifetime. In 68 percent of the cases, the FFQ was completed before the diagnosis of cancer. Multiple logistic regression was used to calculate the odds ratio (OR) and 95% confidence interval (CI) of prostate cancer. The adjusted OR of prostate cancer for the highest tertile compared to the lowest tertile of calcium intake was 0.92 (95% CI, 0.48-1.77; p-trend, 0.89). Likewise, there were no significant trends for phosphorus, vitamin D, fructose, and animal protein intakes. Dairy products, including milk, were not associated with an increased risk of prostate cancer. The adjusted OR of prostate cancer was 1.26 (95% CI, 0.57-2.79; p-trend, 0.73) for men with high dairy intakes compared to low dairy intakes. This study suggests that calcium intake within moderate limits is not associated with a notably increased risk of prostate cancer.

We are currently continuing to examine the role of dietary factors in prostate disease. We are completing work on examining the risk of prostate cancer in relationship to serum testosterone levels. In addition, we are starting to evaluate the relationship of urinary symptoms to prostate diagnoses. This includes examining how changing urinary symptom scores impact on quality of life, and the time course of change in urinary symptoms.

Effects of Age on Muscle Strength, Body Composition, and Health Status

Age-associated losses of strength occur slowly over the adult life span. Most research has focused on what occurs in the elderly. However, the primary processes start at a much earlier age. Changes in strength are associated with functional disability and frailty in the elderly. In young and middle-aged workers, they are a contributing factor to work-related injuries and for some occupations, job performance. The causes of age-related strength losses are now being studied and are multifactoral. Much of current scientific interest is on age changes in muscle and the loss of muscle with age that has been referred to as sarcopenia. The focus of work on sarcopenia has been on the elderly, where the greatest changes in muscle mass and strength manifest. However, by age 50, the average individual has lost 10 percent of his or her maximal strength. Although sarcopenia is clearly a major factor in strength loss, there are other contributors to the changes in maximal function. To understand sarcopenia, these other factors need to be studied. Furthermore, less is known about the causes in young and middle-aged adults, where other factors may be more important than sarcopenia. A better understanding of these causes can lead to more directed methods of prevention. Our goal is to understand the time course of strength loss, factors that contribute to the loss, to what degree the exercise response differs between old and young individuals, and what forms of motivators and alternative exercise programs might impact on the losses.

First are descriptive studies using the BLSA. These studies focus on describing the characteristic losses that occur in muscle strength mass and physical functioning with aging by examining the entire adult life span. Over the past year, these studies have shown that declining muscle strength and rate of change of muscle strength are independent contributors to mortality in men when considering age, physical activity, and muscle mass. In addition, muscle power is a stronger independent contributor to mortality in men than is muscle strength, though both have independent contributions to mortality. In addition, we reported genetic studies showing that IGF-II genotype was related to muscle strength but not muscle mass. This is consistent with the mortality data, where muscle mass and muscle strength have common and different effects on outcome. We also found that testosterone and free testosterone index had modest contributions toward muscle strength independent of muscle mass. Their action through body composition appeared to be more related to fatness than directly to muscle mass. In addition, SES may be an important influence on the age-associated relationship with muscle strength in African Americans with younger, lower SES subjects being markedly weaker than higher SES subjects of the same age.

Second are reports from an intervention comparing the response to resistive strength training between young and old subjects. The main finding of the study was that exercise response to resistive training is very similar in young and old subjects. In this reporting period, we found that myostatin mRNA decreases in response to heavy resistance strength training. Myostatin is of interest because high levels are associated with prominent muscle atrophy and in the elderly with the development of frailty. Our observation demonstrates that resistive training can lower the level of myostatin within muscle and thus alter one factor that is involved with the loss of muscle mass. In addition, we observed differences in skeletal muscle gene expression when looking at approximately 4,000 genes known to be involved with muscle. Sex had the strongest influence on muscle gene expression, with differential expression (>1.7-fold) observed for ~200 genes between men and women (~75% with higher expression in men). Age contributed to differential expression as well, as approximately 50 genes were identified as differentially expressed (>1.7-fold) in relation to age, representing structural, metabolic, and regulatory gene classes. Sixty-nine genes were identified as being differentially expressed (>1.7-fold) in all groups in response to strength training, and the majority of these were down regulated. These results provide evidence for significant differences in skeletal muscle gene expression between men and women, between young and older individuals, and as a result of strength training. Thus, although the response to strength training may be similar by age, there are clear differences in muscle responsiveness as represented by gene expression.

Two interventions were reported that examined alternative strategies for exercise intervention in subjects with osteoarthritis of the knee. First was electromyostimulation, a passive activation of the knee extensor muscles using an electric stimulator. Typically, it is used to generate near maximal forces or added to active contractions to increase the force generated. This form of treatment has been successfully used in treating patients following knee surgery. Our goal was to test a protocol that used neuromuscular electrical nerve stimulators (NMES) at much lower force levels, to make the stimulation more acceptable (i.e., with less or no pain), and to minimize the likelihood of injury in individuals with osteoarthritis of the knee. We hypothesized that weak elderly subjects do not require maximal force generation to improve strength. The NMES group used a portable electrical muscle stimulator to incrementally increase the intensity of isometric contraction over 12 weeks up to 20-40 percent of their maximal voluntary strength. We found an increase in muscle strength in response to this passive activity, and a decline in knee pain immediately following the treatment (though not a sustained effect). The second approach was to use a home-based pedometer-driven motivational program, which resulted in improved walking, increased knee extensor strength, and modest functional improvements.

Both alternative approaches to exercise gave indications that they may be a useful alternative to more traditional exercise programs. What we have demonstrated is the feasibility of using these (and similar) approaches in patients with osteoarthritis, and potentially in others with some levels of disability. Work in the National Guard will determine whether a simple motivational tool when properly implemented might increase participation in healthy subjects.

Race and Gender Differences in Intracerebral and Carotid Arterial Velocity—Aging

This project studies the carotid artery and intracerebral blood flow velocity using doppler ultrasonography in BLSA participants. The goal is to determine how arterial anatomic and physiologic properties are associated with cerebrovascular diseases and aging. We currently are examining the relationship between several carotid arterial measurements and alcohol usage in the BLSA. We find that mild to moderate alcohol usage is associated with greater arterial elasticity and decreased stiffness in the common carotid artery. A less impressive association was observed with arterial wall thickness and diameter. The changes were independent of blood pressure and age. The response of the artery to alcohol usage may represent one mechanism for its protective effect against cardiovascular disease. In previous work, we had shown that the use of estrogen replacement in postmenopausal women was associated with lower arterial stiffness. Male sex hormones are known to decline with increasing age, and have been associated with atherosclerotic disease and with risk factors for atherosclerosis. We have examined the relationship between androgenic hormones and arterial stiffness (beta stiffness index). Both testosterone and free testosterone (assessed by the free testosterone index) were negatively correlated with age, pulse pressure, and stiffness index, while sex-hormone binding globulin was positively correlated with age and stiffness index. Multiple regression analysis revealed that testosterone (T) was the only hormone that predicted the arterial stiffness index after adjustment for risk parameters. T values 5 to 10 years prior to the carotid study were also a predictor of the stiffness index. A path analysis revealed that decreasing T with advancing age increased stiffness index directly and indirectly through increasing pulse pressure. Dehydroepiandrosterone sulfate did not appear to directly contribute to arterial stiffness. Current work is examining the response of arterial stiffness and wall thickness to the state of reported anger. A positive relationship is being seen between anger and arterial stiffness that varies across age. In addition, we are examining the impact of the metabolic syndrome on arterial properties.

1.2.5.2 Performance Measures

Publications:

- Description of possible early diagnostic markers of prostate disease.
- Development of prostate/urinary symptoms score to improve detection of prostate disease.
- The role of dietary factors on prostate disease development.
- The relationship between urinary symptom score and quality of life.
- Identification of factors that contribute to sarcopenia in the middle age life course.
- Examination of factors important in strength loss over the middle years.
- The role of exercise in preventing strength loss and muscle mass loss in the middle aged and the elderly.

Proven accrual and retention of Hispanic Americans and low-SES cohorts within the BLSA.

1.2.5.3 Outcome Measures

- Successful dissemination of findings to the extramural research community for validation of findings.
- Over 1,000 publications in the biomedical literature.

1.2.6 Objective Six: Healthy Aging Neighborhoods of Diversity Across the Life Span (HANDLS)

The NIA IRP long has been interested in the cellular and molecular mechanisms of normative aging and age-related disease development. The program has pursued basic laboratory and longitudinal clinical research in normative aging to address these interests. NIA intramural investigators have expanded the program's capacity to address hypotheses about aging and health disparities in minority and poor populations. By posing fundamental questions about differences in rates and risks for pathological conditions associated with aging and studying groups with diverse racial, ethnic, and economic origins, IRP clinical researchers hope to understand the significance of environmental and genetic risk factors for disease. The need to understand the driving factors behind persistent Black-White health disparities in overall longevity, cardiovascular disease, and cerebrovascular disease has led to the effort to develop and plan the NIA IRP Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) study, a community-based, epidemiologically driven research effort designed to focus on evaluating health disparities in socioeconomically diverse African Americans and Whites in Baltimore. This study is unique because it is a multidisciplinary project that assesses physical parameters as well as evaluating genetic, biologic, demographic, psychosocial, and psychophysiological parameters of Black and White participants of higher and lower SES over a 20-year period. It also employs novel research tools: mobile medical research vehicles to improve participation rates and retention among non-traditional research participants. The initial examination and recruitment phase will take approximately 3 years to complete. The study data will be collected in two parts. The first part consists of an in-home interview that includes questionnaires about the participant's health status, health service utilization, psychosocial factors, nutrition, neighborhood characteristics, and demographics. The second part will be collected on the medical research vehicles and includes medical history and physical examination, dietary recall, cognitive evaluation, psychophysiology assessments including heart rate variability, arterial thickness, carotid ultrasonography, assessments of muscle strength and bone density, and laboratory measurements (blood chemistries, hematology, biomarkers of oxidative stress, and biomaterials for genetic studies).

Conduct a longitudinal study of minority health focused on investigating the differential influences of race and SES on health in an urban population (Baltimore, Maryland).

1.2.6.1 Action Plan

The HANDLS study is a multidisciplinary, prospective epidemiologic longitudinal study examining the influences and interaction of race and SES on the development of cardiovascular and cerebrovascular health disparities among minority and lower SES subgroups.

The baseline HANDLS sample will consist of approximately 4,000 community-dwelling African American and White adults aged 30-64. Participants will be drawn from 12 pre-determined census tracts in Baltimore City, sampling representatively across a wide range of socioeconomic and income circumstances. The heuristic study design is a factorial cross of four factors: age, sex, race, and SES with approximately equal numbers of subjects per "cell." HANDLS is planned as a 20-year longitudinal study. Using our mobile medical research vehicles, we will visit each census tract for 3 months and we will re-visit every census tract in a 3-year cycle.

The 12 census tracts identified were selected because they are likely to yield representative distributions of individuals between 30 and 64 years old who are African American and White, men and women, and lower and higher SES. Individuals calling themselves multi-ethnics will be included and categorized by the group with which they most strongly identify, but their multi-ethnic identification will be recorded for subsequent statistical analyses. Multi-ethnic individuals who identify strongly with neither African Americans nor Whites will be excluded from the present study.

Initial estimates based on 2000 Census data indicate that we will need to visit approximately 35 percent of the households in each census tract to collect the required 333 individuals. The initial sample of 4,000 participants is based on power analyses and assumptions about attrition over 20 years. For a power of 80 percent (the likelihood of finding an effect if it is really present), we can identify moderate effects (magnitude of the differences between groups) for various outcomes with as few as 30 participants per group at the end of the study. Working backward by assuming 20 percent attrition after the baseline assessment and 15 percent attrition between subsequent assessments, we need approximately 4,000 participants at baseline to yield 1,680 after 20 years. The recruitment phase and initial examination will take approximately 3 years to complete. The study has completed a pilot that was conducted in two waves (October 2000 to December 2001 and February 2003 to November 2003). The epidemiologic phase of the study will commence in fall 2004.

Aims

The scientific research questions for this multidisciplinary epidemiologic study of minority health and health disparities are:

- Do race and SES influence health disparities independently or do they interact with several factors (race, environmental or biologic factors, and cultural or lifestyle practices)?
- What re the influences of SES and race on age-related declines in function in an urban population?

- What are the influences of SES and race on the incidence and natural history of age-related disease?
- Are there early biomarkers of age-related health disparities that may enhance our ability to prevent or ameliorate the severity of these diseases?
- For specific systems we will test the following hypotheses:
  - Cardiovascular
    - There will be significantly greater decline in cardiovascular health status as a function of SES and race independent of the effects of age in both men and women. For example:
      - Intimal medial thickness is greater in African Americans than Whites and is greater in African Americans of lower SES as compared to age-matched African Americans with higher SES, in both men and women; and
      - Vascular stiffness, as assessed by pulse wave velocity, will be greater in African Americans with low SES, as compared to age-and gender-matched African Americans with higher SES.
  - Body Composition and Bone Quality
    - African Americans have higher lean mass, bone density, and fat mass than corresponding groups of White adults. For example:
      - African Americans will exhibit a higher rate of loss of muscle mass, accumulation of fat mass and decline in bone density, relative to White adults.
  - Cognition
    - The rates of decline of various cognitive abilities will be the same in all groups regardless of race, ethnicity, or SES.
  - Autonomic Functioning
    - Baseline heart period variability (HPR) is associated with performance on tests of the susceptibility to attentional interference and to tests of affect recognition;
    - Increasing HPR during testing predicts greater accuracy on the attentional interference and affect recognition tasks;
    - Declines in HPR predict cardiovascular and cerebrovascular morbidity and mortality; and
    - Differences in HPR explain racial but not socioeconomic differences in hypertension.
  - Muscle Strength
    - African Americans will exhibit better preservation of muscle strength into older ages than other ethnic and racial groups;
    - African Americans have the same trajectory of muscle loss as other ethnic or racial groups after accounting for differences in occupational history, nutrition, and body mass and composition;
    - All ethnic and racial groups will show the same relationships among changes in muscle strength, physical activity, and cardiovascular fitness regardless of socioeconomic factors, nutrition, and co-morbid conditions such as diabetes; and
    - The greater strength reductions at older ages among lower SES individuals will be attributable to their greater severity of chronic diseases.

- Covariates
  - Other variables such as nutrition; environment and neighborhood effects; genetic makeup; family history; activity level; access to health care; prevalent medical, dental, and psychiatric conditions; oxidative stress; and DNA repair capacity may modulate the effects of SES and race on cardiovascular, musculoskeletal, cognitive, and autonomic functioning. For example:
    - The nutritional domain of the study will examine the effects of race and SES on nutritional status and identify nutritional factors that may contribute to health disparity in cardiovascular and cerebrovascular health and cognitive function.
    - The biomarkers domain of the study will examine possible biologic covariates of health disparities and aging. The early appearance and increased severity of age-associated disease among African Americans and low-SES individuals suggests that the factors contributing to the emergence of health disparities may also induce a phenotype of "premature aging" or "accelerated aging." Although we do not posit that health disparities result from genetic alterations in genes associated with the known heritable progeroid syndromes, we do hypothesize that in low-SES populations with high rates of early onset age-associated disease, the interaction of biologic, psychosocial, socioeconomic, and environmental factors may result in a phenotype of accelerated aging biologically similar to these syndromes, with increased susceptibility to oxidative stress, premature accumulation of oxidative DNA damage, defects in DNA repair, and higher levels of biomarkers of oxidative stress. Health disparities, therefore, may be the end product of this complex interaction in populations at high risk. HANDLS will examine this hypothesis by measuring biomarkers of oxidative stress, assessing levels of the most widely studied oxidative DNA adduct, and measuring DNA repair capacity in study participants. Prospectively measuring biomarkers of oxidative stress in a longitudinal study may clarify whether oxidative stress plays a pivotal role in aging and in the development and or progression of age-associated disease. It also may provide insights into the different trajectories of aging observed in individuals.

1.2.6.2 Performance Measures

- Publications highlighting findings from pilot study and cross-sectional analyses of baseline cohort data to focus on areas such as:
  a. The role of SES and/or race in health disparities
  b. The utility of C-reactive protein and other inflammatory markers as a predictive risk assessment tool for cardiovascular disease
  c. Risk factors for cognitive decline in low-SES White and African American populations
- Development of effective recruitment and retention strategies for low-SES and minority research participants
- Successful recruitment of baseline cohort for epidemiologic phase by 2008

1.2.6.3 Outcome Measures

- Development of HANDLS Cardiovascular Risk Score as a risk assessment tool appropriate for use in low-SES and African American populations
- Widespread dissemination and validation of recruitment and retention strategies developed by HANDLS investigators in other low-SES and minority cohorts
- Validation of mobile medical research vehicles as viable platforms for community-based clinical research

1.2.7 Objective Seven: Bogalusa Heart Study—Study of Aging

Disability, morbidity, and mortality due to heart disease remain high in older adults. Longitudinal epidemiology studies from childhood to adulthood are valuable for identifying childhood risk factors for heart disease and provide an opportunity to study disease pathways from younger ages. The Bogalusa Heart Study is a long-term study of a biracial (Black-White) population in the United States to follow individuals from childhood into middle age. The study began 32 years ago to research the onset of adult heart diseases in childhood and over the years has evolved into a study of aging. Longitudinal cohorts identified as children in 1973-1974 have now matured into middle-aged adults.

1.2.7.1 Action Plan

The next wave of analysis of the Bogalusa Heart Study cohort, expected to begin in the fall of 2004, will continue a long history of characterizing traits (intrinsic aging changes versus cardiovascular disease risk factor burden) in a biracial population that may influence progression of subclinical cardiovascular disease in an aging population. This study has previously reported a marked secular trend of increasing obesity and childhood obesity to be associated with silent, underlying cardiovascular structure-function changes. New research will focus on pathophysiologic studies of structural changes and hemodynamic function along with telomere studies of Bogalusa study participants. Findings from this research will provide a greater understanding of the evolution of cardiovascular disease risk in normal aging and may also lead to the development of effective preventive strategies against premature morbidity and mortality from cardiovascular diseases, and promote long and healthy survival.

1.2.7.2 Performance Measures

- Funded extension and expansion of the 25-year Bogalusa Heart Study to examine relationships of genetic factors, ethnicity, and changes in risk factors in early life in cardiovascular disease and other outcomes.

1.2.7.3 Outcome Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Lifestyle programs for successful aging and longevity, including cardiovascular disease prevention.
- Development of preventive strategies (e.g., modification of risk factors through exercise and/or dietary interventions) or new therapeutic strategies such as novel drug development.

1.3 Area of Emphasis Three: Biology of Aging—Genetic Explorations in Diabetes and Parkinson's Disease

1.3.1 Objective One: Hawaii Family Diabetes Study (HFDS)

Advance the process of identifying genetic susceptibility related to Type 2 diabetes in a unique population of older Japanese Americans living in Hawaii.

1.3.1.1 Action Plan

There is strong evidence for genetic susceptibility for type 2 diabetes. Currently, there are at least 20 major gene-searching activities underway that utilize the affected sib pair approach, but progress in duplication of linkage findings and identification of specific genes have been slower than anticipated. An additional affected sib pair study in a rather unique population of older Japanese Americans living in Hawaii with a high prevalence of diabetes could provide the opportunity of advancing the process of identifying genes related to type 2 diabetes. This population of men, aged 71-93 years, has recorded family roots in two distinct areas of Japan: the mainland region around Hiroshima and Okinawa.

A group of 82 affected sib pairs of Japanese Americans with similar background but living in Seattle, Washington, was found to have a marker (D14S608-17cM) linked to impaired glucose homeostasis (LOD = 1.53) as part of a broader study (Genetics of Non-Insulin Dependent Diabetes Mellitus; GENNID). There are a number of other markers identified with LOD scores greater than one, suggesting that a replication in a similar population is warranted. A total of 527 affected sib pairs from 170 families have been identified with known diabetes or an abnormal glucose tolerance test. This is in a population that has been under study for over 25 years with documentation of being generally lean and with most eating a modest diet. These circumstances suggest the possibility of a genetic basis for the high frequency of glucose dysregulation. This study will attempt to replicate in a new group of Japanese Americans the previously identified borderline significant linkages of impaired glucose homeostasis and diabetes phenotypes with genetic markers, as identified previously in the GENNID Study, especially on Chromosome 1, which has been confirmed as well in other studies, and on Chromosome 14, a less frequent finding.

In this study population of Japanese American men in Hawaii aged 71-93 years, the prevalence of reported diabetes was 17 percent; another 19 percent were diagnosed as diabetic on testing, and an additional 32 percent had impaired glucose tolerance by the more liberal World Health Organization (WHO) criteria. This total of about 68 percent of older men is a major health concern in this population. Also, it should be noted that when these men were evaluated for the first time in 1965-68, when they were middle-aged, a comparison with a national sample using a non-standard glucose challenge found twice as many men with glucose greater than 160 mg/dL in this population. This observation suggests that in this Japanese American population there may be a life-long tendency to glucose dysregulation that may have a genetic component.

1.3.1.2 Performance Measures

- Successful identification of potential genes on chromosomes 1 and 14 implicated in type 2 diabetes mellitus among Japanese Americans.
- Publications describing genetic findings and relevance to diabetes mellitus risk in Japanese Americans.
- Refinements of linkage analysis of the adiponectin gene on chromosome 14 that has been preliminarily linked with diabetes mellitus incidence in Northern European families.

1.3.1.3 Outcome Measures

- Improved understanding of the genetics of type 2 diabetes mellitus in Japanese Americans.
- Widespread dissemination of findings to the research community and development of additional genetic studies examining other gene pathways of glucose regulation in minority cohorts

1.3.2 Objective Two: Genetic Analysis of Parkinsonism and Parkinson’s Disease

Gain insight into the mechanism of Parkinsonism and Parkinson’s disease and to provide an animal model to test viable therapeutic strategies.

1.3.2.1 Action Plan

Although Parkinson's disease has been considered the archetypal non-genetic disorder, recent analysis has shown that it is, in fact, at least partly genetic in origin with variability in three genes (synuclein, parkin, and ubiquitin hydrolase) known to be associated with the disease and seven genetic linkages identified but not resolved. NIA work, in collaboration with the Bob Nussbaum (National Human Genome Research Institute; NHGRI) and Katrina Gwinn-Hardy (NINDS) laboratories, is on collecting families with Parkinson's disease, carrying out genetic analysis of known genes, and carrying out linkage analysis and positional cloning to identify new loci for this prevalent disorder. One surprising feature of our work has been that we have found that spinocerebellar ataxias can masquerade as Parkinson’s disease in African and Asian populations.

In a related area of investigation, dystonia represents a clinical syndrome characterized by involuntary sustained muscle contraction often resulting in twisting, repetitive movements and abnormal postures. Dystonia can be both primary (idiopathic) or symptomatic. Symptomatic or secondary dystonias are caused by varied structural or metabolic disturbances of the nervous system, which may result from an underlying disease or drug treatment. Idiopathic dystonias are composed of a spectrum of disorders in which dystonia is the predominant clinical feature. X-linked dystonia Parkinsonism (XDP) is a recessively inherited, severe, adult-onset movement disorder. It is characterized by dystonia, predominantly focal at presentation, progressing to a generalized form with co-incidental Parkinsonism in about 50 percent of cases. XDP is believed to originate from a common ancestor on the Philippine island of Panay. Linkage and allelic association studies have mapped the gene defect causing this disorder to a small interval in Xq13.1. We aim to identify the disease-causing mutation for X-linked dystonia Parkinsonism. As part of this effort, we have assisted in the collection of blood samples from more than 50 XDP patients and their immediate families in addition to samples from 100 male Filipino controls. We have performed haplotype analysis on affected individuals, their nuclear families, and controls. We have used an electronic database mining and positional cloning strategy to identify genes within the critical region and have constructed a physical map of the candidate region using a series of bacterial artificial chromosomes (BACs), P1-derived artificial chromosomes (PACs), and cosmids. We have sequenced all nine genes in two haplotype-confirmed XDP cases and their mothers. Additionally, we have sequenced the coding exons of two genes 200 kb centromeric to the candidate region. We have examined full-length gene transcripts from all nine genes amplified in adult and fetal cDNA libraries and lymphocyte DNA from an XDP case, his mother, and an unrelated control. The lack of a coding mutation in all known genes suggests a non-coding regulatory region may harbor the pathogenic change. In an effort to identify this or any mutation within the region, we are constructing a genomic cosmid library from an affected individual. We intend to identify clones from the candidate region using a pooled PCR approach and sequence the entire segregating region (350 kb) using a shotgun cloning methodology.

In collaboration with Mayo Clinic investigators, we have further characterized the clinical and pathological aspects of this disorder in an attempt to better understand the disease process. This work is not only aimed at gaining insight into the pathogenesis and etiology of this disorder but also to that of dystonia and Parkinsonism in general. Following the identification of this genetic defect and in conjunction with NIA IRP investigators, we will construct both cellular and transgenic models of this disease in an attempt to gain insight into the mechanism of disease and to provide a model to test viable therapeutic strategies.

1.3.2.2 Performance Measures

- Publications of findings regarding clinical presentation of movement disorders among minority populations.

- Expansion of genetic and clinical studies of movement disorders among diverse population groups to identify additional information about divergent clinical presentations among minority groups.
- Identify disease-causing mutations in XDP.
- Construct cellular and transgenic models to facilitate research on movement disorders.
- Identification of triplication of the synuclein gene as a cause of Parkinson's disease.

1.3.2.3 Outcome Measures

- Dissemination of findings from movement disorder clinical and genetic studies to the medical community.
- Development and implementation of collaborative studies with opportunities to join made available to a diverse cadre of investigators.
- Use and dissemination of genetic information acquired to provide a model for development and testing of effective therapies to ameliorate symptoms of this and other movement disorders.

1.4 Area of Emphasis Four: Behavioral and Social Aspects of Growing Older—Racial and Ethnic Differences

The NIA contracted with the National Research Council (NRC) in 2001 to conduct a follow-on study to inform NIA "…about recent research findings on racial and ethnic disparities in later life and help in developing a future research agenda for reducing them." The initial NIA-funded NRC study, entitled *Racial and Ethnic Differences in the Health of Older Americans*, was published in 1997. The resulting Panel on Race, Ethnicity, and Health in Later Life sent NIA a "Prepublication Copy" of the first volume of the new study in late June, 2004, entitled *Understanding Racial and Ethnic Differences in Health in Late Life: A Research Agenda.* Following the release of the remainder of the report, anticipated during the summer of 2004, NIA will carefully examine the NRC proposed research agenda and begin to design specific research initiatives addressed in the NRC report.

1.4.1 Objective One: Understanding Racial and Ethnic Differences in Health in Later Life: A Research Agenda

NIA will target specific recommended research gaps specified in the NRC volumes that address reducing health disparities in older persons.

1.4.1.1 Action Plan

Multiple scientific gaps in knowledge are suggested in the NRC volumes warranting significant scientific investment. The volumes will be examined carefully by staff and experts in the area of health disparities for research initiatives that can be funded, with the objective of publishing PAs and/or RFAs in targeted areas.

1.4.1.2 Performance Measures

- Identify areas needing research from the NRC report using both staff expertise and the input of Workshop members.
- Assess priorities and feasibility of research areas in need of research.
- Secure funding for needed areas of research and input from other NIH Institutes and Centers.
- Conduct a Workshop to help prioritize NRC recommendations.

1.4.1.3 Outcome Measures

Publish appropriate RFAs and/or PAs.

1.4.2 Objective Two: Early Life Factors

Explore the influence of early life factors on late-life health.

1.4.2.1 Action Plan

There is an unresolved tension between the proximal and distal causes of poor health. Many studies have identified significant risk factors for the development of chronic diseases that pre-date onset of symptoms by at least a decade. Population-based studies in which individuals are tracked from birth to their adult death help researchers observe the continuities and discontinuities in health over time, and have the potential to provide the necessary data to foster understanding of the large variations in health across racial and ethnic populations. Such combined studies would provide us with full life-course data on health and risk factors. This initiative would continue collaborative efforts with the National Institute of Child Health and Human Development (NICHD) and with researchers in other countries to understand the impact of early-life factors, including prenatal nutrition in the first trimester, on adult health. This initiative also would encourage research that examines early life factors and their impact on health disparities.

1.4.2.2 Performance Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address the causes of health disparities among older adults.
- Develop networks of researchers working in the area of early life factors and their impact on health disparities which become apparent in later life.
- Prepare and publish a PA encouraging research to disentangle the effects of early life factors on late-life health.

1.4.2.3 Outcome Measures

- Knowledge of the temporal order of health disparities and identification of the critical periods for interventions
- Number of publications in peer-reviewed literature from NIA-supported studies that address the linkage between early life factors and late life health as a mechanism that gives rise to health disparities.
- Identify and verify early life factors that correlate with late-life health in multiple populations and data sources.

1.4.3 Objective Three: Projections of Burden and Costs of Illness

Produce projections of burdens and costs of illness by minority status net of other factors.

1.4.3.1 Action Plan

The determination of future costs of illness and how the burdens of illnesses are distributed across the population is crucial for policymakers charged with implementing federal health policy. NIA is involved in an ongoing effort to support research that produces projections of burdens and costs of illness, healthy life expectancy, longevity, and mortality trajectories by race and ethnic status. NIA is also working with the Centers for Medicare and Medicaid Services (CMS) to provide researchers access to health care data necessary to facilitate cost-of-illness research. Results from successful projects would develop more complex behavioral models to specify a health production function for different race and ethnic groups allowing analysts to determine which interventions are likely to have the highest cost/benefit ratios. Workshops could be developed to bring together researchers from the modeling and intervention areas to consider means by which projection models can incorporate known effects based upon completed health intervention studies to model the impact of broader health initiatives on the cost of specific illnesses.

1.4.3.2 Performance Measures

- Solicit research grants on modeling costs of illness that specifically address differences by minority subgroup.
- Acquire access to CMS data for qualified, NIA-supported researchers.
- Develop workshop on integrating health interventions and cost-of-illness analysis.
- Develop networks designed to integrate health interventions and cost-of-illness analysis.
- Improve measures of burden of illness and cross-group comparisons using vignette and other technologies.

1.4.3.3 Outcome Measures

- Number of peer-reviewed journal articles on the projection of burdens and costs of illness by minority status.
- Number of peer-reviewed journal articles on the cost of illness by minority status that calculate the impact of specific health interventions.

1.4.4 Objective Four: SES, Racial, and Ethnic Differences in Health Outcomes

To clarify the degree to which SES produces racial and ethnic differences in health outcomes over the life course. This initiative will identify the mechanism through which SES produces racial and ethnic differences in health among the elderly and will elucidate other factors that complicate the effects of SES on racial and ethnic health disparities.

1.4.4.1 Action Plan

Higher morbidity and mortality rates are associated with lower SES levels. These differences persist into older age, and evidence suggests that the SES-related mortality rate differentials at older ages are growing. These differences in observed mortality levels may be explained, in part, by lifestyle, psychological, and social factors. The long-term effects of SES, behavioral risk factors, prejudice, and discrimination (and their interactions) still need to be examined. In addition, the relative contribution of income, wealth, education, or occupation is not clearly documented in the elderly. The results of this research will help policymakers focus on what types of policy changes will have the largest effects on bridging the disparities health gap.

1.4.4.2 Performance Measures

- Identify the factor(s) or interactions used in assessing SES (income, wealth, education, or occupation) that has greatest implications for health outcomes.
- Identify the effects of variability of SES over the lifetime.
- Elucidate reciprocal causation between SES, health, and morbidity across the life course.
- Develop a workshop to help elaborate the best approach to this multidisciplinary project.
- Organize workshops on the interaction of SES, race, and ethnicity.
- Develop and publish RFAs and PAs on this topic.

1.4.4.3 Outcome Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Number of peer-reviewed publications by grantees.

1.4.5 Objective Five: Race, Ethnicity, and Stress

To clarify the degree to which different racial and ethnic populations experience, react, and recover from stress. This topic also will assess the interaction between health and the accumulation of stress over time in diverse populations. Does greater experience of and exposure to chronic stress account for some racial and ethnic health differences among older adults?

1.4.5.1 Action Plan

The connection between stress and morbidity and mortality has been demonstrated in various studies. Job strain, bereavement, and caregiving for a chronically ill relative are stressful life events linked to mortality and illness. Stressors also can take other forms such as economic difficulties, physical deprivation, low status, occupational strain, neighborhood instability, and discrimination. The role of perception of stressors and one's self efficacy in dealing with stressors is a major portion of this initiative in diverse populations.

1.4.5.2 Performance Measures

- Identification of racial and ethnic variation in exposure to stressors (acculturative stress, discrimination, low SES).
- Identification of racial and ethnic differences in response to stressors—both psychological (depression, anger, anxiety?) and physiological (catecholamine, cortisol levels, blood pressure regulation, allostatic load differentials).
- Identification of racial and ethnic differences of self-report measures of stress exposure.
- Develop a workshop to elaborate the scientific approach to differential stressor reaction in diverse populations.
- Prepare and publish appropriate RFAs and PAs.

1.4.5.3 Outcome Measures

- Number of grants funded that result in knowledge enabling scientists to better understand the differential role of social stressors in the health of disparate populations of older adults.
- Development of improved biomarker measures such as urinary catecholamine/cortisol.
- Number of peer-reviewed publications by grantees.

1.4.6 Objective Six: Subjective and Physiological Well-Being in Special and Diverse Population Groups

Develop culturally appropriate indices of subjective and physiological well-being in special populations for use in longitudinal studies.

1.4.6.1 Action Plan

Reports by elderly persons in social science surveys of declining health but high levels of life satisfaction, point to the need to improve our understanding of how well-being, health, preferences, and clinical indicators are measured or mis-measured in surveys. The measurement of well-being and satisfaction, individual decision-making to improve well-being, and adaptation are also interrelated with the psychological foundations of economic evaluation. This topic has broad implications for the array of population surveys that are currently supported by NIA and fits into a broader NIH and Departmental concern with improving the measurement of the burden of illness. This topic needs specific focus on racial and ethnic minority populations for capturing some of the variation in well being between and among populations.

1.4.6.2 Performance Measures

- NIA will consider a workshop on the measurement of well-being that will emphasize interdisciplinary research involving economists, psychologists, clinicians, and epidemiologists.
- NIA will solicit input from representatives of diverse populations to ensure adequate ethnic and racial diversity in both the workshop and subsequent initiative.
- NIA will consider producing an RFA or PA on the topic of physiological measures based upon issues of allostatic load that can be used specifically in large surveys of disparate populations to measure health and morbidity.
- The unique combination of science involved in this multi-level approach will require that NIA actively solicit applications from specific communities of diverse and multi-disciplinary scholars to address this problem area.

1.4.6.3 Outcome Measures

- NIA will increase the numbers of grants submitted addressing well-being, the economy, and physiological indicators in diverse populations.
- Grantees and workshop participants will publish results regarding well-being in diverse populations in leading journals.

1.4.7 Objective Seven: Race, Ethnicity, and Biopsychosocial Interactions

To clarify how biopsychosocial factors affect physiological health outcomes over time in racial and ethnic groups of middle-aged and older adults.

1.4.7.1 Action Plan

Psychosocial and behavioral factors can have a profound impact on physiology. Psychosocial and behavioral factors have been shown to affect the cardiovascular, endocrine, immune, and nervous systems. These biological systems interact indirectly with the social and physical environments.

When one of these systems fails to regulate appropriately, the result can be disease. Physiological reactivity, allostatic load, psychoneuroimmunology, metabolic syndrome and psychosocial factors and finally, neurovisceral integration are potential mechanisms through which racial and ethnic disparities may present themselves.

1.4.7.2 Performance Measures

- Identification of differences between African Americans and Whites in stress-induced reactivity and its relation to hypertension.
- Identification of racial and ethnic differences in allostatic load and relation to health outcomes.
- Identification of racial and ethnic differences in metabolic syndrome and whether mediation is through stress or other psychosocial factors.
- Identification of racial and ethnic differences in neurovisceral integration elucidation of imbalances in the parasympathetic and sympathetic nervous systems.
- Identification of physiological reactivity to psychosocial stressors within various racial and ethnic groups (e.g., between Mexican Americans and Caribbean Americans).
- Develop workshops and possibly networks to assess this problem.
- Prepare and publish RFAs and PAs, as appropriate.

1.4.7.3 Outcome Measures

- Number of grants funded that result in knowledge enabling scientists to better understand and address causes of health disparities among older adults.
- Number of peer-reviewed publications by grantees.
- RFA and PA announcements.

1.4.8 Objective Eight: Paradox of Hispanic Health

Study immigration and health disparities of racial/ethnic minorities in the United States to understand why foreign-born Hispanics are seemingly healthier and experience lower mortality risks than U.S.-born Hispanics or non-Hispanic Whites (termed the “Paradox of Hispanic Health”). Recent evidence indicates that the “Paradox” may result from an underreporting of age-specific mortality and morbidity due to the return migration patterns of Hispanics in the United States

1.4.8.1 Action Plan

Enhance ongoing collaboration with NICHD on the New Immigrant Survey, which will provide important longitudinal data on the health of ethnic and racial minorities who are immigrants to the United States and their children. Continue to support the three-generation, cross-national study of Latino elders to determine processes, morbidity, and mortality. Enhance ongoing studies in Mexico and Puerto Rico to understand the origins of health disparities in the U.S. Hispanic population. Consider developing comparable studies in the Caribbean.

1.4.8.2 Performance Measures

- NIA will develop a workshop on data needs for studying this problem.
- NIA will consider developing a network of grantees conducting research on the Hispanic Paradox to better understand the exact nature of the problem.
- NIA will assess the necessity of developing a solicitation on the Hispanic Paradox subsequent to the workshop.

1.4.8.3 Outcome Measures

- NIA will publish the results of the Hispanic Paradox workshop either as a special issue or as a collection of papers in an appropriate scientific journal.
- If an initiative is decided upon, NIA will fund grants related to the topic.

1.4.9 Objective Nine: The Role of Education in Health Status and Health Disparities

Elucidate the role of education as a specific part of SES in contributing to health disparities.

1.4.9.1 Action Plan

Recent research by Goldman and Smith (2002) suggests that education may operate independently of race and ethnic difference to lead to adverse health outcomes because older adults with less education may not be able to comply with complex health regimens. Other research has suggested that education is an important and independent correlate of life expectancy. Education is clearly correlated with both race and ethnicity and is also an important part of SES. In 2001, a joint RFA was issued by NIA, the National Cancer Institute (NCI), NICHD, and the Office of Behavioral and Social Sciences Research (OBSSR) to examine the relationship between education and health. These grants were funded in late 2002, and two workshops have been held involving the investigators funded under this RFA. Current work on exploring common methodologies and metrics continues as a result of this RFA. Although we still do not know the success of the prior initiative, work in this area should continue. This initiative would encourage additional research on the relationship of education to health and health disparities. Research is needed on the use of common measures to verify their validity in different populations.

1.4.9.2 Performance Measures

- Issue a report following up on what was learned from the grants funded under this RFA and the meetings held as part of the RFA.
- Number of grants funded that include standard metrics that resulted from the initial education RFA.
- Number of additional grants addressing the relationship between education and health.

1.4.9.3 Outcome Measures

- Achieve a better understanding of how education contributes to health disparities independently of income and wealth.
- Better understand and develop statistical techniques to address the confounding nature of race, ethnicity, and education.
- Use the body of research knowledge to develop interventions and treatment regimes to increase compliance in the less educated.
- Number of publications in peer-reviewed literature from NIA-supported studies that address the role of education in contributing to health disparities.

1.4.10 Objective One: Minority Subjects in Longitudinal Studies

Ensure that older minority subjects are both well represented and retained in longitudinal studies for the purpose analyzing minority disparities in health.

1.4.10.1 Action Plan

Randomized national samples likely will capture relatively small samples of minority respondents. Further, the differential loss of older minority subjects in longitudinal studies, especially those below the median in income and education, confounds the generalized validity of research findings. Relatively small differentials in retention can, when accumulated over many years, result in substantial losses of minorities in longitudinal studies. Improved tracking is needed, especially for Mexican Americans who move back to Mexico and for minority subjects who move into medical and long-term care institutions. NIA has provided support for a number of unique data collections that address some of these issues. Both the Panel Study of Income Dynamics (PSID) and the Health and Retirement Study (HRS) oversampled minorities in their initial interviews. The HRS has oversampled minorities when new cohorts were added to the study and will continue to do so in the future. The Mexican Health and Aging Study (MHAS), the Health Conditions of the Elderly Adults in Puerto Rico (PREHCO) study, the New Immigrant Survey (NIS), and the Los Angeles Family and Neighborhood Survey (LAFANS) all use sampling frameworks that provide researchers with large samples of minority respondents. All of these surveys employ culturally sensitive interview approaches, which in turn could both increase participation and reduce attrition. NIA also supports the Resource Centers for Minority Aging Research (RCMAR), a collection of six university-based groups charged with focusing on the health of minority elders. One specific task of the RCMAR centers is to develop and provide research infrastructure using tested models to increase participation of minority elders in research studies. In an ongoing effort to meet this objective, NIA will encourage research, workshops, and pilot studies on the development of approaches designed to include and maintain minority respondents and provide researchers with the longitudinal data on minorities they need to conduct research on minority health disparities.

1.4.10.2 Performance Measures

- Funded research/pilot projects on the inclusion and retention of minority respondents in survey data.
- Workshops to develop survey techniques to reduce attrition of minorities from surveys.
- Funded grants that use NIA-sponsored data to analyze health disparities.

1.4.10.3 Outcome Measures

- Reduction in attrition of minority respondents in NIA-funded surveys.
- Number of peer-reviewed publications on strategies to reduce attrition of minorities from surveys.
- Number of peer-reviewed publications on health disparities that utilize NIA-sponsored survey data.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

Reducing health disparities will require multiple fresh approaches including: (1) increased local, regional, and national literacy in science and health; and (2) increased inclusion of minorities in the health and medical research professions. Although it is clear that a researcher need not come from a racial or ethnic minority or a disadvantaged background to contribute to the understanding and remediation of health disparities, it is reasonable to expect that such individuals as a group would possess particular motivation and persistence, as well as familiarity and insight into these problems. Therefore, effective recruiting efforts should tap into this talent pool and focus on bringing underrepresented groups into biomedical research (Slavkin, et al. 1999). In 1997, a NACA Training Task Force strongly urged that NIA give training a high priority, reflecting the belief that progress in research on aging, in general, and minority aging research, in particular, is intimately tied to the success of training, capacity-building, and infrastructure development. This section includes three significant priority initiatives for the NIA. A full description of all NIA initiatives may be found in the comprehensive NIA Strategic Plan to Address Health Disparities at www.nia.nih.gov/strat-planhd/2000-2005.

2.1 Area of Emphasis One: Alzheimer's Disease Research Centers (ADRC) Satellite Diagnosis and Treatment Clinics

2.1.1 Objective One: ADRC Satellite Diagnosis and Treatment Clinics

Increase the diversity of the research patient pool and enhance the research capabilities of the AD Centers.

2.1.1.1 Action Plan

The NIA will continue to fund existing (n = 29) ADCs, in association with 23 Satellite Diagnosis and Treatment Clinics (SDTC) designed to increase the diversity of the research patient pool and enhance the research capabilities of the ADCs. Since initial funding of the satellites, minority recruitment into the ADC Clinical Cores has increased from 4 percent to 20 percent. The satellite clinics extend the diagnostic and management services as well as educational activities offered by the ADCs to underserved areas. The satellite clinics also enhance the clinical research capabilities of the ADCs through the diversification of the research patient pool by offering the opportunity to special population groups to enter clinical drug trials and to participate in other clinical research efforts. Many SDTCs have hired staff reflecting the demographics of the communities to be the liaison with the communities. Most of the satellite clinics focus on outreach, recruitment, and retention of specific minority populations, often working closely with local and state agencies, health care organizations, churches, community clinics, and housing projects. Many are developing culturally and language sensitive cognitive and dementia screening instruments, as well as neuropsychological and neurological examinations. Along with the parent ADCs, several are conducting studies on the onset and course of AD in specific minority populations.

Eighteen SDTCs target urban minority populations and five focus on underserved rural populations. Additionally, three SDTCs combine those minority and rural outreach efforts. Through years of sustained outreach effort to attract and educate people in the community based on regional needs and sensitivities, the SDTCs' visibility in the community continues to improve. Examples of African American outreach include work at Harlem Hospital, the UCLA Drew Health Center, the Mayo Clinic at Jacksonville, Florida, and very successful outreach efforts at the Duke ADC in collaboration with local church leaders, and at the Oregon ADC with collaboration of an African American sorority. Hispanic outreach is successfully continuing in the San Joaquin/Sacramento Valley by the University of California, Davis ADC, and in other parts of California by the University of California, Irvine ADC with the collaboration of Hispanic community programs such as Latino Health Access. Of note, the University of Pennsylvania ADC established an active Hispanic outreach clinic, the Centro del Trastono de la Memoria, with great success. Notable American Indians outreach examples are the continued collaboration between the University of Texas Southwestern ADC and the Choctaw Nation clinic, the Arizona ADC and the Navaho Reservation, and the Oregon ADC and the Warm Springs Indian Reservation. Asian outreach examples include successful efforts to reach Chinese, Korean, Vietnamese, and Japanese communities at the California-based ADCs.

Rural and Underserved Outreach Efforts. Examples include the Oregon ADC Warm Springs Indian Reservation and the Klamath Exceptional Aging Project (KEAP). The Warm Springs Indian Reservation aims at assessing all elders more than 65 years old on the Warm Springs Indian Reservation using a Native American elder trained to perform home visit assessments. The KEAP successfully continues to assess and follow a unique rural oldest old cohort. Also, the Eastern Kentucky Satellite Diagnostic and Treatment Clinic (EKSDTC) in Prestonburg, Kentucky (soon to move to Berea, a location more accessible to Lexington) has for its mission to enhance access to diagnostic and treatment services and clinical research programs for rural populations with AD and other dementing disorders. The patients evaluated at the EKSDTC are from a unique subpopulation of White, non-Hispanic rural Kentuckians, characterized by low educational attainment, poor general health, high poverty, and limited transportation and communication facilities. In addition to teaching rural residents about the etiology, differential diagnosis, treatment, and care of older adults with dementing illness, one of the Washington University ADC's key initiatives is to educate rural physicians through the Clinician Partners Program and the Clinical Dementia Rating on-line training system. The rural outreach to physicians has resulted in expanded awareness, access, and service to patients and families with AD and related disorders in rural Southeast Missouri. Finally, the University of Washington ADC Satellite covers a number of counties across Washington State and focuses on the recruitment of Asian and African American elderly, the two largest ethnic minority groups in the Pacific Northwest. The objectives of the satellite are to validate a simple dementia screening instrument (mini-cog) aimed at being free of language and education biases in a population-based sample of ethnic elderly, enrich the knowledge base on health care and social services needs of demented ethnic elders and their families, and develop qualitative research methods grounded in the literature on Chinese and African American older individuals to design effective recruitment and intervention strategies. For example, evaluation of barriers to needed support services among minority groups showed that despite the growth of services for Chinese elderly, most caregivers were unaware that help was available and were unwilling to burden the government by asking for financial help.

All ADCs have an Education and Information Transfer Core. This core supports both the development of professional staff to improve clinical and research skills related to AD and outreach programs for the lay public that will publicize the ADRC and educate families and other caregivers about the disease. Cultural sensitivity is emphasized and, where appropriate, the outreach programs to minority groups provide information structured so that it can effectively reach minority populations, including non-English-speaking people.

With the Oregon ADC providing the major impetus, the Education Cores have identified the need to increase awareness of manifestations of AD in primary care practices. A national effort is being launched to provide education as to how best to perform assessments and provide care in a primary care practice setting with a particular emphasis on rural and underserved areas. Similarly, the Washington University ADC initiated a new program initiated in 2004 focused on educating rural clinicians on how to assess and counsel families concerning dementia and driving.

NIA plans continued funding through diversity supplements to the ADCs' two research efforts aimed at reducing health disparities in medically underserved Asian American elders and understanding potential explanations for disparities in the cognitive assessment of African Americans. The first study, from the Stanford ADC, sought to identify measurable and modifiable risk factors that contribute to the rate of AD progression in medically underserved Asian American elders. Three candidate groups of risk factors were examined longitudinally: metabolic cardiovascular syndrome (hypertension, obesity, dyslipidemia, and glucose intolerance), cerebrovascular disease (stroke, coronary heart disease, subclinical atherosclerosis, and/or diabetes), and behavioral problems (depression, controlling for delusions, hallucinations, and agitation). This study provided vital research and services to the growing medically underserved Asian American community.

The second study, at the Mayo ADC, aimed at determining the effects of cultural identification and quality of education on neuropsychological performance in 300 older African Americans living in and around Jacksonville, Florida. Neuropsychological tests evaluated cognitive domains commonly affected by dementia and were complemented by a measure of global cognitive functioning (DRS), reading ability, and a short test evaluating level of cultural identification. The ability to measure and account for these influences led to a better understanding of cognitive function and dysfunction in African American elders and helped improve the diagnostic accuracy of neuropsychological tests.

Two of the Centers have had special relationships with historically African American medical schools, the University of Kentucky with Meharry Medical School in Nashville, Tennessee and the University of California at Los Angeles with the Martin Luther King/Charles Drew Medical Center in South Central Los Angeles. These relationships afforded opportunities for patients and families from diversity populations to participate in clinical studies. The UCLA satellite at Drew will continue, but the Meharry satellite is closing next year. The University of Kentucky is refocusing its efforts on recruitment of African Americans at a Lexington clinic located in an African American neighborhood. Another NIA-sponsored program, the Research Centers for Minority Aging Research (RCMARs), has four of its six centers located at university campuses that also house ADRCs (Columbia University, the University of Michigan, the University of California, San Francisco and the University of California, Los Angeles). This proximity includes opportunities for joint staffing and sharing of some programmatic initiatives such as recruitment and education of minority subjects and families.

2.1.1.2 Performance Measures

Development and expansion of culturally and language sensitive screening instruments; number and type of outreach programs.

2.1.1.3 Outcome Measures

Demonstrated outreach to minorities with cognitive problems and AD, including their recruitment into clinical studies and trials.

2.2 Area of Emphasis Two: Centers for Minority Aging and Health Disparities Research (RCMARS and CPHD)

2.2.1 Objective One: Resource Centers for Minority Aging Research

NIA will continue and build upon the successes of the existing RCMARs to create scientific infrastructure for conducting research on health disparities between and within various racial and ethnic groups of minority and non-minority elders. Because of the breadth of this initiative, RCMAR's goals crosscut several of the Strategic Plan's sub-goals. Further, the primary Area of Emphasis identified is Behavioral and Social Research (BSR) Health Disparities. The six RCMAR sites are intended to in part address this leading Area of Emphasis.

2.2.1.1 Action Plan

The RCMARs have been in existence with co-funding from the NCMHD and the NINR since 1997. NIA will examine, revise, and likely reissue the RFA leading to the initial creation of six RCMARs for the third iteration of this Center concept. The RCMARs include: (1) focused research on recruiting and retaining minority group members in research; (2) links between ongoing research for the purpose of recruiting and retaining minority members; (3) research links between other appropriate NIA-supported Centers (e.g., ADCs) and other funded initiatives; (4) development of race/ethnic sensitive, yet comparable measurement; (5) expanded opportunities of mentoring minority and non-minority investigators for research and sustained careers in the health of older minority populations; (6) opportunities to develop research and mentoring links between various institutions; and (7) improved communication between researchers and minority end-result research users.

2.2.1.2 Performance Measures

- The RCMARs will continue to use their *Emphasis and Outcomes* evaluation scheme to ensure continued excellence.
- The RCMARs will continue to mentor minority investigators and non-minority investigators in the conduct of research on the health of older diverse populations.
- Spin-off grant applications based on RCMAR pilot investigator and senior investigators' research will continue to be solicited.
- Workshops supported by NIA funds and organized by the RCMARs will continue to be a feature of the Gerontological Society of America (GSA) pre-conference meeting.
- Workshops and RCMAR general publications on topics such as measurement in diverse populations and recruitment and retention of minority subjects in sociobehavioral and clinical research will be forthcoming.
- A third iteration of the RCMAR concept will be published for funding in 2007.

2.2.1.3 Outcome Measures

- Based upon the RCMAR Emphasis and Outcomes process, grants secondary to the RCMARs will be submitted and awarded.

- The RCMARs will continue to mentor diverse, generally young, investigators for careers in research on eliminating health disparities. This group is called the RCMAR Scholars.
- Publications on topics related to the RCMAR Scholars' areas of interest and the mentoring faculty will continue to increase as will grant applications.
- Publicity and presentations on RCMAR research will continue to grow.
- RCMAR will continue to develop measurement tools and instruments that are racially and ethnically neutral.

2.3 Area of Emphasis Three: Increasing Diversity in Biology of Aging Research

Identify Investigators from underrepresented, disadvantaged, and disabled backgrounds interested in research in relevant topics in biology of aging.

2.3.1 Objective One: Travel Assistance for Investigators From Underrepresented, Disadvantaged, and Disabled Backgrounds

Provide opportunities in biology of aging research training and career development to researchers from underrepresented, disadvantaged, and disabled special populations.

2.3.1.1 Action Plan

The Biology of Aging Program has a permanent announcement on its web site that encourages both: (1) Principal Investigators (PIs) of research grants funded by NIA to apply for travel funds that may be used to increase the pool of candidates, especially candidates from diversity populations with interest in health disparities research, to attend scientific workshops, conferences, and annual meetings relevant to topics in the biology of aging; and (2) students and investigators from diverse backgrounds to self-identify their interest in participating in the same type of meetings and apply for travel funds allowing them to participate.

2.3.1.2 Performance Measures

- The web site announcement will remain on the web site.
- The same notice and instructions are emailed to PIs yearly. Those emailed announcements total approximately 700 and should increase to 1,000 by 2008.
- $5,000 is reserved each year in the operating budget for the Diversity Travel Assistance Program designed to increase focus on health disparities research. This will continue each year. Awarding of funds is subject to response to the application announcement.

2.3.1.3 Outcome Measures

- The "Diversity Travel Assistance Program" has received no applications for travel assistance in FY2004, but has provided funding in previous years.

- Outcome measures will be determined by the numbers of individuals making use of these travel funds.

2.4 Area of Emphasis Four: Special Populations Initiatives—Underrepresented, Disadvantaged and Disabled Scientists Workshops and Career Development Opportunities

2.4.1 Objective One: Special Populations Workshops and Career Development Opportunities

Increase outreach and recruitment activities conducted to apprise minority and underrepresented scientists of research opportunities in an effort to increase the applicant pool in health disparities research.

Provide targeted and inclusive initiatives including workshop and career development opportunities to researchers with an interest in health disparities.

2.4.1.1 Action Plan

The Office of Special Populations, Office of the Director, coordinates initiatives aimed at increasing the quantity and quality of research. Minority and diversity population group members are highly recruited in an effort to apprise minority and majority scientists of research opportunities in minority aging research and health disparities. This office in concert with the NIA Minority Work Group is the lead contact for many Department of Health and Human Services and Office of Minority Health (OMH) activities including Minority Youth Initiatives, Minority Organizations Internship Programs, NIA Regional Meetings, Technical Assistance Workshops, and outreach to minority and community organizations. For example, this Office plans, organizes, and directs NIA's exemplary "Summer Institute on Aging Research." This 1-week training initiative in partnership with the NCMHD is highly competitive and supports training experiences for scientists at the beginning stages of a research career in aging. Applicants from minority and health disparities populations are strongly encouraged to apply to participate in this initiative.

The NIA has taken several steps to increase the opportunity to identify minority investigators interested in aging research. The NIA plans to host on annual basis training and development workshops to enhance grantsmanship skills of early career scientists with interest in minority health and health disparities research. The NIA recognizes the significant disadvantage young scientists, and especially some minority scientists, have in competing against "veterans" for obtaining funds necessary to conduct research. There are few courses or training programs to teach the fine art of grantsmanship. The NIA plans to offer the Summer Institute on Aging Research and a Technical Assistance Workshop in 2002.

2.4.1.2 Performance Measures

- Host scientific sessions, posters and/or lectures highlighting exciting new research findings in minority health, health disparities, and aging research.
- Encourage the participation of minority scientists (n = 45) from Historically Black Colleges and Universities (HBCU), Hispanic-Serving Institutions (HSI; a designation from the U.S. Department of Education used to identify eligible institutions of higher education that seek to enhance and expand their capacity to serve Hispanic and low-income students by providing funds to improve and strengthen the academic quality, institutional stability, management, and fiscal capabilities of eligible institutions), and Tribal Colleges to participate in the Technical Assistance Workshop. All applicants with a doctoral degree will be invited to apply for the Summer Institute.

2.4.1.3 Outcome Measures

- Number of research grants focused on minority health and health disparities as well as the number of racial and ethnic group scientists participating in aging research training and career development activities.
- Numbers of posters and other scientific presentations on aging from minority investigators or addressing research on health disparities.
- Number of grants to former participants in workshops and career development activities.
- Percent increase in reported publications by minority scientists participating in prior NIA training and development initiatives.

2.5 Area of Emphasis Five: Research Training and Career Development Activities for Diverse Segments of the U.S. Population

2.5.1 Objective One: Increase Diversity of the Aging Research Workforce by Supporting Investigators on "Diversity Supplement Awards"

2.5.1.1 Action Plan

Expand opportunities in research training and career development for, and provide research supplements to, investigators from racial and ethnic minority populations and other health disparity populations. The supplement program is currently the Research Supplements to Promote Diversity in Health-Related Research, also known as the "Diversity Supplement Program." The use of race and ethnicity are but one criterion in addition to an interest in health disparities research and scoring well on review criteria published in PA-05-015, http://grants1.nih.gov/grants/guide/pa-files/PA-015.html. The number of supplement awards being funded at any given time is likely to remain the same, or slightly increase, through 2008. The awards are for a limited duration; as some funding is ended, new funding begins. Each year, the availability of the supplemental funding is announced to PIs. Those emailed announcements total approximately 700 and should increase to 1,000 by 2008.

2.5.1.2 Performance Measures

- Sixteen diversity supplement awards are currently being funded from the "Diversity Supplement Program." Awards are made based on applicants with an interest in health disparities research and scoring well on standard review criteria published in the NIH Guide Program Announcement. The number of diversity supplement awards being funded at any given time is likely to remain the same, or slightly increase, through 2008.
- From the current group, we anticipate that at least two will go on to become PIs with their own successfully funded research.

2.5.1.3 Outcome Measures

Successful outcomes would be reflected in publications, ongoing funded research, mentoring of other researchers, and expansion of age-related research areas.

2.5.2 Objective Two: Fellowships and Institutional Training

Attract to aging research laboratories and summer programs a cadre of bright and energetic future scholars addressing challenges and problems associated with variability across and within racial and ethnic groups and spanning basic biology to human clinical trials.

2.5.2.1 Action Plan

Expand opportunities in research training and career development for and offer opportunities for research training to investigators, including those from racial and ethnic minority populations and other health disparity populations.

2.5.2.2 Performance Measures

- The Biology of Aging Program is currently funding one Ruth L. Kirschstein National Research Service Award for Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research, also known as a Predoctoral Fellowship Award to Increase Diversity, and four institutional training awards that collectively support 10 pre- and postdoctoral trainees as follows: three African Americans, six Hispanics, and one American Indian. Awards will continue to be based on scientific merit, significance, approach, investigator, environment, and innovation.
- The awards are for a limited duration; as some funding is ended, new funding begins. The number of trainee awards funded at any given time is likely to remain the same or increase by five through 2008.

2.5.2.3 Outcome Measures

- Number of new research publications by these individuals.
- Employment within a related research community.
- Number of individuals funded for ongoing research by 2008.

2.5.3 Objective Three: Intramural Research Training Awards (IRTA)

Enrich the diversity of the NIA workforce as well as the IRP and to provide cutting-edge training in NIA's laboratories.

2.5.3.1 Action Plan

The IRP of the NIA has several options for engaging a diverse cadre of individuals in training opportunities at the Gerontology Research Center (GRC): visiting scientists, IRTA, the Summer Internship Program in Biomedical Research, and the Summer Research Fellowship Program. Each of these programs is designed to enrich the diversity of the IRP staff and to provide cutting-edge training in NIA's laboratories.

The NIA IRP is composed of the GRC in Baltimore, Maryland; the Laboratory of Neurogenetics (LNG) and Brain Physiology and Metabolism Section (BPMS) in Bethesda, Maryland; and the Laboratory of Epidemiology, Demography, and Biometry (LEDB), located in the Gateway Building in Bethesda, Maryland. The NIA IRP comprises 11 scientific laboratories, a clinical branch, a research resources support branch, and two sections.

2.5.3.2 Performance Measures

- Number of IRTA trainees in NIA laboratories on an annual basis
- Number of former trainees returning for a second year/summer of training in NIA laboratories
- The increasing and documented diversity of trainees in NIA laboratories, especially Hispanic and American Indian trainees.

2.5.3.3 Outcome Measures

- Diversity of NIA workforce.
- Number of former trainees entering science or science-related jobs/careers.
- Publications from former trainees on aging-relevant topics.
- Funded grant awards or travel stipends to former trainees.

2.5.4 Objective Four: Minority Access to Research Careers (MARC)

By 2008, the alumni of the NIA-sponsored Minority Access to Research Careers (MARC) participant number will be sixty (60).

2.5.4.1 Action Plan

In 1975, the NIH NIGMS Minority Access to Research Careers (MARC) program was formally established. The impetus to develop the MARC program came at the end of the 1960s, in response to an increasing demand for minority scientists by academic institutions, industry, and government and a historically low proportion of minority group members among the nation's biomedical scientists. The MARC program supports biomedical research training for students and faculty members at 4-year diverse colleges and universities.

The NIA IRP has been very successful in attracting MARC students for summer training opportunities through the Summer Internship Program. Several of these students are now considering returning for post-baccalaureate and postdoctoral training within the IRP.

2.5.4.2 Performance Measures

- Diversity of NIA workforce
- Number of ITA trainees in NIA laboratories on an annual basis
- Number of former trainees returning for a second year/summer of training in NIA laboratories
- The increasing and documented diversity of trainees in NIA laboratories, especially for Hispanic and American Indian trainees

2.5.4.3 Outcome Measures

- Diversity of NIA workforce.
- Number of former trainees entering science or science-related jobs/careers.
- Publications from former trainees on aging-relevant topics.
- Funded grant awards or travel stipends to former trainees.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

Development of public information and communicating with individuals and communities of color are necessary components in the race to reduce health disparities, change health behaviors, and improve the quality of life for older adults from ethnic and racial minorities. Additionally, the NIA is engaged in several projects to enhance the availability of web-based services to older adults in an organized campaign to enhance outreach to and education for vulnerable populations. NIA staff believes information to be an important first step in changing health behaviors. Communities of color, and racial and ethnic minority health care providers and scientists need to be aware and informed about the latest findings from medical research that can be applied to improving health.

To reiterate, communicating research findings and health messages to older adults is an important part of the NIA mission. In NIA's collective efforts to reduce and ultimately eliminate health disparities for older adults, the focus on public information, community outreach, and health education is the third priority focus. Information on scientific findings and technologies is disseminated to the public and scientific and other health professionals through various methods. This section includes seven priority initiatives. A full description of all NIA initiatives may be found in the comprehensive NIA Strategic Plan to Address Health Disparities at www.nia.nih.gov/strat-planhd/2000-2005.

3.1 Area of Emphasis One: Databases on Health Disparities

3.1.1 Objective One: Ethnic and Racial Databases

Contribute databases as a source of basic information required to address health disparities in African Americans, Asians, Hispanics, Native Hawaiians and other Pacific Islanders, and American Indians

3.1.1.1 Action Plan

Enhance the capacity of various centers such as the National Archive on Computerized Data on Aging (NACDA) and the demography centers, RCMAR, and Centers on Population Health and Health Disparities to: (1) collect and archive databases suitable for secondary data analyses on health disparities; (2) distribute the data through CD-ROMS, FTP, and where necessary the creation of special enclaves that permit analyses of linked administrative or sensitive (e.g., geographic specific) data; (3) provide workshops and summer institutes to assist potential users, especially at non-research universities; and (4) provide post workshop assistance through 800 numbers and online help.

3.1.1.2 Performance Measures

- University of Michigan to distribute 500 copies of the CD-ROM on Minority Aging Research Datasets from NACDA.
- Workshops and summer institutes to assist potential users of the CD ROM on Minority Aging Research Datasets, and lay the foundation for adding new datasets to the CD-ROM.

3.1.1.3 Outcome Measures

- Expanded and new databases on health disparities across population and sub-population groups.
- Increased use of databases for secondary analysis.

3.2 Area of Emphasis Three: NIA Exercise Guide – Language Translations

3.2.1 Objective One: NIA Exercise Guide

Provide health education materials to communities of diversity in language-appropriate venues.

3.2.1.1 Action Plan

The Office of Communication and Public Liaison of the NIA has developed an exercise guide to inform older people about the benefits of exercise in improving and maintaining good health in later life. This guide is based on NIA-supported research results and the recommendations of the U.S. Surgeon General and the Centers for Disease Control and Prevention.

According to the 1990 Census, as many as 40 percent of elderly Hispanics either do not speak English or do not speak it well. To meet the information needs of this growing target audience, health education materials must take into account not only cultural sensitivities, but also language preferences. According to a recent survey conducted by the Health Care Financing Administration (HCFA), older Hispanics would like to have all information, regardless of the way it is communicated, available to them in Spanish. HCFA also found that many of the Spanish-speaking participants in their survey could not read in English or Spanish and therefore would require health and beneficiary information in non-printed form.

3.2.1.2 Performance Measures

Translate and print the NIA Exercise Guide in Spanish.

3.2.1.3 Outcome Measures

Use of the Spanish language Exercise Guide in Spanish-speaking communities, community centers, and senior centers serving Hispanic and Latino elders.

3.3 Area of Emphasis Four: Outreach to Diverse Population Groups in Aging Research

3.3.1 Objective One: Chartbook on Health Disparities in Older Adults

In partnership with the Federal Forum on Aging-Related Statistics, develop a ***Chartbook*** on health disparities in older Americans.

3.3.1.1 Action Plan

The Federal Forum on Aging-Related Statistics is publishing a 2004 ***Chartbook*** on the well-being of older Americans. Although this ***Chartbook*** does contain several graphs and indicators broken down by race, ethnicity, and socioeconomic status, the focus of the ***Chartbook*** is on the overall older population and not on specific subgroups. The goal of this initiative is to work through the Interagency Forum on Aging-Related Statistics to gather data from various federal statistical agencies to identify health disparities and relevant issues. The ***Chartbook*** will identify disparities by race and ethnic status.

3.3.1.2 Performance Measures

- Work with the Forum to compile statistics from various federal agencies by racial and ethnic group and by socioeconomic status.
- Develop well-being measures of older Americans that specifically address health disparities issues.

3.3.1.3 Outcome Measures

- Issue a ***Chartbook*** on the health disparities in older Americans in 2004.
- Disseminate the ***Chartbook*** and ensure its replication at regular intervals, such as every 4 years.

3.4.2 Objective Two: Outreach to Minority, Underserved, Disadvantaged, and Disabled Population Groups

Represent the NIA in minority, underserved, disadvantaged, and disabled population groups throughout the Nation and in particular, to professional organizations.

3.4.2.1 Action Plan

Target magazines serving special populations to promote health materials such as Spanish Age Pages and Age Pages particularly relevant to African Americans, and promote the NIA Exercise Guide for Older People to community groups such as churches, local health care clinics, and community centers serving special populations.

3.4.2.2 Performance Measures

Office of Communication and Public Liaison programs to disseminate information to special populations and monitor, to the extent possible, the racial and ethnic distribution pattern of public health education materials.

3.4.2.3 Outcome Measures

The number of publications disseminated at Office of Communication and Public Liaison programs.

3.5 Area of Emphasis Five: Age Pages—Diverse Topics and Language Translations

3.5.1 Objective One: Age Pages—Diverse Topics and Language Translations

To determine whether Age Pages are read and viewed as useful by Hispanic and other minority, underserved, disadvantaged, and disabled population groups.

3.5.1.1 Action Plan

Translate and print three additional Age Pages into Spanish. Explore the advisability of developing a special version of the NIA Video Exercise Guide for the African American Community. Test the effectiveness of four Age Pages (cancer, stroke, high blood pressure, and diabetes) in an African American community in Baltimore.

3.5.1.2 Performance Measures

- Number of different Age Pages translated into Spanish.
- Steps the Office of Communication and Public Liaison has taken to explore viability of developing a special version of the NIA exercise video for groups in the Hispanic community.
- Number of Age Pages tested in African American communities.

3.5.1.3 Outcome Measures

- Publication of Age Pages in Spanish.
- Decision regarding developing a special version of the NIA exercise video for special populations.
- Evaluative comments from African American communities regarding selected Age Pages.

3.6 Area of Emphasis Six: Outreach to Achieve Diversity in the Health Professions

3.6.1 Objective One: Outreach to Minority and Other Diverse Health Professional Groups

Stimulate the training of investigators who can translate the findings of basic research into medical benefits for older people, and expand the pool of clinical geriatric investigators serving as spokespersons for the NIA.

Reach health professionals from minority, underserved, disadvantaged, and disabled population groups with aging research information.

3.6.1.1 Action Plan

Attend (with NIA exhibit) National Medical Association, National Hispanic Medical Association, and National Black Nurses Association meetings and others to inform health care providers of free health education materials from the NIA. Identify and media-train one or several grantees from diverse backgrounds to serve as spokespersons for the NIA to special patient and subject populations.

3.6.1.2 Performance Measures

Office of Communication and Public Liaison exhibits at the meetings of the National Medical Association, National Hispanic Medical Association, National Black Nurses Association, and Native American physician groups.

3.6.1.3 Outcome Measures

- Contacts and partnerships established with participants at the National Medical Association.
- Number of linkages and activities with minority professional organizations.

3.7 Area of Emphasis Seven: Dissemination of Public Information

3.7.1 Objective One: Public Health Education

Identify and translate NIA research findings into plain language for utilization by health professionals, professional associations, and lay communities.

3.7.1.1 Action Plan

Over the past 3 years the NIA Office of Communications and Public Liaison has carried out a number of activities related to reducing health disparities among older people and populations. Activities have included newsletters, press releases, and other health communication projects.

Newsletters: The Office of Communication and Public Liaison provides creative, editorial, and logistical support for the NIA Work Group on Minority Aging newsletter *Links*, which is produced twice a year. Each issue includes: profiles of successful minority scientists with an interest in aging research; highlights from research focusing on aging issues within minority communities; and research support available from NIA for minority researchers. Examples of past press activities: AD briefing, which included a discussion of the growing minority population at risk for AD (Dr. Maurice Morrison-Bogorad) and a presentation on behavioral and social aspects of AD focused on African American families (Lisa Gwyther, M.S.W.)

Press release: “Older disabled women have trouble managing pain” from an article (Marco Pahor and Jack Guralnik) in *the American Journal of Public Health*, with data from the Women's Health and Aging Study in Baltimore. Press release on REACH, “Innovative programs to be tested for Alzheimer’s disease caregivers” announcing the study, and an article, “Reaching Out to Dementia Caregivers” by Richard Schulz and Marcia Ory in *Innovations.* Article on RCMARs: “Centers work to enhance minority research” in *Innovations.*

Health Communication Activities: Developed Spanish-language radio broadcast on forgetfulness for Dr. Elmer Huerta. Produced and distributed a Spanish-language version of *Age Page: Forgetfulness*. Updated packaged literature search, *Ethnicity and AD: Assessment, Research, and Education*, for distribution to health professionals. Sent promotional mailings for the ADEAR Center’s Spanish-language, cost-recovery materials to organizations concerned with ethnic and minority issues. Developed exercise exhibit featuring minorities. Promoted and distributed five Spanish-language bulletins produced by the Suncoast Gerontology Center about AD and related care issues. The Office of Communication and Public Liaison will develop a proposal to the NCMHD to develop a Spanish-language exercise video.

3.7.1.2 Performance Measures

- Number of different Age Pages translated into Spanish.
- Steps the Office of Communication and Public Liaison has taken to explore viability of developing a special version of the NIA exercise video for groups in the Hispanic community.
- Number of Age Pages tested in African American communities.

3.7.1.3 Outcome Measures

- Printed Age Pages in Spanish.
- Decision regarding developing a special version of the NIA exercise video for Special Populations such as Hispanics.
- Evaluative comments from African American communities regarding selected Age Pages.

CONCLUSION

As our population rapidly grows older, it is ever more urgent that we find effective ways to address the often devastating diseases and conditions associated with advanced age. Since the NIA’s founding in 1974, groundwork has been laid for today’s important advances in understanding basic aging; preventing disease and disability, including AD; and defining special social and behavioral issues for older individuals, their families and caregivers, and clinicians. The latest studies provide additional basic understandings as well as improved interventions to treat and even prevent some of the more devastating and disabling aspects of aging. With such research continued and intensified, we can move forward in meeting the promise of extended life by improving the health and well-being of older people in America.

NATIONAL INSTITUTE ON AGING

Strategic planning is one way for the NIA to take advantage of key scientific opportunities across all components of its structure and bring its resources to the challenge of reducing and ultimately eliminating health disparities. The inaugural comprehensive NIA Strategic Plan to Address Health Disparities is available at www.nia.nih.gov/strat-planhd/2000-2005. The NIA is working with other NIH Institutes and Centers to develop an overall strategy that, in total, will address the diseases and conditions that challenge older men and women. This plan does not address all health disparities but rather is a plan to address health disparities within the context of the congressionally mandated mission of the NIA.

The National Institute on Alcohol Abuse and Alcoholism

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

MISSION/VISION STATEMENT

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) provides leadership to the alcohol research community by directing, supporting, and conducting biomedical and behavioral research on the causes, consequences, treatment, and prevention of alcoholism and alcohol-related problems. The Institute conducts its programs primarily by supporting research grants, contracts, and training awards at colleges, universities, and other public and private research institutions nationwide. Important to the mission of the NIAAA is research designed to identify racial and ethnic disparities in the causes and consequences of alcohol-use disorders and to develop treatment and prevention strategies to ameliorate them. Research on alcohol problems in rural and economically disadvantaged populations also is important.

The special emphasis areas, objectives, and proposed action plans that follow compose an overall strategy to make progress towards NIAAA's goal of a greater understanding of the biological, behavioral, cultural, environmental, and ethnic factors that contribute to differences in alcohol-related problems. Through this understanding, we will devise more effective prevention and treatment approaches for everyone affected by alcohol-related problems.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Although NIAAA's plan to address health disparities includes many specific objectives, activities and approaches, there are five components or themes to the Institute's overall strategy.

I. **Encourage research on health disparities.** This strategy requires actively recruiting established alcohol researchers to address issues related to minority populations in their research. By highlighting disparities issues in our Requests for Applications (RFAs) and Program Announcements (PAs), we will signal our intention to support additional research on health disparities.

II. **Build the capacity of Historically Black Colleges and Universities (HBCUs) to conduct alcohol research and to contribute to our understanding of alcohol problems.** With the support of the National Center on Minority Health and Health Disparities (NCMHD), the NIAAA has pilot tested several approaches to establishing and improving the capacity to conduct alcohol research at HBCUs. Workshops, contracts, and cooperative agreements have been used to develop collaborative relationships between scientists/clinicians in HBCUs.

III. Develop a diverse research workforce by fostering recruitment and training of alcohol investigators across a broad spectrum of academic institutions, including those that are not research intensive and serve economically disadvantaged communities.

IV. **Bring resources to the alcohol research community.** This strategy is linked with strategic components I-III. Minority educators, health care professionals, clinicians, and investigators are integral to promoting health disparities research. Minority populations and study cohorts in minority intensive settings are also essential resources. The NIAAA will work to ensure the availability of these resources to those who conduct research in response to this plan.

V. Transfer research knowledge to practice and experiential/clinical knowledge to alcohol research. The NIAAA recognizes the need to ensure that this knowledge is transferred to those conducting health disparities research.

VI. Build multi-disciplinary, multi-ethnic collaborating teams to address specific research areas. With encouragement and co-funding from NCMHD, the NIAAA has developed an approach to establish interdisciplinary collaborative teams. The results of piloting this model for international collaborative research on fetal alcohol syndrome (FAS) is an example of the potential success of this approach. This strategy will be used for a number of research and training initiatives in the plan.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Prevention and Interventions for High Risk Groups

Research on the general population has identified a number of effective or promising strategies for preventing alcohol abuse and its consequences. These include implementation of public policies (Hingson et al., 2000); multi-component community, school, and family-based programs (Holder et al., 2000; Perry et al. , 1996); brief interventions for high-risk college students (Marlatt et al., 1995); a variety of communication/media strategies; and selected worksite and primary care interventions.

The Institute's top priority in this area is research to address underage drinking. Congress has charged the NIAAA with providing leadership in developing model longitudinal prevention/intervention community-based programs focusing on how individual families and school and community networks can help reduce underage drinking in rural and small urban areas. In developing these model programs, NIAAA is charged with recognizing the importance of other high-risk behaviors such as tobacco use, illegal drug use, risky sexual behavior, and psychological and parental risk factors for these problem behaviors. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2002 National Survey on Drug Use and Health, drinking rates among persons aged 12 to 17 are higher in non-metropolitan than in small and large metropolitan areas and highest in completely rural areas. For instance, the prevalence of lifetime drinking among 12- to 17-year-olds in completely rural areas is about 50 percent. Compared to youth living in more urbanized areas, youth aged 12 to 17 living in completely rural areas also had the highest rates of past year drinking (42%) and past month binge drinking (14%). Rates of tobacco product use and illicit drug use by 12- to 17-year-olds are also higher in more rural areas.

To address the research need for studies on practitioner-based interventions among rural youth, NIAAA collaborated with the Association of Academic Health Centers (AAHC) to convene an invitational advisory meeting on February 11, 2004. The AAHC is a national, non-profit organization dedicated to improving health by advancing the leadership of academic health centers in health professions education, biomedical and health services research, and health care delivery. The AAHC identified 20 community-based academic health centers that serve rural and medically underserved communities to participate in this meeting. Several of these centers are located in the Mississippi Delta region of the United States. The goal of the meeting was to solicit input regarding the feasibility of launching a research initiative to reduce high-risk behavior in rural areas by fostering working partnerships between academic health centers and their communities.

Although some prevention approaches have been shown to be effective among populations that include members of minority groups, it is unclear whether interventions specifically targeted toward particular minority groups would be even more beneficial than those designed to prevent alcohol problems in the general population. In addition, it is important to study whether and how key components of prevention strategies (such as community activation techniques) and critical precursors of behavioral change (such as alcohol expectancies or beliefs about the benefits and hazards of drinking) vary across racial/ethnic groups and in rural or low socioeconomic (low-SES) settings.

Alcohol-focused prevention research also has developed effective environmental strategies that are now being re-tested in minority urban neighborhoods. For example, community-based interventions have sought to alter zoning laws as a means of reducing alcohol-outlet densities and attendant problems in poor, ethnic minority communities. However, further study of such environmental problems and effective solutions is necessary.

Hingson, R., Heeren, T., and Winter, M. *Injury Prevention* 6:109-114, 2000.
Holder, H., Gruenewald, P.J., Ponicki, W.R., Treno, A.J., Grube, J.W., Saltz, R.F., Voas, R.B., Reynolds, R., Davis, J., Sanchez, L., Gaumont, G., and Roeper, P. *Journal of the American Medical Association* 284:2341-2347, 2000.
Perry, C.L., Williams, C.L., Veblen-Mortenson, S., Toomey, T.L., Komro, K.A., Anstine, P.S., McGovern, P.G., Finnegan, J.R., Forster, J.L., Wagenaar, A.C., and Wolfson, M. *American Journal of Public Health* 86:956-965, 1996.
Marlatt, G.A., Baer, J.S., and Larimer, M. In: Boyd, G., Howard, J., and Zucker, R.A., eds. *Alcohol Problems Among Adolescents: Current Directions in Prevention Research*, Hillsdale, New Jersey: Erlbaum Associates, 1995. pp. 147-172.

1.1.1 Objective One: Enhance Prevention of Alcohol Abuse and Alcoholism in Minority Communities

Develop research initiatives that address gaps in the current state of basic behavioral and applied knowledge on alcohol-focused prevention strategies that are effective for specified minority populations. Ascertain whether prevention interventions that have been proven effective in the general population are also effective for minority groups and subgroups.

1.1.1.1 Action Plan

Support projects to evaluate the current knowledge base and support future pre-intervention research to determine those aspects of minority drinking environments, patterns, and problems as well as expectancies, risk perceptions, community norms, values, and unique cultural factors that are likely to influence the outcomes of preventive intervention efforts.

Support studies to explore the ways that various prevention messages, information strategies, and emerging technologies can be tailored to address those social and cultural factors that increase risk for specific racial/ethnic minority groups and for those in rural or low-SES settings.

Timeline

FY2004 - Award support for four to six renewal and new studies.
FY2005 - Continue support for five to seven renewal and new projects on this topic.
FY2006 - Continue support for five to seven projects.
FY2007 - Continue support for three to five projects.
FY2008 - Review findings from projects.

Estimated Completion Date for Objective: FY2008

1.1.1.2 Performance Measures

1. Number of meetings/workshops/technical assistance programs convened to increase research on the effectiveness of alcohol prevention in minority communities.
2. Number of RFAs and PAs that: (a) include language encouraging new pre-intervention research on specific economically disadvantaged and racial/ethnic minorities' alcohol expectancies, risk perceptions, and unique cultural factors; and (b) encourage research on the social environments in which alcohol is consumed by these groups to enhance the design of effective prevention programs.

1.1.1.3 Outcome Measures

1. Number of new research grant applications submitted and number funded as the result of programmatic efforts including RFAs and PAs.
2. Number of journal articles, book chapters, reports, monographs, and other documents published on the topic of this action plan as a result of research supported by the NIAAA.

1.1.2 Objective Two: Expand Analysis of Extant Data on Effectiveness of Alcohol Research in Minority Populations

Improve our ability to prevent problems due to alcohol abuse and alcoholism in racial/ethnic minority communities. Continue to develop and expand strategic, coordinated, methodological, and conceptual approaches for evaluating prevention interventions in minority groups and subgroups.

1.1.2.1 Action Plan

Review and synthesize existing data on effectiveness of prevention interventions among minority populations, and based on the ongoing literature review, support future secondary analyses of data sets that contain minority-focused outcomes but have not yet been analyzed in terms of minority groups.

Timeline

FY2004 - Continue support for three to six new projects.
FY2005 - Continue support for projects; initiate two new secondary analysis projects.

Estimated Completion Date for Objective: FY2006

1.1.2.2 Performance Measures

1. Number of meetings/workshops/technical assistance programs convened that focus on increasing research on the effectiveness of alcohol prevention in minority communities, including the identification of data sets for future ethnic-group analyses, and eliciting suggestions for future secondary analyses of existing research data sets.
2. Number of RFAs and PAs that invite applications to further characterize the effects and effectiveness of prevention programs in minority populations and/or the effects of laws and policy decisions on minority populations.

1.1.2.3 Outcome Measures

1. The number of new secondary analysis research grant applications submitted and the number funded.
2. The number of journal articles, book chapters, reports, monographs, and other documents published as a result of the findings.
3. Instances of scientific findings disseminated through peer-reviewed journals and NIAAA publications or number and types of publications disseminated by NIAAA relevant to this action plan.

1.1.3 Objective Three: Promote Research to Prevent Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) Infection Among Individuals With Alcohol Problems in Minority Communities

Develop culturally relevant interventions for primary and secondary prevention of HIV/AIDS infection among alcohol abusers in ethnic minority communities.

1.1.3.1 Action Plan

Support studies to test the efficacy and effectiveness of prevention interventions including laws and policies, culturally sensitive family-based interventions, multi-component community interventions, and preventive interventions for specific minority and other high-risk groups with increased risk of HIV/AIDS infection.

Timeline

FY2004 - Continue support for six to eight ongoing projects; initiate four to eight new applications.
FY2005 - Continue support for projects; initiate four to eight new studies.
FY2006 - Continue support for 10 projects.
FY2007 - Continue support for eight projects.
FY2008 - Review findings from projects.

Estimated Completion Date for Objective: FY2008

1.1.3.2 Performance Measures

1. Number of meetings/workshops or technical assistance programs convened that were directed toward encouraging research on the effectiveness of various alcohol prevention strategies among individual minority communities.
2. Number of RFAs and PAs that solicit studies to further characterize the effects and effectiveness of prevention programs in minority populations and/or the effects of laws and policy decisions on minority populations at risk for HIV/AIDS.

1.1.3.3 Outcome Measures

1. The number of journal articles, book chapters, reports, monographs, and other documents that are published relevant to this action plan due to research support from NIAAA.
2. The number of scientific conference presentations, symposia, and other dissemination activities that are conducted as a result of this action plan.
3. The number and type of publications disseminated by NIAAA relevant to this action plan.

1.1.4 Objective Four: Enhance Research Focused on Prevention of Alcohol Problems in Rural Communities

Develop and evaluate culturally sensitive prevention interventions for specific minority populations and for areas where rural populations are at high risk.

1.1.4.1 Action Plan

Develop, test, and evaluate strategies for improving prevention interventions in rural communities. Encourage and support partnerships between experienced prevention researchers and academic health centers or other community groups to design effective prevention and intervention approaches.

Timeline

FY2004 - Identify NIAAA scientists experienced in developing, testing, and evaluating prevention programs**.**
FY2005 - Encourage academic health centers to form partnerships with experienced NIAAA scientists to produce effective prevention and intervention strategies for rural communities. Identify target rural communities; fund two to three partnerships.
FY2006 - Continue support for partnerships to develop and test effective prevention and intervention strategies for rural communities.
FY2007 - Continue support for two projects.
FY2008 - Identify interventions that are feasible and acceptable.

Estimated Completion Date for Objective: FY2010

1.1.4.2 Performance Measures

1. Number of productive and constructive "partnerships" supported.
2. Number of academic health centers that develop research infrastructure capacity to partner effectively with experienced research scientists to conduct studies of prevention interventions.
3. Number of communities participating in developing baseline indices for research.

1.1.4.3 Outcome Measures

1. Increased awareness in target communities of the need to address high-risk behaviors.
2. Increased capacity among academic health center staff to meet community needs for alcohol interventions.
3. Increased development and implementation of feasible, acceptable, and sustainable interventions aimed at prevention, treatment, and recovery from underage drinking, smoking, and other high-risk behaviors.
4. A measurable decrease in high-risk behavior in an underage cohort in the target community.

5. Number of publications in the peer-reviewed literature.

1.2 Area of Emphasis Two: Alcoholism Treatment and Health Services Research

Contemporary alcohol treatment providers recognize increasing diversity in American society and appreciate the potential importance of race and ethnicity in response to treatment. However, the number of models that incorporate diversity in the context of treatment conceptualization (Castro & Garfinkle, 2003) and health services research is limited. A workshop proposed in NIAAA's previous Health Disparities Strategic Plan was convened in September 2002. The "NIAAA Workshop on Treatment Research Priorities and Health Disparities" included 15 experts from the treatment research field who presented epidemiologic and treatment outcome data on Hispanic, African American, Alaska Native, and American Indian populations. The results of this workshop were published in *Alcoholism: Clinical and Experimental Research*, Volume 27(8).

Subsequent to discussions at the workshop, one participant conducted a secondary analysis of Project MATCH data to examine whether treatments tailored to the health needs of minority populations would be more effective than generic treatments. Project MATCH, a multi-site NIAAA-sponsored clinical trial, previously found no differences in treatment outcomes among minority participants as compared to non-Hispanic Whites. Additional examination of the mediators of treatment outcome showed that there are indeed culturally relevant factors that influence the process or "path" to treatment outcomes as a function of ethnicity (Lowman & Le Fauve, 2003). Studies of the social and cultural factors that may influence motivation for treatment, adherence to treatment, and improved treatment outcomes among minority populations are essential to advance understanding in this area. Further, research is needed to validate knowledge about alcoholism treatment gained in studies with non-minority patients, and to extend knowledge about treatment effects in minority populations.

Access, utilization, cost effectiveness, and cost benefit of alcohol abuse and alcoholism treatments also are significant factors in the disproportionate adverse consequences of alcoholism in certain populations. In addition, the absence of insurance coverage for alcoholism treatment may be an important barrier to treatment access, while the lack of culturally appropriate aftercare may similarly impede the effective delivery of treatment to non-majority patients. Although access to treatment for some minority populations has not been assessed widely, some factors have been studied.

Castro, F.G. and Garfinkle, J. *Alcoholism: Clinical and Experimental Research* 27:1318-1320, 2003.
Le Fauve, C.E., Lowman, C., Litten, R.Z., Mattson, M.E. *Alcoholism: Clinical and Experimental Research* 27:1318-1320, 2003.
Lowman C. and Le Fauve, C.E. *Alcoholism: Clinical and Experimental Research* 27:1324-1326, 2003.

1.2.1 Objective One: Improve Our Understanding of the Impact of Race, Ethnicity and Other Sociocultural Factors on Treatment

Continue and expand a research program that examines the influence of race/ethnicity and associated sociocultural factors on health disparities. Such research should include investigation of their combined impact on the effectiveness of treatment and health services delivery for alcohol abuse and alcoholism in minority populations. Where appropriate, develop new, culturally sensitive treatments for racial and ethnic minorities and for those who are economically disadvantaged. Develop and improve the existing program of research for special subgroups within racially and ethnically diverse populations, such as persons with concurrent psychiatric comorbidity, those with alcohol-related medical comorbidity and/or HIV/AIDS, individuals in the criminal justice system, adolescents, the elderly, and pregnant alcoholic women who place their children at risk for FAS.

1.2.1.1 Action Plan

Support research to evaluate the effectiveness of established behavioral/psychosocial and pharmacological treatments for alcohol abuse and alcoholism in minority populations and to develop and test new approaches hypothesized to enhance treatment outcomes in these populations. Fund research to critique reliability and validity of culturally relevant constructs and measures (e.g., demographic, economic, and sociocultural), and encourage the development of new indices where appropriate. Participate in NIAAA-wide RFAs wherever possible to achieve these objectives. Conduct a literature review to identify the nature and scope of what is currently known about the influence on alcoholism treatment outcomes of race/ethnicity and associated sociocultural variables.

Continue research projects to identify social and cultural factors that influence motivation for treatment, adherence to treatment, and treatment outcomes; replicate and test in minority populations the relative effectiveness of established treatments for alcoholism, including Brief Intervention, Cognitive Behavioral Therapy, Motivational Enhancement Therapy, Twelve-Step Facilitation Therapy, or combinations of these with pharmacological treatment (e.g., naltrexone, disulfiram); test and implement “customized” treatment strategies to increase motivation, improve treatment entry, promote treatment adherence, and address relapse; develop and evaluate new medications and behavioral/psychosocial therapies that are tailored to the needs of specific racial/ethnic populations. Conduct grant writing and mentoring workshops to provide technical assistance to potential applicants where appropriate.

Timeline

FY2004 - Continue support of ongoing projects; award two new research project grants, career development awards, and/or supplements; continue to solicit research applications; disseminate information on scientific findings and other research issues.
FY2005 - Continue support of ongoing projects; award one to three new research project grants and follow priorities specified above for FY2004.

FY2006 - Continue support for ongoing projects; award one to three new research project grants and follow priorities specified above for FY2004. Conduct grant writing workshops and use other strategies to provide technical assistance for potential applicants.
FY2007 - Continue support for ongoing projects; convene meeting of investigators to review important research findings, identify and address common methodological problems, and recommend directions for future research.
FY2008 - Continue support for ongoing projects; publish and disseminate research findings. Develop and publish updated statement of priorities. Award one to three new research project grants based on new priorities.

Estimated Completion Date for Objective: FY2010

1.2.1.2 Performance Measures

1. Number of working groups convened to develop recommendations for future directions in research.
2. Number of literature reviews conducted.
3. Number of PAs and RFAs that solicit treatment and health services research among ethnic and economically disadvantaged populations or that address alcoholism treatment issues disproportionately affecting these populations.
4. Number of grant writing and mentoring workshops convened.
5. Number of brochures, fact sheets, web pages, and other publications developed to promote effective alcoholism treatment among ethnic minority and economically disadvantaged populations.

1.2.1.3 Outcome Measures

1. Number of research project grants and contracts awarded that address issues of health disparities and the treatment of alcohol abuse and alcoholism.
2. Number of relevant journal articles, book chapters, reports, monographs, and other documents that are published from projects supported by NIAAA.
3. Number of public information documents, scientific conference presentations, symposia, and other research dissemination activities that convey results of research supported under this objective.
4. Evidence of increased use in the community of research findings from NIAAA-supported research.

1.2.2 Objective Two: Examine the Effect of Access to Alcoholism Treatment on Health Disparities

Evaluate the current knowledge base and support future research on how to meet special treatment and service needs for alcohol problems in minority subgroups, including persons with concurrent psychiatric comorbidity, alcohol-related medical comorbidity, and/or HIV/AIDS, as well as individuals in the criminal justice system, adolescents, the elderly, and pregnant alcoholic women who place their children at risk for FAS.

1.2.2.1 Action Plan

Support research to learn how to improve access to and utilization of alcohol treatment services (including access to health coverage) in targeted economically disadvantaged and racial/ethnic minority subgroups. Determine how to increase the cost effectiveness of services for specific racial/ethnic and low-SES groups. Evaluate the current knowledge base and support research on understudied issues related to disparities in access to and utilization of treatment for alcohol abuse and alcoholism (including disparities in coverage under health insurance policies). Investigate disparities in the cost effectiveness and cost benefit of treatments tailored to specific socioeconomic, racial, and ethnic minority groups. Publish results of a literature review, workshop proceedings, and research findings in peer-reviewed journals and NIAAA publications. Support projects that evaluate interventions and services designed to improve alcohol-related treatment outcomes in minority subgroups. Support research to assess the effectiveness of established treatments through secondary analyses and to develop and evaluate new treatments, or combinations of treatments, hypothesized to meet the special needs of minority and economically disadvantaged subgroups. Support research to examine and reduce disparities in access to and utilization of treatment.

Timeline

FY2004 - Continue support of ongoing projects; award one to three new research project grants, career development awards, and/or supplements; continue to solicit research applications; disseminate information on scientific findings and other research issues.
FY2005 - Continue support for ongoing health services projects; award one to two new research project grants and follow priorities specified above for FY2004.
FY2006 - Continue support for ongoing health services projects; award one to three new research project grants and follow priorities specified above for FY2004.
FY2007 - Continue support for ongoing health services projects; convene meeting of investigators to review important research findings, identify and address common methodological problems, and recommend directions for future research. Publish and disseminate findings.
FY2008 - Continue support for ongoing projects. Develop and publish updated statement of priorities related to research on best practices for improving alcohol treatment outcomes among ethnically diverse subgroups at high risk for alcohol abuse and dependence. Include access to care for rural, economically disadvantaged and minority subpopulations in RFAs or PAs based on new priorities. Award one to three new research projects, career development awards, and/or diversity supplements based on new priorities. Continue support for ongoing health services projects. Develop and publish updated statement of priorities related to research on racial/ethnic disparities in access to, utilization of, and cost/cost effectiveness of alcohol treatment services. Include findings that reflect new priorities in RFA or PA.

Estimated Completion Date for Objective: FY2010

1.2.2.2 Performance Measures

1. Number of working groups convened with health disparities and alcohol health services research experts.
2. Number of literature reviews conducted to identify the nature and scope of what is currently known about the influence of income level and racial/ethnic group differences on access to, utilization of, and cost of alcohol treatment services.
3. Number of PAs and RFAs issued that address alcoholism, health services, and health disparities issues.
4. Number of grant writing and mentoring workshops convened.
5. Number of brochures, fact sheets, web pages, and other publications produced by NIAAA staff.
6. Number of working groups convened to critique the status of treatment and health services research on minority and socioeconomic subgroups.
7. Number of major gaps identified in research on the relationship between race/ethnicity, health disparities, and alcoholism treatment outcomes.

1.2.2.3 Outcome Measures

1. Number of research project grants and contracts that address issues of health disparities and access to treatment, utilization of treatment, and cost/cost effectiveness of treatment.
2. Number of journal articles, book chapters, reports, monographs, and other documents published that are relevant to this action plan and that ensue from NIAAA-supported activities.
3. The number and type of research information publications disseminated by NIAAA and the number of scientific conference presentations, symposia, and other research dissemination activities that are conducted relevant to the results of this action plan during each fiscal year.
4. Number of research project grants that evaluate interventions and services designed to improve alcohol-related treatment outcomes in minority subgroups that may have special treatment and service needs.
5. The number and type of publications disseminated by NIAAA and the number of scientific conference presentations, symposia, and other research dissemination activities that are conducted relevant to the results of this action plan during each fiscal year.

1.3 Area of Emphasis Three: Adverse Pregnancy and Infant Health Outcomes Related to Alcohol Use

Fetal Alcohol Syndrome (FAS) is the leading cause of preventable birth defects in the United States. It produces lifelong neurological, behavioral, and cognitive deficits that prevent normal learning and socialization. It also causes organ abnormalities, other physical malformations, and growth deficiency. Some minority groups suffer far more from FAS than other groups. For example, data from the Centers for Disease Control and Prevention indicate that FAS incidence appears to be seven times higher among African Americans than Whites, whereas some American Indian communities have up to a 10-fold greater incidence of FAS than the general population.

Fetal Alcohol Spectrum Disorders (FASD) is the term used to describe the range of conditions caused by maternal alcohol consumption. For example, the incidence of alcohol-related neurodevelopmental disorders in children exposed to alcohol during prenatal development is several times higher than that of the physical malformations of FAS. Further research is needed to identify why ethnic minority groups appear more vulnerable to the neuronal and behavioral effects of prenatal ethanol exposure. Research to understand the developmental course of these effects and identify the genetic and environmental variables that produce symptoms is also important.

The problems inherent in making progress toward the understanding of the underlying mechanisms of FASD and their diagnosis, treatment, and prevention are many. Among them are the small numbers of similar age cases in any one site, the need for close collaboration between basic and clinical research scientists, and the need to exchange information quickly from research to practice and to transfer experiential knowledge from practice to research. NIAAA proposes to expand efforts to accomplish this and to address FASD-related issues by developing collaborative multi-ethnic, multi-disciplinary teams. This approach was found to be exceptionally successful and scientifically productive in an NIAAA/Office of Research on Minority Health (now National Center for Minority Health and Health Disparities [NCMHD])-supported study of FASD conducted in South Africa, which yielded numerous co-authored publications and presentations.

In addition, research presented in a recent working group meeting co-sponsored by the National Institute of Child Health and Human Development (NICHD), NIAAA, and the Office of Rare Diseases revealed that there is a high incidence of prenatal alcohol consumption in certain minority communities experiencing high incidences of sudden infant death syndrome (SIDS) and stillbirths. The working group included representatives of the American Indian and Alaska Native communities as well as SIDS and alcohol research scientists. The communities assisted in planning a research agenda to address the issues presented.

Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report* 51:433-435, 2002.
National Institute on Alcohol Abuse and Alcoholism. Alcohol-Related Birth Defects: An Update. *Alcohol Research and Health* 25:149-210, 2001.
Jacobson, J.L., Jacobson, S.W., Sokol, R.J., Martier, S.S., Ager, J.W., and Kaplan-Estrin, M.G. *Alcoholism: Clinical and Experimental Research* 17:174-183, 1993.

1.3.1 Objective One: Develop Interventions to Prevent and Mitigate FASD in High-Risk and Minority Populations

Develop, test, and evaluate targeted strategies to prevent or decrease maternal drinking of alcohol. Develop, test, and evaluate interventions to prevent or otherwise mitigate behavioral problems (including alcohol use and abuse) among affected children and youth.

1.3.1.1 Action Plan

Stimulate research that develops and tests interventions to prevent maternal drinking of alcohol and FASD among high-risk minority and low-SES populations. Encourage investigators to develop and test interventions to prevent behavioral problems (including alcohol use/abuse) among affected children.

Timeline

FY2004 - Continue to support the seven projects funded in FY2003; fund two or three additional projects. Encourage poster presentations and articles on the effectiveness of preventive interventions from investigators who were funded before FY2002.
FY2005 - Continue support for projects funded in FY2004 and fund one or two new projects on this topic. Where appropriate, encourage requests for diversity supplements to the studies funded in FY2004 and 2005. Fund two new diversity supplements.
FY2006 - Continue funding for ongoing projects. Encourage poster presentations and articles that summarize baseline and follow-up data collected thus far across the various studies. Convene a meeting of all NIAAA-funded investigators who have conducted preventive intervention research on FASD among minority and non-minority populations to determine what strategies work best for whom. Fund at least two new intervention studies among minority populations.
FY2007 - Continue support for projects funded in FY2004-2006. Publish and disseminate important findings to date using appropriate media (*Alcohol Alert*, Director’s Report, etc.).
FY2008 - Continue support for projects funded in FY2004-2006. Convene a meeting of funded investigators to review important research findings, identify the policy and practice implications of those findings, and recommend directions for future research.

Estimated Completion Date for Objective: FY2008

1.3.1.2 Performance Measures

1. Number of RFAs and PAs incorporating language to stimulate research among ethnically diverse populations concerning the prevention of maternal drinking, consequent FASD, and behavioral problems (including alcohol abuse) among children with alcohol-related birth defects.
2. Number of meetings/workshops/technical assistance programs convened to increase research in the area of health disparities in FASD.

1.3.1.3 Outcome Measures

1. Number of new grants funded for research on health disparities in FASD.
2. Number of supplements funded for research on health disparities in FASD.
3. Number and types of prevention strategies being tested or retested.
4. Number of publications in peer-reviewed journals resulting from research supported by NIAAA.

1.3.2 Objective Two: Determine Biological, Genetic, and Environmental Factors That May Contribute to Disparate Neuropsychological and Cognitive Outcomes Due to Maternal Alcohol Consumption

Determine biological, genetic, and environmental risk factors that lead to the disproportionately high incidence of FAS and other adverse pregnancy outcomes due to alcohol consumption in African American, Alaska Native, and American Indian populations. Investigate possible causes for the disproportionate impact of prenatal alcohol consumption on certain groups of individuals within minority communities by conducting research on the genetics and metabolism of the mother-child unit, maternal nutrition, and other environmental factors that may affect vulnerability to fetal injury. Determine core deficits in specific age groups of affected minority children. Identify and evaluate pharmacologic and behavioral therapies designed to mitigate the effects of FASD in minority children and develop interventions that improve cognitive function. Identify and evaluate potential therapies for preventing fetal injury. Determine the extent to which high rates of alcohol consumption during pregnancy contribute to the high incidences of stillbirths, infant mortality, and SIDS among some minority groups. Determine if there is common pathology for FAS, stillbirths, and other adverse pregnancy outcomes.

1.3.2.1 Action Plan

Develop a multi-site, multidisciplinary initiative to integrate basic biological and clinical research on FASD and to accelerate translation of research findings to practice. Involve multidisciplinary teams of alcohol research scientists collaborating with minority and underrepresented communities, scientists from minority and underrepresented communities, and scientists at HBCUs. Increase research funding for studies that involve investigators and clinicians from diverse populations in determining risk factors for adverse pregnancy outcomes.

Support studies to identify factors responsible for differential susceptibility to FAS and other adverse pregnancy outcomes due to alcohol consumption. Fund projects to evaluate alcohol-metabolizing enzyme variants among minority populations for their capacity to eliminate alcohol from the body. Identify environmental factors that predict alcohol-related adverse birth outcomes. Collaborate with the NICHD in developing methods for evaluating the role of alcohol in the pathophysiology of SIDS and stillbirths.

Identify specific emotional and cognitive deficits associated with lower levels of prenatal exposure to alcohol. Identify individuals more vulnerable to these effects. Examine specific measures of learning, memory, emotional functioning, and brain structure in children exposed to high prenatal alcohol levels. Obtain electrophysiological data on these children. Assess African American and South African children to further characterize the distinctive pattern of alcohol-related attention deficits and to examine the relationship between prenatal alcohol exposure and socio-emotional function, psychopathology, and adolescent alcohol and drug use. Re-examine MRIs (Magnetic Resonance Images) and use other or newly developed methods to identify additional brain structures affected by prenatal alcohol exposure. Compare these images with neuropsychological test outcomes previously obtained in White, African American, and American Indian subjects.

Timeline

FY2004 - Continue support for projects funded in FY2003 to determine risk factors for alcohol-related fetal injury and to ameliorate the impact of such injury. Continue research. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.

FY2005 - Continue support for projects funded in FY2003. Where appropriate, encourage requests for diversity supplements to the studies funded in FY2003. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.

FY2006 - Continue support for projects funded in FY2003. Initiate support for new projects. Convene meetings of investigators from multi-site programs to share findings, identify and address common methodological problems, and recommend future directions. Continue support for ongoing projects if warranted by progress made during Phase I of projects. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.

FY2007 - Continue support for projects funded in FY2006. Publish and disseminate findings from Phase I of both projects. In partnership with SAMHSA, add an education component to accelerate translation of research findings to practice, particularly in communities at high risk for alcohol-related adverse pregnancy outcomes. Translation activities will include a workshop for health care professionals, educators, and educational psychologists to develop educational materials that will enhance communication across disciplines and accelerate the identification and delivery of services to affected children. Submit abstracts to national and international conferences and present data and discuss results at invited seminars, lectures, etc. Prepare manuscripts for submission to peer-reviewed journals.

FY2008 - Continue support for projects funded in FY2006. Continue information dissemination and translation activities. Assess progress in meeting with collaborators; continue to support projects, ensure publication of findings.

Estimated Completion Date for Objective: FY2008

1.3.2.2 Performance Measures

1. Number of NIAAA and NICHD jointly supported projects to evaluate the role of maternal alcohol consumption in the occurrence of stillbirths, SIDS, and other causes of infant mortality.
2. Number of collaborative studies underway to study FAS using national and international cohorts of families with similar-aged children.
3. Number of significant research findings related to this project (i.e., enhancement of methods used in studies).
4. Number of abstracts submitted to meetings, conferences, and similar venues.
5. Number of manuscripts submitted to peer-reviewed journals.

1.3.2.3 Outcome Measures

1. Number of basic and clinical publications identifying neuropsychological and behavioral consequences of fetal alcohol exposure in minority populations.
2. Number of publications and meeting presentations examining the role of maternal alcohol consumption in stillbirth, SIDS, and other causes of infant mortality.
3. Number of publications and meeting presentations resulting from collaborative, integrative studies.
4. Number of communities with demonstrated benefits resulting from collaborative studies on the role of alcohol in adverse pregnancy outcomes, as measured by improvements in infant mortality rates, continuing approval of projects, and involvement in working group meetings, among other indicators.
5. Number of additional high-quality grant applications that address health disparities objectives for the neurobiological and behavioral consequences of prenatal ethanol exposure.

1.4 Area of Emphasis Four: Incidence, Prevalence, and Patterns of Alcohol Use, Abuse, and Effects

Detailed epidemiologic information about patterns of alcohol use and alcohol-related problems among various racial and ethnic minorities is fundamental to effective efforts to address alcohol-related health disparities. Epidemiological research increases understanding of the nature and scope of these disparities and generates hypotheses for subsequent research.

Alcohol consumption is associated with a broad range of adverse health and social consequences, both acute (e.g., traffic deaths, other injuries) and chronic (e.g., alcohol dependence, liver damage, stroke, cancers of the mouth and esophagus). The scope and variety of these problems are attributable to differences in the amount, duration, and patterns of alcohol consumption; differences in genetic vulnerability to particular alcohol-related consequences; and differences in economic, social, and other environmental factors.

NATIONAL **I**NSTITUTE ON **A**LCOHOL **A**BUSE AND **A**LCOHOLISM

Over the past several decades, epidemiologic research has documented substantial variation in patterns of alcohol consumption and differential consequences of that consumption across various racial and ethnic groups. Recent studies have continued to indicate important differences (e.g., Caetano, 2003; Spicer, 2003). We also have learned that racial, ethnic, and cultural disparities in alcohol-related problems vary with the problem under consideration. For example: the alcohol-related death rate (i.e., for all categories of alcohol-related mortality combined) is higher among African Americans than Whites (U.S. Alcohol Epidemiologic Data Reference Manual, 1996); cirrhosis death rates are very high among White Americans of Hispanic origin, lower among non-Hispanic African Americans, and lower still among non-Hispanic Whites (Stinson, Grant, & Dufour, 2001); alcohol-related traffic deaths are many times more frequent (per 100,000 population) among American Indians or Alaska Natives than among other minority populations (U.S. Department of Health and Human Services, 2000); the incidence of FAS appears to be higher in some African American and American Indian communities than in the general population (Stratton, Howe, & Battaglia, 1996); and recent increases in risky drinking behavior (i.e., drinking and driving) have been reported among Hispanics (Voas et al., 1998).

Although substantial progress has been made, much remains to be understood if we are to adequately describe differential drinking patterns, their consequences, and associated risk and protective factors by race and ethnicity. Disparities in the sequelae of alcohol consumption may be related to biological and/or environmental factors as well as their complex interactions. Thus, while genetic differences in alcohol metabolism or central nervous system reactivity to alcohol may be important risk factors, so too may be differences in access to health care. Research on the interaction of race, ethnicity, culture, and environment as they affect patterns of alcohol consumption also may provide valuable information about the underlying causes of the differential alcohol-related pathology found in some minority populations and subpopulations.

Continuing to develop scientific knowledge about the incidence, prevalence, etiology, and course of alcohol-related problems among minority populations and subpopulations is clearly of central importance to reduction of alcohol-related disparities. The nation’s increasing cultural and ethnic diversity adds to the complexity of this task but affords opportunities for significant new insights. Several applications have been funded to conduct secondary analyses of existing data sets in which the primary focus has been health disparities-related issues. This has provided a low-cost opportunity to expand our knowledge base of health disparities concerns by using existing data bases.

NIAAA (with co-funding from NCMHD) recently has funded two new initiatives that promise to expand our knowledge of the epidemiology of ethnic and racial minority use of alcohol. One national study will survey Hispanics, with specific attempts to sample from specific national origins groups (e.g., Mexican, Puerto Rican, Cuban, and Central and South American). This will provide the first broad-based information on alcohol use among the increasingly diverse Hispanic population. NIAAA is also sponsoring developmental efforts to conduct epidemiologic surveys of Native Hawaiians, Pacific Islanders, and Asian Americans in Hawaii.

Caetano, R. *Alcoholism: Clinical and Experimental Research* 27:1337-1339, 2003.
Spicer, P., Beals, J., Croy, C.D., Mitchell, C.M., Novins, D.K., Moore L., and Manson, S.M. *Alcoholism: Clinical and Experimental Research* 27:11:1785-1797, 2003.
Stinson, F.S., Grant, B.F., and Dufour, M.C. *Alcoholism: Clinical and Experimental Research* 25(8):1181-1187, 2001.
Stratton, K., Howe, C., and Battaglia, F., eds. *Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention, and Treatment*. Washington, DC: National Academy Press, 1996.
U.S. Department of Health and Human Services. *Healthy People 2010*: Volume II. Objectives for Improving Health. Washington, DC: U.S. Government Printing Office, November 2000, p. 26-13.
National Institute on Alcohol Abuse and Alcoholism. *State Trends in Alcohol-Related Mortality, 1979-92. U.S. Alcohol Epidemiologic Data Reference Manual, Volume 5, First Edition.* Bethesda, MD: National Institute on Alcohol Abuse and Alcoholism. NIH Publication No. 96-4174, 1996.
Voas, R.B., Wells, J., Lestina, D., Williams, A., and Greene, M. *Accident Analysis & Prevention* 30:267-275, 1998.

1.4.1 Objective One: Assess Changes in the Prevalence of Alcohol Disorders and Disability in the United States

The aim of this objective is to ascertain patterns of alcohol use and to determine the incidence and prevalence of alcohol dependence and abuse and their associated disabilities in the U.S. general population and its racial/ethnic subgroups.

1.4.1.1 Action Plan

Conduct a nationally representative longitudinal survey of 48,000 individuals, with African Americans and Hispanics oversampled, to derive more precise estimates of major alcohol-related variables. This National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) will also include Alaska Natives and Native Hawaiians. (Data were collected in FY2001-2002 and will be collected again in FY2004.)

Timeline

FY2004-2005 - Finish Wave 2 interviews.
FY2005-2006 - Analyze Wave 2 data.
FY2007 - Release public use tape (Wave 2 data).

Estimated Completion Date for Objective: FY2007

1.4.1.2 Performance Measures

1. Number of persons interviewed; the Wave 2 target number is 39,654.
2. Percent of respondents who are African-American (target: 19%).

3. Percent of respondents who are Hispanic (target: 19%).

1.4.1.3 Outcome Measures

1. Number of publications based on NESARC Wave 2 data that focus on racial/ethnic groups.
2. Number of publications based on NESARC Wave 2 data that contribute to development of national policy objectives.
3. Numbers of presentations at professional conferences based on NESARC Wave 2 data that focus on racial/ethnic and other groups affected disproportionately by alcohol.

1.4.2 Objective Two: Improve Our Knowledge of Differential Patterns of Alcohol Consumption, Use, and Abuse Among Racial/Ethnic Minority and Disadvantaged Populations and Subgroups

Where appropriate, maintain and expand scientific research about patterns of alcohol consumption and alcohol-related problems within specific minority populations (e.g., African Americans, Hispanics, Asians/Pacific Islanders, and low-SES and rural populations) and subgroups of these populations (e.g., Hispanics of Mexican origin, Asians of Korean origin).

1.4.2.1 Action Plan

Continue to support existing grants and increase the number of grants for alcohol-related epidemiologic research focused on specific minority populations and subgroups of these populations. Continue to encourage secondary analysis of existing data sets that focus on health disparities.

Timeline

FY2004 - Renew continuing grants and solicit relevant new grant applications.
FY2005 - Award three to four new or renewal grants.
FY2006 - Continue support for three to four grants.
FY2007 - Continue support for three to four grants; award two new grants.
FY2008 - Continue support for five to six grants.

Estimated Completion Date for Objective: Ongoing

1.4.2.2 Performance Measures

1. Number of RFAs/PAs soliciting research on the epidemiology of alcohol problems among racial/ethnic minority and disadvantaged populations and subgroups.
2. Number of scientific meetings/workshops in which NIAAA staff participate and encourage applications in this area.

3. Number of potential grant applicants contacted directly or through professional/scientific organizations.

1.4.2.3 Outcome Measures

1. Number of relevant grant applications received.
2. Number of grants awarded.
3. Number of presentations at national meetings and published abstracts resulting from NIAAA-supported research.
4. Number of publications in peer-reviewed journals resulting from awarded grants.

1.5 Area of Emphasis Five: Biomedical Risk Factors That Contribute to Disparities in the Toxic Effects of Alcohol on Organ Systems

Genetics: Recent data suggest that ethnic groups exhibit genetic diversity in their biologic sensitivity to alcohol. Variations have been observed between activity levels of the alcohol metabolizing enzymes prevalent among Asian Americans, African Americans, Mexican Americans, and Caucasians. These potential differences in alcohol sensitivity may result, in part, from genetic differences in alcohol metabolizing enzymes.

Different minority populations also may have genetic traits that either increase or decrease their susceptibility to alcohol-mediated tissue damage. Evidence suggests that genetic factors may predispose members of particular minority groups to a number of medical complications related to alcoholism, including damage to the liver, heart, pancreas, brain, and central nervous system. Studies are needed to determine whether other factors interact with genetic variations in metabolizing enzymes to produce ethnic differences in rates of organ damage. Likewise, additional research is needed to integrate specific genetic, physiologic, and pathologic processes contributing to the high risk for alcoholism among certain populations and subgroups. Measurements of the physiological and pathological outcomes of gene expression will yield more refined markers (e.g., specific physiological traits) that indicate genetic ethnic differences in sensitivity to alcohol.

Cirrhosis: Approximately 50 percent of all deaths due to liver cirrhosis, the tenth-leading cause of death in the United States, are alcohol related. Although the death rate due to alcohol-related cirrhosis has been dropping in recent years among African American men, it still was greater than that among Caucasian males as recently as 1997 (Stinson et al., 2001).

Cardiomyopathy: Chronic alcohol abuse can result in alcoholic cardiomyopathy, and there too, disparities appear to exist. One study ascribed the differences in survival rates of African American (71%) and Caucasian (92%) cardiomyopathy patients to socioeconomic factors, but another shows that a serum protein variant (transthyretin Ile 122), which is more prevalent in African Americans, is associated with cardiac disease (Afolabi et al, 2000). The role heavy alcohol consumption plays in cardiomyopathy among African Americans is not known. Similarly, the role alcohol plays in inducing hypertension in hypertension-prone African Americans merits further investigation.

Pancreatitis: This difficult-to-treat, potentially fatal inflammation of the pancreas is more prevalent among African Americans, both men and women, than Caucasians. This disparity may be related to dietary factors, type and quantity of alcohol consumed, or other factors that need to be determined.

Interactions with immune system and immune–mediated organ damage: Alcohol causes an increased absorption of endotoxin from microorganisms, and this has been shown to be injurious to the liver and other organs. This cellular injury may be mediated by production of inflammatory cytokines and chemokines, and may be unopposed since the immune response is modulated by alcohol.

HIV/AIDS: Given an incidence of AIDS 21-fold higher among African American women and sevenfold higher among Hispanic women compared with Caucasians, there is a significant disparity in exposure rates among minority children. Alcohol use has well-documented adverse effects on reproductive and immune function in women, and perinatal alcohol exposure adversely affects the developing immune system. Emerging evidence suggests that maternal alcohol use may exacerbate negative birth outcomes associated with perinatal HIV transmission. Studies are urgently needed to evaluate the prevalence and patterns of alcohol use among pregnant women infected with HIV-1; the impact of alcohol use on HIV transmission, immune status, and disease progression in mothers and their children; and the impact of alcohol use on the efficacy and metabolic complications of highly active antiretroviral therapy usage.

Afolabi, I., Hamidi Asl, K., Nakamura, M., Jacobs, P., Hendrie, H., and Benson, M.D. *Amyloid* 7:121-125, 2000.
CDCP, *HIV/AIDS Surveillance Report* 11:1-44, 1999
Russo, D., Purohit, V., Foudin, L., and Salin, M. *Alcohol* 32:37-43, 2004.
Stinson, F.S., Grant, B.F., and Dufour, M.C., *Alcoholism: Clinical and Experimental Research* 25:1181-87, 2001.

1.5.1 Objective One: Determine Risk Factors for Organ Damage and Alcohol Dependence in Certain Minority Communities and Disadvantaged Populations Using Genetic Parameters

Determine specific genetic factors that may increase risk for alcohol-induced organ damage in certain racial or ethnic groups. Determine how known differences in alcohol-metabolizing enzymes interact with other variables to influence alcohol consumption patterns in minority communities and disadvantaged populations. Study genetic or genetic-environmental interactions (e.g., dietary factors) that may increase our understanding of the increased vulnerability of some minority groups to alcoholic liver disease (ALD) and other disorders. Study the mechanism of onset and disease progression in groups with different survival rates for cardiomyopathy, pancreatitis, and other organ system diseases due to alcohol consumption.

Develop interventions that address those mechanisms.

1.5.1.1 Action Plan

Encourage submission of applications for biomedical research that identifies alcohol's effects on mechanisms and processes that cause health disparities in racial and ethnic minority and other populations. Support the involvement of students, including ethnically diverse students, and scientists through supplements and fellowships. Stimulate research to identify mechanisms that explain the onset and progression in cardiomyopathy, pancreatitis, and other organ system damage due to alcohol consumption in groups with disparities in survival rates.

Timeline

FY2004 - Publish results of health disparities workshop.
FY2005 - Encourage applications for biomedical research on health disparities. Continue support for ongoing projects.
FY2006 - Continue support for projects.
FY2007 - Encourage researchers to convene a workshop/symposium/working group composed of trans- and inter-institute, agency, academic, and business individuals to discuss recent scientific advances in integrative basic medical science of health disparities and translation of results from bench to bedside.
FY2008 - Post results on appropriate web sites and publish results from the working group in an appropriate journal.

Estimated Completion Date for Objective: FY2008

1.5.1.2 Performance Measures

1. Number of applications received that address biomedical research objectives in health disparities.
2. Percentage of NIAAA program administrators proactively recruiting investigators to respond to health disparities solicitations.
3. Number of contacts with grantees at meetings/workshops to monitor progress and identify research opportunities.
4. Publication of scientific results in peer-reviewed journals.

1.5.1.3 Outcome Measures

1. Number of additional high-quality applications that address health disparities objectives for basic research.

2. Number of basic and clinical publications on increased susceptibility to alcoholic liver disease, cardiomyopathy, pancreatitis, and other adverse medical consequences of alcohol abuse and alcoholism observed in minority and disparity populations.

1.5.2 Objective Two: Determine the Impact of Alcohol on the Susceptibility to HIV/AIDS and Perinatal HIV Infection

Determine specific pathogenic factors that may increase risk for HIV and organ damage in alcohol-dependent persons in certain minority groups. Determine alcohol's effects on HIV infection in alcohol abusers and pregnant women who abuse alcohol. Determine genetic or genetic-environmental interactions that may explain increased vulnerability of some minority groups to HIV and alcoholic liver disease (ALD), hepatitis, and other disorders. Identify mechanisms that explain onset and progression of HIV in liver, gut, and other organ systems and that produce damage due to alcohol consumption in groups with disparities in survival rates. Develop interventions that address those mechanisms.

1.5.2.1 Action Plan

Increase NIAAA support for biomedical research that identifies alcohol's effects on mechanisms and processes that cause health disparities in racial, ethnic, and other minority populations. Encourage research on the effects of alcohol consumption on HIV/AIDS disease progression, with focus on HIV/AIDS-induced organ damage and HIV/AIDS-defining opportunistic infections in populations at increased risk.

Timeline

FY2004 - Encourage HIV/AIDS researchers to extend their work to include alcohol and HIV in populations at increased risk. Continue funding relevant applications.
FY2005 - Continue funding of applications.
FY2006 - Continue funding of applications.
FY2007 - Encourage researchers to convene a workshop/symposium/working group composed of trans- and inter-Institute, agency, academic, and business individuals to discuss recent scientific advances in integrative basic medical science of health disparities and translation of results from bench to bedside.
FY2008 - Post results on appropriate web sites and publish results from the working group in an appropriate journal.

Estimated Completion Date for Objective: FY2008

1.5.2.2 Performance Measures

1. Number of applications that include aims with HIV and alcohol in populations at increased risk.

2. Number of investigators at HBCUs participating in HIV/AIDS and alcohol research studies.
3. Publications on research areas of health disparities and HIV/AIDS.

1.5.2.3 Outcome Measures

1. Percentage increase in research information on the viral and host mechanisms associated with the pathogenesis of HIV/AIDS immune dysfunction and disease progression in diverse populations across the spectrum of age, gender, and national and international settings.
2. Number of basic and clinical research findings and publications related to increased susceptibility to alcoholic liver disease, cardiomyopathy, pancreatitis, and other adverse medical consequences of alcohol abuse and alcoholism observed in minority populations with a special focus on those who are HIV positive.

1.6 Area of Emphasis Six: Neurobiological and Behavioral Risk for Alcohol Dependence

Alcoholism disproportionately affects social, environmental, and neurological outcomes in some minority groups with devastating consequences. Ethnic groups exhibit genetic diversity in their biologic sensitivity to alcohol. These potential differences in alcohol sensitivity may result, in part, from genetic differences in metabolic factors but also may be due to differences in the central nervous system's reactivity to alcohol. Measurements of the physiological and behavioral outcome of gene expression will yield more refined markers (e.g., specific physiological traits) that indicate genetic ethnic differences in susceptibility to alcoholism.

Minority individuals may possess genetic traits that either increase or decrease their vulnerability to alcohol dependence. Variations have been observed between the structures and activity levels of the alcohol metabolizing enzymes prevalent among Asian Americans, African Americans, and Caucasians. The flushing reaction, found most frequently among people of Asian ancestry, is one example of a protective trait. Flushing has been linked to variants of genes for enzymes involved in alcohol metabolism. It involves a reddening of the face and neck due to increased blood flow to those areas and can be accompanied by headaches, nausea, and other symptoms. Although flushing appears to deter alcohol use, people with the trait may continue to consume alcohol. Additional research is needed to clarify whether specific genetic, physiologic, and behavioral factors may explain the high risk for alcoholism among certain minority groups and subgroups. Alcoholism and its consequences are pervasive in some American Indian populations. For the development of treatment and prevention strategies, it is vital to establish the role and identity of causative factors in these groups.

1.6.1 Objective One: Neurobiological and Behavioral Risk for Alcohol Dependence

Through this objective we hope to determine how known differences in alcohol-metabolizing enzymes interact with other variables to influence alcohol consumption patterns in minority populations. We also plan to study specific genetic factors that may increase risk for alcohol dependence in minority groups; examine behavioral, neurological, and electrophysiological expression of those factors; and develop interventions that address those mechanisms.

1.6.1.1 Action Plan

Support research that identifies mechanisms and processes associated with disparities in racial and ethnic minority populations' vulnerability to alcohol abuse.

Continue research that reveals heritable phenotypes that contribute to alcoholism susceptibility and severity in African Americans. Study phenotypes of high risk of alcohol abuse and dependence to quantify their association and linkage to candidate genes and quantitative trait loci (QTLs). Assess the heritability of quantitative phenotypes of neural disinhibition and the correlation with clinical diagnoses of predisposing and/or co-morbid Axis I and II disorders.

Define novel phenotypes of the acute response to alcohol and the alcohol elimination rate. Continue support for genome-wide survey analysis, candidate gene association studies, and studies on genetic polymorphisms in a cohort of African American subjects. Encourage new research examining genetic polymorphisms associated with vulnerability to alcohol abuse in Mexican Americans. Continue the involvement of students and scientists from diverse ethnic and economic backgrounds by encouraging them to apply for diversity supplements and fellowships.

Timeline

FY2004 - Continue funding of renewal applications.
FY2005 - Continue support for projects.
FY2006 - Continue support for projects.
FY2007 - Continue support for projects.
FY2008 - Continue support for projects.

Estimated Completion Date for Objective: 2012

1.6.1.2 Performance Measures

1. Percentage of NIAAA program administrators encouraging investigators to address health disparities issues in ongoing research.
2. Number of meetings/workshops convened with grantees (every 2 years) to monitor progress and identify research opportunities.

1.6.1.3 Outcome Measures

1. Number of additional high-quality applications that address health disparities objectives for basic research.

2. Number of basic and clinical publications related to increased susceptibility to alcoholism and its consequences in minority populations.

1.6.2 Objective Two: Promote Research That Identifies Factors That Lead to Increased Prevalence of Alcoholism Among American Indian and Mexican American Populations

Identify vulnerability and protective alleles that underlie alcoholism's measured heritability. Identification of these alleles will lead to a better understanding of the mechanisms of vulnerability, individualization of treatment, and definition of gene-environment interactions. Assess the level of alcohol consumption among Mexican American young adults (21-25 yr) and identify potential risk and protective factors associated with alcohol involvement in this population. Continue to include members of racial and ethnic minority groups being studied in the research as scientific researchers, research support staff, subject interviewers, pedigree researchers, and in other, similar positions.

1.6.2.1 Action Plan

Continue the following studies: (1) a linkage study in an American Indian tribe that has a low rate of alcoholism; (2) an electroencephalogram linkage study in a tribe with a relatively high rate of alcoholism; (3) the Ten Tribe study, a genetic epidemiological study comparing tribes with low and high rates of alcoholism to identify gene-environment interactions; and (4) a project that uses whole genome linkage analysis and direct scanning of candidate genes to examine functionally significant sequence variations in genes expressed in the brain and their role in alcoholism and other behaviors.

Sustain research to elucidate the effect of alcohol on gene/environment interactions among American Indian populations. Support studies that use genotyping assays to identify variants in the genes that we have previously linked to specific behavioral disorders, including alcoholism, in other populations. Screen for variants in alcohol-metabolizing genes associated with individual responses to alcohol, such as the flushing response in Asian populations. Assess the level of alcohol consumption in Mexican Americans, and look for potential risk and protective factors associated with alcohol involvement in this population. Evaluate neurological functioning in low-risk and high-risk Mexican American subjects following consumption of alcohol. Examine research to learn whether brain responses to alcohol associated with risk for alcoholism in non-Hispanic populations are also characteristic of high-risk individuals of Mexican descent.

Timeline

FY2004 - Continue research. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.
FY2005 - Continue research. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.

FY2006 - Continue research. Submit abstracts to national and international conferences. Prepare manuscripts for submission to peer-reviewed journals.
FY2007 - Continue research. Submit abstracts to national and international conferences and present data and discuss results at invited seminars, lectures, etc. Prepare manuscripts for submission to peer-reviewed journals.
FY2008 - Continue research. Submit abstracts to national and international conferences and present data and discuss results at invited seminars, lectures, etc. Prepare manuscripts for submission to peer-reviewed journals.

Estimated Completion Date for Objective: FY2012

1.6.2.2 Performance Measures

1. Number of significant research findings related to this project (i.e., enhancement of methods used in studies).
2. Number of abstracts submitted to meetings, conferences, etc.
3. Number of invited lectures.
4. Number of manuscripts submitted to peer-reviewed journals.

1.6.2.3 Outcome Measures

1. Number of manuscripts accepted into peer-reviewed journals with high impact.
2. Evidence of long-term beneficial effects on the public health of American Indians and Mexican Americans.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

NIAAA has identified two areas where new and enhanced activities could strengthen its alcohol research infrastructure and better equip the Institute to address health disparities. The areas are increased support for collaborative capacity development at HBCUs and expansion of efforts to attract and retain ethnically diverse investigators to alcohol research.

Ethnically diverse clinicians and scientists have much to add to our understanding of alcohol-related health disparities. Established alcohol researchers have demonstrated a willingness to collaborate with minority clinicians/investigators and to include minority populations and communities in their research. Efforts to enhance research at HBCUs and an emphasis on health disparities research have evolved into a model for promoting health disparities research participation at several institutions. Principal investigators are showing increasing numbers of minority research staff at all levels how to conduct rigorous alcohol research. Research in racial/ethnic minority, rural, and low-SES populations is emphasized.

The action items in this plan will expand and strengthen the existing NIAAA initiatives:

Cooperative Agreements - In 1997, NIAAA initiated three Collaborative Minority Institution Alcohol Research Development (CMIARD) programs using developmental cooperative agreements. These institutions are HBCUs. In FY2003, one these CMIARD programs successfully competed for a second 5 years of funding at a more advanced level. In 2002 and 2003, NIAAA added four new cooperative agreements. These are exploratory/developmental grants for planning alcohol research at HBCUs. Each cooperative effort relies on strong collaborations with established alcohol research scientists to build on existing expertise at the HBCUs. Program advisory committees and substantial involvement of Institute scientific staff are also important features of this program.

Developmental Research Project Grants - NIAAA issued a PA titled Developmental Grants for Minority Collaborative Projects (R21) to support pilot projects developed collaboratively between scientists in minority institutions and established alcohol researchers. These awards enhance and extend the alcohol research activities of minority scientists. The goal is to provide a transition from mentored collaborative research development to more independent investigator-initiated research projects. This program will be reviewed to ensure that it furthers NIAAA's science and scientific workforce needs and NIH expectations and policies regarding equitable access to research opportunities for all population groups.

Distance Learning and Mentoring for Potential Grant Applications - In 1999, with co-funding from ORMH-NIH (currently NCMHD), NIAAA issued a contract to support distance learning entitled the Alcohol Research Mentoring System. The program matched new investigators from racial or ethnic minority groups (or non-minority investigators located at HBCUs) with senior NIAAA-funded researchers who mentored the new investigators through the development and submission or revision and resubmission of applications in prevention research. The ultimate goal was to increase the number of racial/ethnic minority investigators and expand research with underserved populations. More than 20 mentoring partnerships were fostered. Eleven grant applications were submitted, and four competed successfully and were awarded.

Special Efforts in Alaska and Hawaii - With co-funding from ORMH-NIH (currently NCMHD), NIAAA increased its support for studies on health disparities among Alaska Natives, including a special research project grant (funded on its own merits) to the University of Alaska on pathways to Alaska Native sobriety. NIAAA also supported the State of Hawaii in conducting a symposium on alcohol research as well as co-sponsoring a workshop and symposium with the HMO Research Network. We now support a developmental cooperative project at the University of Hawaii. The aim of this project is to develop a collaborative alcohol epidemiology research program at the University.

Training of Health Care Professionals - Efforts are under way to facilitate moving research results into clinical practice through the development of curricula for pediatricians and prenatal care professionals. A program has been developed to help clinicians identify children affected by prenatal exposure to alcohol. It also promotes screening women of childbearing age for at-risk drinking. A companion booklet in English and Spanish also has been developed to help women cooperate with their health care providers to reduce at-risk drinking.

Technical Assistance Workshops - NIAAA has conducted several workshops to attract faculty at HBCUs to alcohol research. One offered guidance in project development and grantsmanship. Other technical assistance initiatives include programs in distance and face-to-face mentoring in prevention research, discussions of strategies and requirements for doing clinical alcohol studies, and sessions to stimulate collaborative projects.

Diversity Supplements - NIAAA continues its participation in the NIH PA (PA-05-015) entitled "Research Supplement to Promote Diversity in Health-Related Research." Through this program, a diverse range of scientists at all experience levels work with funded NIAAA grantees on their research projects. The principal investigator serves as a mentor for these scientists who sometimes bring expertise and another dimension (such as cultural competence) to the project. Investigators mentored under diversity supplements often continue research and go on to submit their own grant applications. In fact, past participants in this program now have their own grants and are, in turn, mentoring other young investigators.

Mentor Awards - NIAAA encourages and supports established alcohol scientists on research project grants, centers, and contracts to initiate collaborations with diverse institutions, including HBCUs.

2.1 Area of Emphasis One: Extramural Alcohol Research Infrastructure Development

2.1.1 Objective One: Increase Alcohol Research Capacity at Historically Black Colleges and Universities (HBCUs)

Develop alcohol research infrastructure at HBCUs to plan and implement research endeavors. Increase research capacity development at HBCUs through support of mutually beneficial collaborative research with leaders in alcohol research. Involve minority populations and communities in alcohol research and wellness strategies.

2.1.1.1 Action Plan

Provide support for promising areas of alcohol research development at HBCUs. Incorporate lessons learned from NIAAA's current collaborative research development programs. Provide technical assistance and promote strategies to improve institutional expertise and systems to handle the administrative and fiscal responsibilities associated with business management for federal grant programs

Timeline

FY2004 - Continue support for three to five Collaborative/Exploratory grants. Collect data for evaluation.
FY2005 - Continue support for three to five Collaborative/Exploratory grants. Collect data for evaluation.
FY2006 - Continue support for Collaborative/Exploratory grants. Award program evaluation contract.
FY2007 - Provide technical assistance to promote applications from diverse populations.
FY2008 - Fund 8 to 10 targeted and non-targeted grants to promote applications from diverse populations.

Estimated Completion Date for Objective: FY2012

2.1.1.2 Performance Measures

1. Number of meetings/workshops or technical assistance programs convened to encourage scientists, including those from underrepresented groups, and diverse institutions, including HBCUs, to participate in NIAAA grant programs.
2. Number of grant solicitations to which scientists at diverse institutions, including HBCUs, could reasonably be expected to respond.
3. Number of grant solicitations designed to supplement or further the advancement of alcohol research at HBCUs.
4. Number of staff contacts to advise scientists at diverse institutions, including HBCUs, of requirements for alcohol research grants, programs, and activities.

2.1.1.3 Outcome Measures

1. Number of grant applications received and/or funded at HBCUs.
2. Number of HBCUs that are conducting alcohol research relevant to the needs of their communities and populations.
3. Number of alcohol research projects pursued at HBCUs.
4. Number of alcohol research projects being pursued at HBCUs specifically targeted to populations that reflect the multi-ethnic, multi-cultural heterogeneity of the U.S. population.
5. Number of presentations at national meetings and published abstracts resulting from NIAAA-supported research at HBCUs.
6. Number of publications in peer-reviewed journals resulting from NIAAA-supported research at HBCUs.

2.1.2 Objective Two: Increase the Participation Of Ethnically Diverse Investigators In Alcohol Research

Attract and develop investigators from diverse backgrounds to conduct alcohol research. Promote career development for investigators from diverse backgrounds by seeking candidates at all levels to conduct alcohol research and by encouraging funded alcohol researchers to recruit and include ethnically diverse students, scientists, and clinicians as investigators on their studies. Increase the number of alcohol research scientists, particularly at HBCUs, and increase the amount and complexity of research conducted by these investigators. Bring scientists and clinicians with experience working with ethnically diverse populations into the alcohol research field.

2.1.2.1 Action Plan

Contact organizations such as the Hispanic Association of Colleges and Universities (HACU), the Minority Health Professions Foundation, the Interamerican College of Physicians & Surgeons, the National Hispanic Medical Association (NHMA), the National HBCU Substance Abuse Conference, and the Association of American Indian Physicians to promote alcohol research opportunities for minority investigators. Support diversity supplements for clinicians, faculty, and students. Alert training grant directors to opportunities for students and trainees. Continue mentoring programs and awards. Encourage training grant program directors to seek out ethnically diverse investigators. Encourage the Research Society on Alcoholism Education Committee to promote outreach programs for ethnically diverse students and investigators. Encourage ethnically diverse investigators to apply for Career Development Grants (K-award series).

Timeline

FY2004 - Continue to support research initiatives, career development awards, and diversity supplements and fellowships. Continue to advise individuals from ethnically and economically diverse backgrounds of NIAAA grant opportunities.
FY2005 - Encourage principal investigators who are from ethnically and economically diverse backgrounds to apply for NIAAA grants. Identify barriers that limit investigators from competing successfully for NIH funding. Encourage grantees to identify strong candidates for diversity supplements and to mentor clinicians, faculty, and students from ethnically and economically diverse backgrounds. Encourage potential applicants to apply for career development awards. Continue to support student research initiatives. Participate in meetings or other activities sponsored by HACU, HBCU, or other groups that represent health professionals and scientists or potential scientists from ethnically and economically diverse backgrounds.
FY2006 - Solicit applications from investigators from ethnically and economically diverse backgrounds. Encourage grantees to identify strong candidates for diversity supplement awards and to mentor clinicians, faculty, and students from ethnically and economically diverse backgrounds. Take steps to overcome impediments to investigators competing successfully for funding. Continue

to support existing and encourage new career development awards. Continue to support research initiatives for students from ethnically and economically diverse backgrounds.
FY2007 - Advise all individuals of NIAAA funding opportunities. Encourage grantees to identify strong candidates for diversity supplement awards and to mentor clinicians, faculty, and students from ethnically and economically diverse backgrounds. Encourage investigators to present their findings at national research meetings.
FY2008 - Continue to identify and support additional investigators from ethnically and economically diverse backgrounds. Encourage investigators to present their findings at national research meetings and publish findings in peer reviewed venues.

Estimated Completion Date for Objective: Ongoing until investigators from ethnically and economically diverse backgrounds are no longer underrepresented in alcohol research.

2.1.2.2 Performance Measures

1. Number of NIAAA-sponsored health disparities research meetings and technical assistance workshops.
2. Number of diversity supplements awarded to promote involvement of individuals from ethnically and economically diverse backgrounds in alcohol research.
3. Number of investigators from ethnically and economically diverse backgrounds with NIAAA grant support (targeted and non-targeted).
4. Number of new NIH applications resulting from NIAAA-sponsored meetings and workshops.
5. Number of partnerships between experienced alcohol researchers and clinicians, or faculty investigators from ethnically and economically diverse backgrounds, resulting from NIAAA-sponsored meetings and workshops.
6. Number of new strategies identified to improve applicants' expertise in developing sound research hypotheses and writing responsive grant applications and contract proposals.
7. Number of students from ethnically and economically diverse backgrounds participating in grant and orientation activities at NIH.
8. Number of scientists from underrepresented groups on staff at NIAAA.

2.1.2.3 Outcome Measures

1. Number of principal investigators from ethnically and economically diverse backgrounds conducting alcohol research.
2. Number of presentations by scientists from ethnically and economically diverse backgrounds at national meetings that present results of NIAAA-sponsored grants or activities.
3. Number of publications produced by scientists from ethnically and economically diverse backgrounds in peer-reviewed journals resulting from NIAAA-sponsored research or activities.

2.2 Area of Emphasis Two: Intramural Research Development Activities

The NIAAA intramural program is in a unique position to offer a range of opportunities to encourage and recruit scientists from ethnically and economically diverse backgrounds and to include minority communities in alcohol research. The NIAAA intramural scientists are experts in a broad range of scientific areas. Also, conditions that include a location in a metropolitan area that is racially, ethnically, and economically very diverse; the proximity of other NIH intramural programs; the number of HBCUs and other institutions of higher learning; the number of health care providers; and the range of local government structures strengthen the potential offerings for scientists, clinicians, and students from various backgrounds.

2.2.1 Objective One: Identify and Encourage High School and Undergraduate Students From Ethnically and Economically Diverse Backgrounds to Consider Careers in Alcohol Research

Give high school and/or college and graduate level students and their teachers an opportunity to participate in the NIAAA Intramural Program’s cutting-edge basic science research, with the hope that this experience will lead students to choose careers in alcohol-related biomedical research.

2.2.1.1 Action Plan

Host four high school, college, or graduate students and one teacher from diverse institutions for 2 months every summer in the NIAAA intramural laboratory. Assign each individual to a specific laboratory to learn the basics of biological research under the mentorship of the laboratory director or another senior scientist. Encourage the more successful students to return the following summer and let them become more actively involved in specific research projects. At the end of the research period, give students and teachers an opportunity to present their work at a laboratory meeting. Give students/teachers feedback from NIAAA intramural scientists on research projects and presentations. Develop and maintain a database to follow the career development of these students.

Timeline

FY2004 - Develop PA and disseminate to educational institutions.
FY2005 - Recruit applicants for summer.
FY2006 - Bring back successful students from previous summer and recruit more so total equals four participants. Develop database and requirements to evaluate success of project.
FY2007 - Bring back successful students from previous summer and recruit more so total equals four participants. Review requirements evaluating success of individuals. Enter career path information into database.
FY2008 - Continue support for returning and/or new summer students and teachers. Review requirements for evaluating success of individuals. Enter career path information into database.

Estimated Completion Date for Objective: Ongoing until scientists from ethnically and economically diverse backgrounds are no longer underrepresented.

2.2.1.2 Performance Measures

1. Number of students participating in Summer Intern Poster Day and number of intramural presentations per trainee (i.e., student or teacher trainee).
2. Number of students returning each successive year and subsequent presentations and abstracts/posters presented at the NIH Summer Student Fair.

2.2.1.3 Outcome Measures

1. Number of students who study science-related curricula at universities and colleges.
2. Number of students who obtain a bachelor's degree in a scientific field.
3. Number of students who obtain advanced degrees in a scientific discipline.

2.2.2 Objective Two: Develop a Model Program for Research on Screening and Interventions for Alcohol-Related Health Problems

NIAAA and NCMHD supported the development of an Alcohol Research Center Program at Howard University. This successful program has been competitively renewed and includes an outreach component to educate the community and to empower health care providers to screen patients for alcohol-related problems and refer them as appropriate for treatment and follow-up within their health care system, Howard University, or the NIAAA intramural program. Unity Health Care, Inc. administers and manages a health care system of clinics within the high-risk areas of Washington, D.C.

NIAAA will initiate a partnership between the NIAAA intramural program and the facilities of Unity Health Care, Inc. in Washington D.C. NIAAA will provide opportunities to address health disparities across a broad spectrum of alcohol-related disorders (alcohol abuse, alcoholism, alcoholic liver disease, pancreatitis, cardiomyopathy, etc.) in a community-based primary care setting.

2.2.2.1 Action Plan

Collaborate with Howard University and Unity Health Care to provide alcohol-related client services and education for patients, families, health care professionals, and community organizations:

1. Client Services:
    a. Alcohol Health Education: Provide educational flyers, pamphlets, and other community literature regarding alcohol use and alcohol dependency.

   b. Alcohol Screening: Perform voluntary brief interviews to assess alcohol abuse/alcoholism. Use a variety of brief screening instruments and, where indicated, conduct 5- to 10-minute one-on-one sessions designed to reduce harmful drinking.
   c. Medical Screening: Consult with individual health care providers on liver disease and other alcohol-related medical complications in their patients.
   d. Cognitive Behavioral Therapy (CBT) and Motivational Enhancement Therapy (MET): CBT and MET will be used to treat alcohol problems in Unity patients.
2. Screen Clients for potential participation in alcohol health disparities research at Howard University and the NIAAA Intramural Clinical Program in Bethesda.
3. Recruitment to Research Careers: Provide information and a platform for patient providers to become more active in research.
4. Community Outreach: Disseminate findings about alcohol problems at local health fairs, church gatherings, and other community-based programs and activities.

Timeline

FY2004 - Develop and execute a Memorandum of Understanding with Unity Health and Howard University. Initiate community outreach efforts. Provide feedback to NIAAA regarding the types of publications that would be effective for this community.
FY2005 - Establish working relationships with churches and other community-based programs. Convene seminars, workshops and other activities to familiarize patient providers with knowledge of research procedures, protocol, and other requirements. Get feedback from providers about constraints they face in delivering alcohol treatment services. Formulate an evaluation strategy for this program.
FY2006 - Train Unity staff clinicians to provide brief and other treatment and preventive interventions.
FY2007 - Continue studies, seminars, and trainings.
FY2008 - Continue ongoing efforts.

Estimated Completion Date for Objective: 2012

2.2.2.2 Performance Measures

1. Number of patients screened and given interventions and referred for services.
2. Number of outreach and education activities completed.
3. Number of community-based physicians participating in alcohol research studies
4. Number of patients participating in program.
5. Number of community-based research studies conducted.
6. Number of community agencies and organizations involved in education, recruitment, and outreach efforts.

2.2.2.3 Outcome Measures

1. Number of patients served.
2. Number of findings from community-based studies.
3. Effectiveness in increasing minority participation in alcohol research.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Increase At-Risk and Minority Access to Alcohol-Related Health Messages

Data suggest that some minority groups suffer more adverse effects from alcohol abuse and alcohol dependence than do other populations. Important to the mission of NIAAA is research designed to identify racial and ethnic disparities in the causes and consequences of alcohol-related problems, develop methods to ameliorate them, and disseminate research-based, culturally relevant information to these special populations through appropriate venues. Groups of particular concern include Hispanics, African Americans, American Indians/Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders, and rural and low-SES populations. In addition, there is significant variability within populations.

3.1.1 Objective One: Increase Awareness of Alcohol Abuse, Alcohol Dependence, and Alcohol-Related Problems Experienced by Minority, Rural, and Economically Disadvantaged Populations

Develop culturally relevant health messages on a variety of alcohol-related issues. During FY2004, Spanish-speaking focus groups pre-tested three new publications on the following topics: medication interactions with alcohol, alcohol and women, and genetics and alcoholism. The booklets were printed and widely disseminated; the number of publications disseminated and the dissemination venues are being monitored and tracked. In addition, we are conducting focus groups to pretest radio public service announcements that target African American and Hispanic parents. For FY2004 National Alcohol Screening Day (NASD), a number of culturally relevant multimedia products were developed for African American and Hispanic audiences. These included a variety of posters, radio promotions, and newspaper advertisements. These products were used to recruit people for NASD sites where they could participate in free, anonymous screening for alcohol problems.

3.1.1.1 Action Plan

Translate/adapt NIAAA consumer health pamphlets and booklets for minority populations. Pretest materials in focus groups consisting of the members of the targeted communities. Develop a Request for Proposal (RFP) for a 5-Year Health Communications Program for Minority Populations. Get input from experts to improve the cultural relevance of health messages.

Timeline

FY2004 - Complete projects that supported NASD.
FY2005 - Disseminate culturally relevant materials in collaboration with minority-serving organizations.
FY2006 - Develop two additional pamphlets for health professionals with companion information for patients and translate/adapt patient information into Spanish.

Estimated Completion Date for Objective: FY2006

3.1.1.2 Performance Measures

1. Number of consumer health pamphlets and booklets translated/adapted for minority populations.
2. Number of focus groups held to pilot test materials.
3. Number of meetings with experts to improve cultural relevance of health messages.
4. Completion of RFP for communications program for minority populations.

3.1.1.3 Outcome Measures

Number of low-SES and minority ethnic groups being reached by NIAAA health messages.

3.1.2 Objective Two: Develop and Build Partnerships With Government and Private Organizations to Transmit Research-Based Information to Minority, Rural, and Economically Disadvantaged Populations

Form partnerships with government agencies and private organizations and associations whose goals are to promote healthy and safe behaviors and to develop comprehensive research plans to address alcohol-related problems for specific audiences. The work of these partnerships will consist of providing information and educational materials and collaborating to increase the availability of research-based information to their constituencies. Speeches and presentations are included.

3.1.2.1 Action Plan

Identify and establish collaborative partnerships with NIH, other governmental and national organizations such as the National Highway Traffic Safety Administration, the Community Anti-Drug Coalition of America, the National Council on Alcoholism and Drug Dependence, Mothers Against Drunk Driving, CADCA, NCAD, the National Organization on Fetal Alcohol Syndrome, Latino associations, and rural health organizations to implement various alcohol education and outreach programs.

Timeline

FY2004 - Formalize partnerships with organizations by appointing a point person within the Institute for each and develop a work plan and timeline for projects.
FY2005 - Implement work as budget allows.
FY2006 - Continue to actively interact and exchange information.

Estimated Completion Date for Objective: FY2006

3.1.2.2 Performance Measures

Number of organizations participating in the health communications programs for rural and minority populations.

3.1.2.3 Outcome Measures

Number of partner organizations aware of the relevant research of NIAAA and who have received appropriate documents and materials provided by NIAAA or adapted from NIAAA documents.

3.2 Area of Emphasis Two: Health Professions and Science Education Initiatives

Alcohol-related disorders occur in approximately 26 percent of general medical patients, a prevalence rate that is similar to that for hypertension. Given this rate of occurrence, the Institute of Medicine recommends that questions about alcohol use be included among the routine behavioral/lifestyle questions asked of all those seeking medical care. Because medical and other health professional schools provide only minimal training to recognize and treat alcohol problems, NIAAA has developed a program to develop better methods for teaching health care professionals to screen for and treat alcoholism. Special treatment issues for minority groups, such as higher incidence rates for alcoholic liver disease and FAS, treatment barriers, and cultural factors, must be incorporated in our health professions training for those who care for racial and ethnic minority, rural, and economically disadvantaged individuals. Many patients are willing to accept suggestions from health care professionals. The skills to intervene effectively, refer, and follow up with these individuals must be included in training and continuing education programs. Further, there is a need to reach children—future teen and adult patients—with information concerning alcohol and its effects on health. School-based science education is a potentially valuable vehicle for this. It is proposed that alcohol-related science education curricula and curriculum supplements be developed and field-tested in multi-ethnic or predominately minority-serving schools.

3.2.1 Objective One: Continue Development of Health Professions Education Program

Improve physician/health care provider and clergy intervention skills. Make research-based education regarding alcohol use disorders, interventions, and treatment a priority in the training of health professionals serving minority populations. Increase the number of faculty role models on the handling of alcohol use disorders and intervention; improve the patient-physician interaction around the topic of alcohol use, abuse, and alcoholism. Increase knowledge of clergy and pastoral ministers on the science of alcohol abuse and addiction and evidence base of interventions.

3.2.1.1 Action Plan

Improve physicians' and other health care providers' skills in detecting alcohol problems through the targeted use of R25 Alcohol Education Project grants to train both primary care and emergency department health professionals. Materials and training programs from existing grants will be directed toward health professionals serving minority populations or to institutions such as HBCUs. Those that prove most effective will be disseminated to the health education community. Support meetings of health professionals and policy makers to discuss the dissemination of evidence-based practice guidelines for alcohol services and policies for rural communities. Develop a science-based curriculum to educate clergy and pastoral ministers about addressing alcohol problems.

Timeline

FY2005 - Disseminate curricula developed for clergy and social workers.
FY2006 - Develop curriculum materials for physicians and other health care providers.
FY2007 - Develop Web-based continuing education materials for health care professionals.

Estimated Completion Date for Objective: FY2007

3.2.1.2 Performance Measures

1. Number of professional education materials and trainings directed toward health professionals serving minority and underserved populations.
2. Number of health professionals serving these populations who have received trainings.
3. Number of professional meetings held.
4. Development and dissemination of curriculum for clergy.

3.2.1.3 Outcome Measures

1. Pre/post testing of knowledge, attitudes, and skills of health professionals and clergy and competency in identifying, treating, and referring alcohol problems in minority and underserved patients.
2. Acceptance of screening, intervention, and referral for alcohol problems into standard of care in hospital emergency departments and clinics serving minority and underserved populations.
3. Measurement of the impact of expert panel meetings to disseminate evidence-based practice and policy to rural communities.
4. Number of clergy and pastoral ministry education programs that use the NIAAA curriculum.

3.2.2 Objective Two: Science Education Outreach to Minority and Underserved Communities

NIAAA currently supports science education outreach programs targeted to communities in rural North Carolina. Scientists at the University of North Carolina have developed materials to augment science curricula in schools and have well-equipped science laboratory buses and trained staff to deliver instruction to teachers and students in underserved areas. We propose to expand this effort to communities in neighboring Mississippi Delta states. The goal is to enhance existing science education in the Mississippi Delta by providing outreach through mobile laboratories and other means for delivering highly integrated, field-tested, and inquiry-based curricula on the science of alcohol. The plan is to collaborate with communities in the Mississippi Delta to evaluate the effectiveness of these programs on changing risk-taking behavior, increasing academic knowledge, and overall use, adaptability, and enthusiasm as garnered from students, teachers, and other appropriate education officials.

We also plan to work with Howard University's Alcohol Research Center to provide outreach to minority youth in the District of Columbia Public School System. As part of Howard's center grant, they have built in local outreach efforts beginning with a pilot alcohol education program for pre-college students in 2004. They will provide students in the District of Columbia public schools with hands-on research and/or clinical experience that will serve to motivate them toward careers in the biomedical sciences. The program will also give minority high school students evidence-based information on alcohol use and abuse in an effort to reduce the high risk of developing alcohol-related problems.

According to SAMHSA's 2002 National Survey on Drug Use and Health, drinking rates among persons aged 12 to 17 are higher in non-metropolitan than in small and large metropolitan areas and highest in completely rural areas. For instance, the prevalence of lifetime drinking among 12- to 17-year-olds in completely rural areas is about 50 percent. Compared to youth living in more urbanized areas, youth age 12 to 17 living in completely rural areas also had the highest rates of past year drinking (42%) and past month binge drinking (14%). Rates of tobacco product use and illicit drug use by 12- to 17-year-olds are also higher in more rural areas.

J. Edward Hill, M.D., former chair of the American Medical Association Board of Trustees (2002-2003), worked for health education reform and initiated child health programs throughout the Mississippi Delta. In an *amednews.com* editorial to all physicians, he highlighted alcohol as one of the major preventable behaviors in these communities that put children at risk. (*amednews.com* is an Internet newspaper for American physicians.) Dr. Hill promotes the idea to fellow physicians that school programs can reduce and prevent their occurrence. "…We must use our professional authority to help establish and fund the best, science-based comprehensive health curricula in our schools."

3.2.2.1 Action Plan

Adapt and field test NIAAA-funded curriculum supplements and materials in multi-ethnic, minority-serving, and underserved K-12 educational settings. Supplement existing science education grants to provide outreach to schools in the Mississippi Delta region. Three curricula of particular relevance are *Better Safe than Sorry*, a curriculum addressing the prevention of FAS; *Understanding Alcohol*, a curriculum highlighting the pharmacokinetics and pharmacodynamics of drinking alcohol; and *My Brain, My Body*, an interactive multi-media program focusing on the effects of alcohol on human physiology. A mobile science laboratory known as the *Destiny* bus will be used to deliver hands-on inquiry-based instruction to students and teachers in Mississippi Delta communities. Provide District of Columbia public school students with opportunities to be mentored by alcohol researchers and listen to NIAAA intramural and extramural researchers about their experiences and relevant research portfolios. Give students opportunities to tour and interact with scientists in laboratory settings, and potentially, receive appropriate academic credit in preparation for undergraduate science programs.

Timeline

FY2005 - Identify rural communities for science education projects and form partnerships; pilot program of District of Columbia public school students during academic year; identify mentors and presenters to provide local outreach.
FY2006 - Pilot test curricula to determine acceptability to teachers and students.
FY2007 - Adapt curricula and improve presentations to support community input.
FY2008 - Support community and school systems in improving programs.

Estimated Completion Date for Objective: FY2007

3.2.2.2 Performance Measures

1. Supplements given to NIAAA science education grantees.
2. Number of schools in the Mississippi Delta region reached through this initiative.
3. Number of students and teachers participating in the program.
4. Number of NIAAA employees providing outreach in the form of mentoring, laboratory work, recommendations, or presentations to the local community.
5. Number of District of Columbia public school students who participate in the NIAAA/Howard University outreach program.

3.2.2.3 Outcome Measures

1. Validated survey instruments will be used to collect pre/post measures on students.
2. Measures of acceptance and integration of the curricula by teachers and school administrations.
3. Number of District of Columbia public school students who enter college as science majors or express an interest in pursuing research careers.

4. Longitudinal data on substance abuse behaviors and pursuit of research careers by District of Columbia public school minority students within 3 years of graduating from high school.

Response to Public Comments on the NIH Health Disparities Strategic Plan

This plan continues many programs and strategies that address points stressed in public comments on the NIH strategic plans. One new NIAAA program is particularly noteworthy because it responds to many stakeholder comments and because it represents a new direction for the Institute. The Community-Based Treatment and Recovery Program, a partnership between the NIAAA Intramural program and a community health care organization, will provide alcoholism screening and treatment services as well as community outreach activities for African Americans and Latinos in Washington DC. This program will:

- Broaden partnerships and leverage community resources for alcoholism treatment.
- Provide a setting for developing strategies for improving quality of health care or the quality, intensity, and comprehensiveness of diagnostic procedures and treatment choices for minority patients with alcohol problems.
- Integrate alcohol screening and treatment with other health care services.
- Get appropriate health information to a community in need.
- Provide a setting for identifying elements of culturally competent health care training for medical students and caregivers.
- Provide a venue for testing and evaluating strategies for providing culturally relevant information to minority and medically underserved communities.
- Provide a setting for studying health care access issues.
- Provide a setting for understanding environmental, cultural, social, and behavioral factors that influence health and prevention of disease and disability.
- Be a model of community outreach.
- Provide an opportunity to improve our understanding of the effects of non-clinical factors, such as stigma, racism, and patient mistrust, that may have a bearing on health disparities.
- Represent a potential model for community-based research that might involve health care, faith-based, and other government organizations in ancillary services, information dissemination, and outreach activities with the goal of addressing alcohol problems in the community.
- Provide an opportunity for minority patient care providers to become more involved in research.
- Provide an opportunity for recruitment and research career development for African American and Latino students, physicians, and other health professionals.

The National Institute on Deafness and Other Communication Disorders

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

MISSION/VISION STATEMENT

The mission of the National Institute on Deafness and Other Communication Disorders (NIDCD) is to conduct and support basic and clinical research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. Basic and clinical research focused on understanding the normal processes and disorders of human communication is motivated both by intrinsic scientific interest and its importance to the health of the Nation.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The Director, National Institutes of Health (NIH), has requested that each Institute and Center at NIH develop a Strategic Plan for Reducing Health Disparities. In preparation for developing its plan, the NIDCD sought broad input from the National Deafness and Other Communication Disorders Advisory Council (NDCD) and Board of Scientific Counselors, as well as 170 of its constituent groups. Several research opportunities to understand the basis for health disparities within the purview of NIDCD were identified.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Develop New or Improved Approaches for Detecting or Diagnosing the Onset or Progression of Disease and Disability

Hearing and Language Disorders

In this age of information, communication and technology skills are central to a successful life for all Americans, and the labor force of the 21st century will require intense use of these skills. However, for about one in six Americans with communication disabilities and the families who support them, facing each day can be a challenge. The simple acts of speaking and listening, of making their wants and their needs understood, often are impossible. Hearing and language disorders can exact a significant economic, social, and personal cost for many individuals. To address these problems, society needs a more complete understanding of the mechanisms underlying normal communication and the causes of human communication disorders.

1.1.1 Objective One: Develop Language Tests for Non-Standard English (DC82104: Harry Seymour, "Children Who Speak Black English"; DC82100: Aquiles Iglesias, "Bilingual Hispanic Children")

As the United States becomes more culturally, racially, and linguistically diverse, it is becoming increasingly difficult to discriminate between language disorders and language differences in children. Problems in language assessment arise because the majority of currently available measures are designed for identifying speech and language problems in Standard English speakers. Children of multicultural populations are often misdiagnosed as language impaired because culturally appropriate language assessment instruments or procedures are unavailable. In addition, other children from multicultural populations who have genuine language disorders that are in need of remediation may go unrecognized.

1.1.1.1 Action Plan

In response to this need, the NIDCD is supporting projects to develop language tests for non-standard English speakers. NIDCD-supported scientists are developing language tests for children who speak Black English and for bilingual Hispanic children. Investigators are collecting cross-sectional data on language abilities in normally developing 4- to 6-year-old speakers of Black English and bilingual Hispanic children whose primary language is not English or is a non-standard form of English. These data are aimed at developing items for a language assessment instrument or procedure that could be used to differentiate between language impairment and normal language development in these two populations.

The Diagnostic Evaluation of Language Variation (DELV) was recently published, the direct result of an NIDCD contract to create a language assessment instrument for speakers of Black English. The test has met with tremendous enthusiasm in the research and clinical realm, and will play a major role in differentiating language impairment and normal language development. A comparable test for bilingual Hispanic children is currently being developed.

1.1.1.2 Performance Measures

For speakers of Black English and bilingual Hispanic children whose primary language is not English or is a non-standard form of English:

- Collect cross-sectional data on language abilities in normally developing 4- to 6-year-old children.
- Document age-appropriate language milestones/behaviors, including aspects of phonology, syntax, semantics, and pragmatics.
- Use data collected to develop items for a language assessment instrument or procedure that could be used to differentiate between language impairment and normal language development.
- Conduct a study to determine the reliability and validity of the individual items and the overall language assessment or procedure.

1.1.1.3 Outcome Measures

- Track the use of the language assessment instrument or procedure through requests to use it and/or through citations of it in published literature.

1.1.2 Objective Two: Establish Prevalence Estimates for Specific Language Impairment (SLI) in African American children (DC4273: Julie Washington, "Nature and Prevalence of SLI in AAE Speaking Children")

Specific language impairment (SLI) is a delay in language development. SLI affects approximately 3 to 6 percent of children, and causes them to fall behind their peers in learning to speak and understand language. This contributes to learning and reading disabilities in school.

At present there are no data on the prevalence of SLI in African American children. As a result, speakers of African American English (AAE) risk being incorrectly classified as language disordered. These children may be receiving unneeded services, while other AAE speakers who do suffer from SLI may not be identified and are not receiving needed services.

1.1.2.1 Action Plan

By supporting research on prevalence and clinical markers of SLI in AAE speakers, NIDCD hopes to improve diagnosis of SLI in AAE speakers and to inform both public policy decisions and theories regarding the cross-linguistic usefulness of clinical markers for SLI.

1.1.2.2 Performance Measures

- Improve diagnosis of SLI in AAE speakers.
- Inform public policy by developing accurate prevalence estimates for SLI in AAE speakers.

1.1.2.3 Outcome Measures

- Track the use of prevalence estimates for SLI in AAE speakers by monitoring publications in the scientific literature.
- Track the use of clinical markers of SLI in AAE speakers by monitoring references to them in scientific literature.

1.1.3 Objective Three: Establish a Web Site for Parents, Health Care Professionals, Educators, and Others Interacting With Hearing-Impaired Children to Help Them Determine the Most Effective Treatments

Adults trying to provide the best environment for hearing-impaired children are faced with a broad and sometimes confusing range of treatment and support options.

1.1.3.1 Action Plan

NIDCD is supporting development of a web site to help parents, health care workers, daycare providers, educators, and other individuals and institutions as they make decisions about how best to help hearing-impaired children. The web site will provide accurate information about hearing loss, including FAQs answered by a multidisciplinary team of experts, links to other useful hearing loss sites, firsthand accounts of other families facing similar situations, ideas on how to communicate with babies and toddlers who are deaf, and an interactive decision aid to help individuals evaluate different treatment options. The use and impact of the web site will be evaluated, and the evaluation will include measuring the participation of traditionally underserved groups, such as the rural poor, rural and inner-city minorities, young households, and female-headed households, in the decision-making process.

1.1.3.2 Performance Measures

- Develop and implement a web site to facilitate the decision-making process for parents and others working with hearing-impaired children.
- Design and modify the site as needed to address the needs of underserved children with hearing loss and their families, including the rural poor, rural and inner-city minorities, young households, female-headed households, and other infrequent Internet users.
- Market and disseminate information about the site to parents, professionals, and children with hearing loss and assist underserved communities in gaining access to the site.

1.1.3.3 Outcome Measures

Evaluate the use of the site and the impact of the information obtained, including measuring the participation of traditionally underserved groups, such as the rural poor, rural and inner-city minorities, young households, and female-headed households, in the decision-making process. Evaluation and impact will be empirically measured using the following two techniques:

1. Administering a test to naive outreach focus groups followed by two subsequent tests after 6 and 12 months of access to the web site.
2. Collecting responses to an online inventory questionnaire.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: NIDCD Student Research Trainee Program: Partnership Program

In 1994, the NIDCD originally implemented a student research trainee program in collaboration with the National Center on Minority Health and Health Disparities (NCMHD), as well as four institutions including the Atlanta University Complex, the University of Puerto Rico, Gallaudet University, and the University of Alaska. The program’s initial purpose was to recruit and retain individuals underrepresented in the human communication sciences. Currently, students are selected from diverse institutions throughout the country to conduct research in cutting-edge NIDCD laboratory facilities.

2.1.1 Objective One: Recruit Individuals From Underrepresented Groups to Careers in Research in Human Communication Through In-Depth Experiences at the NIDCD

2.1.1.1 Action Plan

The program began with the objectives to expose students to cutting-edge research; however, the majority of current recruits are exposed to research prior to their participation in the program. Thus, the program's new objectives include sharpening the students' competitiveness in biotechnology techniques and competency in human communication science, and increasing their chances for beginning a scientific publication record. The aforementioned opportunities help the students advance in graduate and medical education in the sciences, as well as in a career in research. An NIDCD scientific mentor is assigned to each student to ensure quality learning. Complementary learning includes a series of lectures on science and career development, director's scientific journal clubs, and scientific oral and poster presentations. Since the program's initial class, 101 participants have trained under the program.

2.1.1.2 Performance Measures

Tracking and monitoring of the program participants. A database has been established to track the participants from when they started the program as well as when they ended the program. The database also notes the research training and additional advanced education that they have pursued, as well as whether they have pursued research careers. Key measures include, but are not limited to, academic training in higher education in science and medicine, careers in research, publication records, scientific presentations, and grant activity.

2.1.1.3 Outcome Measures

Increase participation of underrepresented groups working in the field of human communication research.

2.1.2 Objective Two: The Division of Intramural Research (DIR) of the NIDCD and Howard University Graduate School Partnership

In 2002, the NIDCD and Howard University's Graduate School joined in an official partnership to increase the participation of minority faculty and graduate students in human communication research. Since the program's beginning, the partnership has had two graduate students complement their academic training by conducting research in cutting-edge NIDCD research laboratories. The extended research agreements will enhance the students' dissertation work in research.

2.1.2.1 Action Plan

The program includes the following:

- Research training and mentoring within the NIDCD DIR research laboratories.
- NIDCD mentors serve on thesis committees and attend all examination and committee meetings of Howard University students whom they supervise.
- Openness and proactive efforts in establishing collaborative research efforts with Howard University faculty, students and staff.
- Continuing and frequent communication with faculty involved with individual students so that when Howard University students are working primarily in DIR/NIDCD facilities, there remains frequent communication with their Howard University co-mentors and other staff.
- Promulgation and communication of this collaborative effort.

2.1.2.2 Performance Measures

An evaluation process is being established to measure the program's success. Potential measurements of success may include: completion of a doctoral degree in human communication sciences, increased publication record, participation in grant activity, and pursuing a career in human communication research.

2.1.2.3 Outcome Measures

- Collaborations between scientists to gain more participation in science projects inclusive of minority populations.
- Increased participation of minorities in the field of human communication sciences.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Develop Targeted Public Health Education Programs

3.1.1 Objective One: Increase Public Awareness and Prevent Noise-Induced Hearing Loss

Ten million Americans already have suffered irreversible damage from noise, and 30 million are exposed to dangerous levels of noise each day. Exposure to harmful sounds causes damage to the sensitive hair cells of the inner ear, eventually affecting hearing. These structures can be injured by noise in two different ways: from an intense brief impulse, such as an explosion from a firecracker; or from continuous exposure to noise, such as in a woodworking shop.

3.1.1.1 Action Plan

The WISE EARS!® campaign was initiated on July 4, 1999, and now includes a coalition of nearly 100 organizations of workers, employers, health and medical professionals, advocates for children and older Americans, teachers, parents, and children, as well as unions, industry, federal, regional, and local government agencies and institutes, and the general public. The WISE EARS!® campaign health information has been published nationwide in more than 1,388 newspapers with an estimated total readership of 117.5 million. The campaign is designed to reach minority individuals who are identified by specific occupational or recreational risk. Future plans include increasing the coalition membership and expanding the campaign to reach these at-risk individuals.

In addition, special outreach efforts are under way to reach the vulnerable population of schoolchildren through efforts directed to the children themselves and through their teachers and their families. This will include the use of a teacher's guide and instructions developed for grades 3-6 in Spanish and English, "I Love What I Hear," and collaborative efforts with Girl Scouts USA throughout the 50 states. This outreach includes wide dissemination of the new curriculum for grades 7-8 in English, "How Your Brain Understands What Your Ear Hears," targeting students from ages 12 to 18 years in 12,000 schools. This curriculum has been tested to be used by teachers nationwide in urban, rural, and suburban public and private settings.

There will be continuing initiatives to reach Hispanic/Latino/Latina individuals through participation with various Spanish language and Hispanic interest meetings, exhibit opportunities, and collaborative efforts with the NIH Hispanic Communications Work Group, which includes the Radio Unica/Wal-Mart Hispanic Latino/Latina Health Fair series. Most NIDCD health information materials are available in Spanish.

An initiative to reach the rural community with advice about hunting and farming equipment uses shooting instructors as the dissemination source. WISE EARS!® information is provided to these individuals through their classroom instructors.

3.1.1.2 Performance Measures

- Increase public awareness through education and mass media efforts.
- Expand the campaign on the national level by increasing the coalition membership.

3.1.1.3 Outcome Measures

Track outreach efforts through data provided by North American Precis (NAPS) to increase the awareness of the importance of protection against noise-induced hearing loss among underrepresented groups. NAPS will target Spanish language populations specifically.

3.2 Area of Emphasis Two: Early Hearing Detection and Intervention

Two or three out of every 1,000 children in the United States are born deaf or hard-of-hearing. More lose their hearing later during childhood. Many of these children may need to learn speech and language differently, so it is important to detect deafness or hearing loss as early as possible.

3.2.1 Objective One: Increase Public Awareness on the Importance of Newborn Hearing Screening and Communication Options

3.2.1.1 Action Plan

NIDCD established the Early ID Ad Hoc Committee in January 2000. It now includes representatives from 14 organizations. The committee meets quarterly to create, share, and participate in collaborative efforts. These efforts focus on increasing the parents' and families' awareness of the importance of having a child's hearing screened and options for their child if he or she is diagnosed with hearing loss, and emphasizes initiatives to increase follow-through for children who are believed to have hearing loss at birth.

NIDCD began a multi-year campaign called "Labor Day" in September of 2003 and will expand that initiative in 2004 with the support of work group members. The Labor Day campaign is so called because more babies are born around this time of year than any other. The campaign is designed to remind parents to have their newborn babies' hearing screened.

The Hispanic/Latino/Latina community does not receive sufficient health care information. Outreach to this community includes efforts to disseminate information in Spanish about hearing screenings, follow-through visits, and how medical professionals can help increase the number of infants who return for hearing screening evaluations. The campaign also will use the Hispanic/Latino/Latina media services to provide information that will reach their communities. Another focus is to make information available in the Combined Health Information Database (CHID) so that resources are available to health care professionals who work with these communities.

3.2.1.2 Performance Measures

- Increase knowledge about the importance of hearing screening and follow-through for underrepresented groups to ensure improved communication, occupational, and financial outcomes for these children.
- Increase knowledge of professionals about the importance of follow-through after hearing screening for appropriate interventions

The National Institute on Drug Abuse

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL INSTITUTE ON DRUG ABUSE

MISSION/VISION STATEMENT

The mission of the National Institute on Drug Abuse (NIDA) is to lead the nation in bringing the power of science to bear on drug abuse and addiction. This charge has two critical components: The first is the strategic support and conduct of research across a broad range of disciplines, and the second is to ensure the rapid and effective dissemination and use of the results of that research to significantly improve drug abuse and addiction prevention, treatment, and policy.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Unlike other diseases, drug addiction poses many peculiar challenges to health researchers, providers, and public health officials in the search for effective prevention and treatment strategies and policies. These challenges emanate primarily from the fact that drug abuse and addiction are usually the result of illegal activity, and drug users are often viewed as morally corrupt or weak-willed individuals who engage not only in voluntary self- and socially destructive behavior but also in criminal activity. In short, although we know unequivocally that addiction is a disease like any other medical disease, it remains a stigmatized disease. And this stigma spills over to all aspects of drug abuse research, prevention, and treatment (e.g., obtaining measures of use, safety and legal concerns, compromise of early intervention by efforts to hide the disease, and denial of dependency).

Racial/ethnic minority populations are perhaps most adversely affected by this stigma and its effects, leading to misperceptions about drug abuse and addiction in minority communities and the way in which prevention and treatment are delivered to them. For example, the common perception is that minority groups, particularly Blacks and Hispanics, use drugs more than Whites even though epidemiologic data show little difference in overall use by race/ethnicity. In fact, in some instances minority groups are less likely to use licit or illicit drugs. There are, however, great differences in the consequences of drug use for racial/ethnic minorities, creating a great need to better understand the unique prevention, treatment, and health services needs of these communities.

NIDA has made a concerted effort to better understand and address the drug abuse and addiction research needs of racial/ethnic minority populations, focusing on research areas where there are significant gaps in knowledge and/or clear disparities in prevention and treatment. In 1993, NIDA established a Special Populations Office, which has two overall goals: (1) to encourage increased research on drug abuse in minority populations in NIDA divisions, and (2) to encourage and enable increased minority participation in drug abuse research. Moreover, NIDA formed an Institute-wide work group, the Consortium on Minority Concerns, which meets monthly to address research and research development issues of concern to minority populations. Each program division and office is represented on the Consortium.

NATIONAL INSTITUTE ON DRUG ABUSE

Several Institute-wide initiatives and policies were implemented that have led to progress in research that addresses health disparities and the underrepresentation of minority scholars in drug abuse research. Some of these initiatives include:

Historically Black Colleges and Universities (HBCU) Initiative. This was designed to encourage HBCUs to become involved in drug abuse research and to assist them in developing the capacity to conduct drug abuse research. Some selected outcomes of this initiative include: increased support of HBCUs through the National Institutes of Health (NIH) competitive process (which has led to research on underresearched areas such as developing prevention programs for rural African American youth and understanding risk for drug abuse in African American youth at developmental transition points), the establishment of a center on drug abuse research at Howard University (which has since received a substance abuse grant from the Robert Wood Johnson Foundation), and support of an established research scientist cooperative agreement program at three HBCUs in collaboration with the National Center on Minority Health and Health Disparities (NCMHD). North Carolina Central, Morgan State, and Howard Universities have recruited distinguished NIDA scientists to develop drug abuse programs. These programs have been very productive. Each has secured other funding, including NIH awards, established collaborations with other institutions and investigators, and instituted mentoring programs and activities for students and faculty.

Enhancement of the Underrepresented Minority Supplement Program. NIDA instituted a new policy for the receipt, review, and funding of minority supplement applications. Since 1994, NIDA has more than doubled its support of Minority Supplements in amount of funds allocated yearly to the program and the number of new awards made. NIDA also established a policy to include Asians and Pacific Islanders in behavioral and clinical work because they are underrepresented in these areas of drug abuse research. Former recipients are applying for and receiving independent research awards, and these recipients sometimes focus on disparities research issues and/or intend to mentor other underrepresented students and scholars.

In 2005, the NIH replaced the Minority Supplement Program with the Diversity Supplement Program (described in the introduction to the NIH Health Disparities Strategic Plan). NIDA's Consortium on Minority Concerns met in 2005 and adopted procedures to conform with the goals of the NIH Diversity Supplement program.

Summer Research with NIDA. To address concerns about the insufficient pipeline of underrepresented and disadvantaged researchers, NIDA established a summer program to place underrepresented and disadvantaged high school and undergraduate students with extramural scientists. Response has been very positive from students and investigators. The program was initially started with NCMHD funds, but NIDA completely supports the program now. Funding for the program has dramatically increased. In the first 3 years of the program, approximately 25–35 students were placed. In 2003 and 2004, more than 60 students were placed. Both investigators and students have reported positive experiences with the program.

Diversity Recruitment and Training Program. This is an intramural summer research program for students and faculty. It accepts diverse high school, college, graduate, and medical students and faculty members. About 25 students are placed each summer. A successful diversity student development program at Temple University, the Physician Scientist Program, which is now supported by a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) award (NIDA co-funds), places some of their high school students with NIDA's intramural scientists.

The intramural program has over the years provided placements for students and faculty from all population groups. The Diversity Recruitment and Training Program was established to ensure that the pool of applicants included scholars from underrepresented populations. NIDA will review the program to ensure that NIDA's need and goals of achieving diversity in the scientific workforce studying drug abuse and addiction are accomplished while conforming to NIH expectations and policies regarding equitable access to research opportunities for all population groups.

Minority Work Groups. Work groups comprised of experts in substance abuse and addiction or health concerns of minority populations have been created. These Work Groups advise the NIDA Director on research and research development needs of particular minority communities that will lead to effective prevention and treatment approaches for each group. Work groups exist for African American, Hispanic, Asian/Pacific Islander, and Native American/Alaska Native communities. Some outcomes of the work of these groups include new Principal Investigators (PIs), identification of candidates for the supplement program, new opportunities for NIDA to interact with professional and community groups, new ideas for research, new study section members, and increased mentoring and collaboration among group members.

With NIDA support, the Hispanic work group has evolved into the National Hispanic Science Network. The Network is designed to enhance communication; increase the dissemination of research knowledge to practitioners, clinicians, and the public; and mentor underrepresented and disadvantaged students and scientists interested in careers in drug abuse and addiction research. Activities include an annual conference and a summer research training institute for students and new investigators.

Development of PAs and RFAs. NIDA released a new Program Announcement (PA), Minority Institutions Drug Abuse Research Program, to support minority institutions wishing to develop their capacity to conduct drug abuse research. Two programs funded under this PA focused on Hispanic issues in drug abuse. New Minority Institutions Drug Abuse Research Programs (MIDARPs) have been established at Universidad de le Caribe, Hampton University and Florida International University. A Health Disparities Request for Applications (RFA) was released in 2001, which resulted in eight new awards, and a Health Disparities Supplement Program was initiated in 2002, which resulted in 29 supplements (four funded in 2003 by the NCMHD). NIDA also reissued its epidemiologic PA in FY2004. It identified health disparities research as a cross-cutting issue and encouraged applicants to address health disparity issues in all submissions to every extent possible.

The MIDARP is based on a program developed approximately 20 years ago. The current program was developed using the definition of minority institutions commonly used by NIH and other Department of Health and Human Services agencies (e.g., historic designation such as HBCUs). In addition, because this is a capacity development program, consideration is given to the applicant organization's history of sponsored research in drug abuse and addiction. The program will be reviewed to ensure that it furthers NIDA's science and scientific workforce needs and NIH expectations and policies regarding equitable access to research opportunities for all population groups.

Research Development Technical Assistance Workshops. NIDA offers technical assistance to scholars from underrepresented or disadvantaged populations on developing research studies in drug abuse and addiction. Participants are provided information on conceptual and methodological concerns in drug abuse and addiction research in addition to information on the NIH grants application and review processes. Participants in this program have become NIDA/NIH grantees, NIH peer reviewers, and grantees of other agencies and foundations.

NIDA overall offers a variety of grant development workshops and supports for all interested scholars. The participation of underrepresented scholars in these efforts has been lower than desired. The Research Development Technical Assistance Workshops were developed to ensure that underrepresented scholars were recruited and made aware of this type of training opportunity. Participation in the workshops has included scholars from all population groups. The program will be reviewed, however, to ensure that it furthers NIDA's science and scientific workforce needs and NIH expectations and policies regarding equitable access to research opportunities for all population groups.

As a result of these activities and individual division activities, NIDA experienced approximately a 97 percent growth in minority researchers since FY1993. With this growth in minority researchers (although not all are involved in minority-focused research) and an intense focus on drug use and addiction in minority communities, we have observed an increase in interest in drug abuse disparities and needs in minority communities.

This proposed strategic plan reflects NIDA's insights and knowledge gained from our efforts to address health disparities among racial/ethnic groups. In addition, the plan incorporates the recommendations made by the expert work groups described above and an extensive review of NIDA's research programs and activities conducted by staff. Public comments received were also considered and incorporated into the plan.

In addition to its interest in minority health disparities, NIDA has a strong interest in pursuing health disparities in rural communities (among racial/ethnic and other populations). Research suggests that drug use and addiction and its related consequences may be a serious and growing problem in rural areas; however, our knowledge base on drug abuse and addiction is limited. Providing drug abuse prevention and treatment and conducting drug abuse research in rural areas are difficult due to issues such as confidentiality, access to services, and a limited cadre of researchers and health care providers in rural areas. NIDA's Division of Epidemiology, Services and Prevention Research is planning an initiative to address drug abuse needs in rural areas.

Over the next 5 years, NIDA will strive to: (1) improve our understanding of the incidence and causes of drug abuse and addiction in all racial/ethnic groups, recognizing the diversity by gender, socioeconomic status, and other factors within racial/ethnic populations; (2) strengthen and expand the community and research infrastructure for conducting research within racial/ethnic populations; (3) improve prevention and treatment for racial/ethnic groups at highest risk for addiction and medical consequences of drug use and addiction; and (4) widely disseminate information on drug use and the disease of addiction in racial/ethnic communities, identifying best approaches to prevention and treatment. Moreover, NIDA will strive to better identify and understand the drug abuse needs of rural areas.

In 2000, NIDA established a Health Disparities Committee, comprised of staff from all of NIDA's programs including the budget office and intramural program, to develop its Strategic Plan to Address Health Disparities. This committee was made a continuing committee by the Director to oversee the implementation of the strategic plan. As part of its work, the committee establishes Institute-wide priorities, stimulates interest, and develops support for the goals and activities of the plan. This committee is chaired by staff of the Special Populations Office and reports to the Director of the Institute.

Introduction to the 2004 Revised Plan

In 2000, NIDA developed its plan to reduce drug abuse and addiction in health disparity populations as a part of the overall NIH Strategic Plan on Reducing Health Disparities. Although NIDA has a history of encouraging and supporting programs and activities to address drug abuse and addiction concerns in racial/ethnic minority populations, the requirement to develop a broader, long-term strategic plan with research, research capacity, and community outreach components provided an excellent opportunity for all program area staff to critically review drug abuse and research needs within health disparity populations and develop a comprehensive Institute-wide plan.

A number of developments have occurred that necessitate our reviewing and revising our plan beyond the NIH requirement that each Institute or Center review and amend its plan, responding to public comments received, as appropriate. We have made progress in the implementation of our original plan and have learned some lessons that will help us to improve our efforts in addressing health disparities. Moreover, we wanted to review the current status of the drug abuse and addiction research needs of health disparity populations, as evidenced by epidemiologic findings and expert opinion, to reassess our health disparity priorities.

NATIONAL INSTITUTE ON DRUG ABUSE

Progress in Health Disparities Research: Accomplishments and Lessons Learned

Significant Accomplishments:

We have made significant progress in addressing the drug abuse and addiction research needs of racial/ethnic minority and other underrepresented groups. Selected major accomplishments in research, research capacity development including NIDA infrastructure development, and community outreach and dissemination are summarized below.

Research. NIDA has stimulated research in health disparities and increased its support of health disparities-specific research in the following ways:

- Released an RFA on Health Disparities in 2001 titled "Health Disparities: Drug Use and Its Adverse Behavioral, Social, Medical, and Mental Health Consequences." Eight projects were supported. In addition, two additional RFAs were released with implications for health disparities.
- Developed a competitive Health Disparities Supplement program in 2002 that supported 28 projects. Research includes, for example: the use of the brief negotiated interview, using geocoding to examine neighborhood context and drug treatment outcomes, factors that impact service delivery, and examining the risk of stigma and drug overdose in African American and Latino drug users.
- Ensured the inclusion of minority populations in the Clinical Trials Network (CTN) (established to assess the effectiveness of drug abuse treatments in community-based treatment settings). Protocols specific to minority populations include an ongoing study of motivational enhancement treatment to improve treatment engagement for Spanish-speaking individuals (provides materials in Spanish and has bilingual staff) and a planned study on Job Seekers Training for Patients with Drug Dependence with American Indians. A protocol that focuses on African Americans has been accepted for implementation.

Research Capacity Development. NIDA has supported the development of research capacity and infrastructure development through a variety of programs for students, faculty, and institutions, including the following:

- Supports both intramural (Minority Research Training Program) and extramural (Summer Research with NIDA) summer research programs for students, primarily high school and undergraduates (in Summer 2003, more than 100 students participated).
- Supports capacity development at institutions through the HBCU Research Scientist Program (NC Central, Morgan, and Howard) and Diverse Institutions Drug Abuse Research Program at six schools (e.g., Florida International, University of Central de Caribe, Hampton University).
- Co-funds with other Institutes and Centers a number of research capacity programs, such as the Physician Scientist Program (NIDDK), the Clinical Research Education and Career Development program (National Center for Research Resources [NCRR]), and the Specialized Neuroscience

Research Program (National Institute of Neurological Disorders and Stroke [NINDS]), as well as individual grants focused on minority issues.
- Established the National Hispanic Science Network (NHSN), which addresses addiction issues affecting Hispanic populations. Activities include training/mentoring for drug abuse research careers and scientific meetings; web site available to all. A number of other Institutes and Centers and other agencies have expressed interest in collaborating with the NHSN.

Outreach and Dissemination. NIDA has increased its efforts to include and inform minority and other populations about drug abuse and addiction, including the following:

- Supports and participates in numerous meetings/conferences sponsored by racial/ethnic minority organizations and organizations focused on health disparities issues (e.g., Lonnie Mitchell HBCU substance abuse conference, National Asian Pacific American Families Against Substance Abuse, Latino Behavioral Health, and the American Public Health Association).
- Held a national minority health/health disparities conference in 2001; planning a second one for 2005.
- Makes information available to groups in appropriate language and context (e.g., has increased number of publications available in Spanish including information brochures for adolescents and parents, some research report series). Has developed calendars with information on drugs for Native Americans and Asians/Pacific Islanders.
- Revised and released report (2003), “Drug Use Among Racial/Ethnic Minorities.”
- Held two scientific meetings on health disparities. The proceedings of the first meeting, held in 2001, were published in a supplement to *Public Health Reports*, entitled “Drug Use, HIV/AIDS, and Health Outcomes Among Racial and Ethnic Populations.” The second meeting, entitled “Advancing Research To Reduce Drug Abuse and HIV/AIDS Health Disparities: Methodological Considerations,” was held in June 2004.

NIDA Infrastructure. NIDA has encouraged internal processes and procedures to maintain focus on health disparities.

- Regularly convenes race/ethnic minority expert work groups to advise the Director on research needs.
- Has a cross-division Health Disparities Committee that plans NIDA-wide Health Disparities Initiative.
- The CTN has a Minority Interest Group as part of its oversight committee structure.
- The Director has established an African American Initiative to address the disproportionate experience of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and criminal justice involvement by African Americans.
- Staff held a health disparities science meeting that resulted in a special issue of *Public Health Reports.*

Lessons Learned

During the process of developing and implementing the Health Disparities Plan, a number of issues repeatedly arose among staff, grantees, other scholars and researchers, and the public. The first among these issues concerned the definition of health disparity, its intent, and the groups captured by the term. Some suggested that a health disparity population could be any group in which differences in and/or limitations in our knowledge about the group's drug use and addiction appeared to exist. These groups could be defined, for example, by socioeconomic status, race/ethnicity, and residence including rural/urban. But the inclusion boundaries seemed to be elastic and capable of capturing other groups in which differences were found or inadequate information was available (but problems were likely). They could be defined, for example, by gender; sexual orientation, preference, and behavior; or medical condition (e.g., HIV or hepatitis C virus [HCV] status).

The second concern involved determining the criteria by which research should be considered as health disparity research. Options included counting any research pertinent to the health disparity issue, research related to the health disparity issue that includes the health disparity population as participants, or research that focuses on the health disparity issue and population (e.g., research questions and hypotheses are specific to the health disparity issue; health disparity population accounts for a majority of the participants). The third concern involved the process of implementing studies that would yield valid and useful information on health disparity concerns. The third concern proved to be the most difficult challenge. Numerous questions arose concerning design and methodological issues, such as the necessity of using a comparison group from the majority population, the availability of appropriate measures, operationalizing culture/culturally appropriately, and obtaining adequate sample sizes (related to the NIH inclusion policies).

In 2003, the NIH addressed the first two concerns by further clarifying the Health Disparities definition and providing a method for determining research that is appropriate to the definition. The NIH definition is as follows:

Health Disparities Research (HD) includes basic, clinical, and social sciences studies that focus on identifying, understanding, preventing, diagnosing, and treating health conditions such as diseases, disorders, and such other conditions that are unique to, more serious, or more prevalent in subpopulations in socioeconomically disadvantaged (i.e., low education level, live in poverty) and medically underserved rural and urban communities.

Overall, health disparities research includes three components:

- Minority health research and related activities;
- Rural health research and related activities; and
- Research and other activities related to the socioeconomically disadvantaged in the urban setting.

Grappling with these issues has taught us that we have to provide stronger guidance and leadership in defining NIDA's health disparity priorities and preparing the field to conduct meaningful health disparity research that will advance the field. We also learned that we need more researchers with expertise, experience, resources, and interest in conducting health disparities research.

The Revised Plan

NIDA has reviewed its original health disparities plan and found that overall, it still reflects the needs of the field and conforms with the intent of the national and NIH Health Disparities Initiatives. Moreover, based on the epidemiologic data, racial/ethnic minority populations are consistently and greatly overrepresented in the United States as: (1) groups who suffer disproportionately from the consequences of drug use and addiction, or (2) groups for whom we have little good scientific data about their drug use but for whom there are disturbing prevention, therapeutic, and service concerns. For example, since the first plan was written, HIV and other medical consequences of drug use have been steadily increasing among African Americans. Today, African Americans comprise about 11-12 percent of the U.S. population but more than half of new HIV/AIDS cases. The rate for Hispanics is also disproportionately high. We have very limited epidemiologic data on Asian Americans, but some local data and the reports of clinicians and service providers working in those communities suggest that drug use and addiction are a hidden and growing problem. Moreover, the problem varies by ethnicity/country of origin within the broader racial/ethnic classification of Asian American/Pacific Islander.

NIDA, therefore, maintains racial/ethnic minority populations as its priority health disparity population in its Health Disparities Plan. This is consistent with the three major categories in the NIH Health Disparities definition. Following this priority, NIDA has great interest in rural populations, followed by the other categories of health disparities as described in the NIH definition.

NIDA also maintains its priority rankings of endeavors to be pursued through the plan. Namely, research infrastructure is the first priority. This includes not only the development of scientists in the field but also the development of resources and NIDA's/NIH's infrastructure to provide guidance and support to the field. Research and public information and outreach are the next two major priority areas, respectively.

Overall, few substantive revisions were made to the plan. Clarifying language has been inserted where needed and dated information (e.g., reference to the next generation prevention program which is no longer open to new awards) has been deleted. Changes of note include the following:

- Explicit references to rural health disparities have been added to the plan;
- Additional goals and action steps have been added to the Infrastructure section; and
- An item to explore supporting Diversity Supplements with the Center for Substance Abuse Treatment (CSAT) has been deleted.

NATIONAL INSTITUTE ON DRUG ABUSE

Response to Public Comments

We reviewed the public comments to determine how to improve our strategic plan and make it more responsive to the needs of our various constituent groups (e.g., academic institutions, professional associations). A number of concerns expressed in the comments had been addressed in our original plan, such as the need to focus on diversity within racial/ethnic minority populations (e.g., by ethnic/regional subgroups within populations, gender), attend to language and cultural differences, provide research capacity development support to researchers from diverse backgrounds and a variety of institutions, and communicate with representatives from health disparity populations to ensure their perspectives are heard.

A number of comments referred to the need for NIH to provide more guidance in conducting valid and appropriate health disparity research (e.g., NIH must define standards for cultural competence, more must be done to adjust research methodologies to the needs of minority communities). In our revised plan, we state more strongly our need to provide this type of leadership in research capacity development.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Epidemiology of Drug Abuse, Health Consequences, and Infectious Diseases Among Minority Populations

Rationale and Priority

This is our first research priority.

Our understanding of drug use and addiction in racial/ethnic minority populations and the disparities resulting from drug abuse and addiction is limited. Over the next 5 years, we want to improve our understanding of the incidence and causes of drug abuse and addiction and their consequences in all racial/ethnic groups, recognizing the diversity by gender, socioeconomic status, and other factors within racial/ethnic populations. Aggressively pursuing research in this area will strengthen the discovery of better, more appropriate prevention and treatment strategies with diverse racial/ethnic populations.

Having a good knowledge base on the incidence and patterns of drug use, abuse, and addiction is critical to assessing the need for and shaping the content of prevention and treatment programs. Current surveys such as the NIDA-supported Monitoring the Future study (a national survey of 8th, 10th, and 12th graders) and the Substance Abuse and Mental Health Services Administration (SAMHSA)-supported National Survey on Drug Use and Health (formerly the National Household Survey on Drug Abuse), a national survey of persons 12 and older residing in households, provide important information on drug use patterns and trends. However, they are limited in the extent to which they reveal in-depth information about racial/ethnic groups. For example, neither survey has adequate representation of Native Americans, Alaska Natives, Asians, or Pacific Islanders. African Americans and Hispanics are included, but their numbers are not sufficient to form reliable subgroups to investigate within-group profiles (e.g., develop separate profiles for Mexicans and Puerto Ricans). Moreover, there are selection biases that disproportionately affect minorities that may suppress their numbers in these general surveys. For example, Hispanics have a higher school dropout rate than other groups and therefore may be more likely to be excluded from the school surveys and may be difficult to reach in household surveys. Since dropout rates correlate with higher risk for deviant behavior, we may be missing information on a group with a high risk for drug abuse and addiction.

More work is needed to better understand the causes of drug use in minority communities. Promising studies are under way on risk and protective factors, especially on the role of culture, religiosity, ethnic identity, and family, peer, and environmental/community level factors in drug initiation. For example, minority youth tend to initiate drug use later than White youth. Yet, when African Americans start using, they seem to progress to addiction faster. Among Hispanic youth, drug use seems to increase with increased acculturation to U.S. norms and with years and generations in the United States. We know little about predictors of use in Pacific Islander and Asian subpopulations.

Better measures and designs are needed to appropriately assess drug abuse and addiction and related behaviors in specific racial/ethnic populations.

Minority populations are disproportionately affected by HIV/AIDS and other infectious diseases that are a consequence of using drugs and engaging in other risky behaviors. African Americans and Hispanics, especially women, comprised 69 percent of the AIDS cases reported to the Centers for Disease Control and Prevention in 2001. This percentage is far greater than their representation in the general population. Other studies indicate a plethora of ways in which members of minority groups may be adversely affected by drug abuse-related diseases: women, particularly African American women, are at higher, unique risk for HIV/AIDS; injection drug users are at increased risk for *Mycobacterium tuberculosis* infection and hepatitis B and C infection; there possibly is an association between vascular injury of the neonatal central nervous system and the level of prenatal cocaine exposure; and Hispanic homeless are more likely to share needles. We know relatively little about the varying patterns of initiation of drug use and addiction among women of diverse racial and ethnic groups.

NIDA continuously has attempted to be responsive to the need to understand the patterns and causes of drug abuse in all populations through a number of activities such as releasing PAs and RFAs and convening conferences and meetings. For example, in 2004 NIDA reissued its “Epidemiologic Research on Drug Abuse” PA, which encourages a number of epidemiologic strategies including monitoring of trends over time of drugs of use/abuse, identification and measurement of health problems associated with drug abuse, and international epidemiology of drug abuse. Applications submitted in response to this PA are expected to guide the development of interventions; define subpopulations; identify groups at risk for various health conditions such as HIV, tuberculosis, hepatitis, poor pregnancy outcomes, attention deficit hyperactivity disorder, mental disorder, and other conditions (predisposing and consequential to drug use/abuse); inform and influence local state and federal health agencies; and provide guidance for public policy and expand our knowledge about the consequences of drug use within and across different populations. Investigators have been strongly encouraged to conduct analyses by race/ethnicity.

NIDA staff has been working actively at numerous meetings to increase the number of grant applications in such areas as HIV in the African-American population, health care/primary care access and utilization among minority drug abusers with HIV infections, and epidemiology of HIV in the Caribbean.

1.1.1 Objective One

Improve the knowledge base on the patterns and origins of drug abuse and addiction in all racial/ethnic populations including producing estimates of racial disparities in the incidence and prevalence of drug use and addiction within those populations, examining both risk and protective factors.

1.1.1.1 Action Plan

- Assess, within and across racial/ethnic groups, the magnitude, incidence, and prevalence of drug abuse, analyzing by gender, socioeconomic status, and age.
- Identify and assess individual and community/environmental vulnerability, risk and protective factors for drug use and abuse, and related consequences in various racial/ethnic populations, analyzing by gender, socioeconomic status, and age.
- Develop better sampling methods for hard-to-reach minority populations and more effective ways to reduce survey non-response and increase the validity of self-reported drug use and associated behaviors, as these may differentially affect minority populations.
- Encourage and support the secondary analysis of data obtained under NIH-supported research pertinent to understanding the epidemiology and etiology of drug abuse and addiction in specific racial/ethnic populations, including analyses by gender, socioeconomic status, and age.

1.1.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research opportunities in this area through PAs, RFAs, and/or Diversity Supplements.	Announcements by FY2005
Increase number of studies supported.	Annual increases through FY2005
Prepare the field for research in this area through technical assistance, resource materials, and meetings.	Annual activities

Routinely monitor and discuss implementation progress, concerns and needs to determine if activities need to be modified.	Annually

1.1.1.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies with specific aims focused on the investigation of drug use, abuse, and addiction patterns; incidence; and prevalence in racial/ethnic minority populations.	Annual increases through FY2007
Increased number of articles in the scientific literature.	Annual increases through FY2008
Increased number of scientific presentations.	Annual increases
Development of better, culturally appropriate measures and procedures.	Annual progress
Increased understanding of drug use within and across racial/ethnic minority populations (e.g., by gender, age, and urban/rural settings).	Annual progress

1.1.2 Objective Two

Identify and examine issues of health disparities in infectious diseases associated with drug abuse, particularly HIV/AIDS, within racial/ethnic populations including analyses by gender.

1.1.2.1 Action Plan

- Increase scientific knowledge about the medical and health consequences of drug abuse among women and men in racial/ethnic minority groups, including assessing the magnitude, incidence, and prevalence of HIV/AIDS and other sexually transmitted infections, hepatitis B virus, HCV, and tuberculosis and their impact on racial/minority populations; identifying the associated risk and protective factors for these infectious diseases, mental disorders, and socioeconomic status among racial/minority populations; and identifying subgroups within racial/minority groups (e.g., homeless, homosexuals, prison inmates) at greatest risk.
- Develop and implement appropriate intervention strategies for reducing risk factors among women and men in these groups.

- Increase access to, utilization of, and adherence to antiviral therapies by HIV-infected ethnic minority male and female drug users through identifying new, simplified, and innovative strategies/approaches and mechanisms to complement and improve traditional approaches for individuals in this population.
- Increase scientific knowledge on how gender and other factors such as community, culture, education, and socioeconomic status affect HIV transmission within racial/ethnic populations.

1.1.2.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research opportunities in this area through PAs, RFAs, and/or Diversity Supplements.	Announcements by FY2005
Increase number of studies supported.	Annual increases through FY2008
Prepare the field for research in this area through technical assistance, resource materials, and meetings.	Annual activities
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annually
Coordinate with other Institutes and Centers or agencies where appropriate and likely to advance the research.	On-going

1.1.2.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies that focus on the investigation of HIV/AIDS and other medical consequences of drug involvement for racial/ethnic minority populations.	Annual increases through FY2008
Increased number of articles in the scientific literature.	Annual increases through FY2008
Increased number of scientific presentations.	Annual increases
Development of accessible and culturally appropriate adherence approaches.	Annual progress

Increased understanding of the risk and protective factors associated with drug use and HIV among racial/ethnic minority drug user populations particularly as determined by gender, age, environment, and urban/rural setting.	Annual increase

1.1.3 Objective Three

Identify the short- and long-term effects of drug use, abuse, and addiction on overall health (including physical, mental and emotional health) and related consequences (e.g., violence and crime) in racial/ethnic minority populations.

1.1.3.1 Action Plan

- To respond to the great and growing disproportionate incidence of HIV/AIDS and criminal justice involvement related to drug use in the African American population, support research to better understand this phenomenon.
- Identify and assess issues of co-morbidity across the life cycle for all racial/ethnic groups and the relationships among drug abuse, co-morbid conditions, and health disparities within and across those groups and by gender within these groups.
- Investigate health and developmental disparities across racial/ethnic groups for children and adolescents who have experienced prenatal drug exposure and/or early use of illicit drugs by gender within these groups.
- Identify and review the state of knowledge and availability of data on the coexistence of substance abuse and mental/emotional disorders and the presence of health disparities across and within racial/ethnic groups including analyses by gender.
- Identify the impact of the drug-using environment on racial/ethnic minority women and men living under those conditions. Assess proposed strategies for interventions to reduce drug abuse in these groups.
- Evaluate the role of stress (e.g., cultural adaptation) in initiating and escalating drug use/abuse and its impact on various male and female racial/ethnic populations. Sensitivity and responsiveness to the needs of the target audience must be considered in all instrument development, administration, analysis, and evaluation of the data.
- Explore the contextual relationships between drug use, violence, employability, school performance, family structure, and economic well-being of the community.

1.1.3.2 Performance Measures

Major Performance Measures	Target/Timeline
Develop research opportunities in this area	

through PAs, RFAs, and/or Diversity Supplements.	Announcements by FY2005
Increase number of studies supported.	Annual increases through FY2008
Prepare the field for research in this area through technical assistance, resource materials, and meetings.	Annual activities
Routinely monitor and discuss implementation progress, concerns and needs to determine if activities need to be modified.	Annually

1.1.3.3 Outcome Measures

Major Outcome Measures	**Target Date/Timeline**
Increased number of studies on disparities related to co-morbidities, environment, stress, and other contextual variables.	Annual increases through FY2008
Increased number of articles in the scientific literature.	Annual increases
Increased number of scientific presentations.	Annual increases
Advances in research methods and assessment tools related to this line of research.	Annual progress
Increased knowledge of consequences of drug use and addiction specific to racial/ethnic minority women and children.	Annual increases

1.2 Research Area of Emphasis Two: Prevention of Drug Abuse and Addiction

This is our second research priority.

NIDA has made great strides in the last few years in its prevention research program. NIDA has supported two long-term minority prevention research centers that focus on African Americans, Hispanics, and Native Americans, as well as several other research projects that include ethnic minorities. Results from these and other research studies suggest that racial/ethnic minority populations may have special prevention needs, and prevention strategies may have to be specific to their culture and circumstances to be successful. For example, research indicates that including culturally specific components in a generic prevention program enhances effectiveness with African Americans.

Epidemiologic data show that racial/ethnic groups differ in patterns of drug use, preferences, and accessibility and risks, requiring prevention programs that attend to these needs. For example, Hispanic youth are more likely to be school dropouts, making school-based prevention programs unlikely to reach Hispanic youth at greatest risk. African Americans have late onset of (or delayed onset of) drug use, suggesting that they may be particularly in need of prevention programs after high school, in their late adolescent/early adult years. Native Americans on reservations need prevention programs at an early age, and such programs must be acceptable to tribal councils. Second-generation immigrants may be at higher risk for drug use than first-generation. Moreover, the heterogeneity or diversity within racial/ethnic groups must be acknowledged in prevention efforts (e.g., gender, socioeconomic status, education, cultural styles, rural/urban), and the specific risk factors for these subgroups need to be better understood to inform prevention efforts.

More prevention programs are needed to reach minority populations in high-risk settings and neglected, hard-to-reach areas or communities. This includes, for example, persons in correctional facilities (more likely to be African Americans and Hispanics), persons in rural areas, migrant workers/seasonal farm workers (often Hispanic and Haitian), children in drug abusing families, and minority women addicts (who are at great risk for infectious diseases). More research is needed on prevention efforts with Asians/Pacific Islanders and Native Americans/Alaska Natives and their subgroups.

1.2.1 Objective One

Support prevention research targeting racial/ethnic minorities.

1.2.1.1 Action Plan

- Determine the drug abuse and HIV/AIDS prevention needs of minority populations across the life span, with specific attention to very early and late onset initiation of use and diversity in vulnerability to use across the life cycle (e.g., immigrant groups adapting to new environment, transition points, stress).
- Develop culturally appropriate prevention interventions and guidance on how to adapt “generic” prevention models for specific minority populations.
- Examine the effectiveness of mass media prevention/education messages that target specific minority populations.
- Develop more prevention interventions that reach minority populations in contexts such as the family, church/faith community, and other community programs to ensure that prevention expertise becomes a permanent part of the community.

- Address the complexities and requirements of developing effective prevention programs for diverse groups within multiethnic, multicultural settings (e.g., schools with multiethnic student bodies, persons with multiple ethnic identifications or affiliations).
- Explore how cultural norms and protective and risk factors affect gender differences in responsiveness to prevention strategies.

1.2.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research opportunities in this area through PAs, RFAs, and/or Diversity Supplements.	Announcements by FY2006
Increase number of studies supported.	Annual increases through FY2008
Prepare the field for research in this area through technical assistance, resource materials, and presentations at professional meetings.	Annual activities
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annually

1.2.1.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies focusing on specific prevention needs of each ethnic minority population.	Annual increases through FY2008
Increased number of articles in the scientific literature.	Annual increases
Increased number of scientific presentations.	Annual increases
Increased number and/or refinement of prevention strategies/models.	Annual progress

1.2.2 Objective Two

Ensure that the new directions for prevention research, such as research-to-practice initiatives and basic prevention research, include members of racial/ethnic minority, rural, and other underserved communities. Further ensure that new directions in prevention are encouraged that involve the study of minority-specific concepts (such as reduction of acculturation stress, prevention through naturally occurring protective factors, and the role of ethnic identity in the prevention of substance abuse) and factors specific to rural populations (such as access to programs).

1.2.2.1 Action Plan

NIDA staff will review plans for studies to make certain that concerns of racial/ethnic minorities and rural populations are adequately addressed.

1.2.2.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Encourage research applications in this initiative.	Continuing
Require the inclusion of ethnic minority issues and rural populations in research supported through this initiative.	Continuing
Monitor inclusion of minority populations and rural populations in studies.	Continuing

1.2.2.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Adequate inclusion of ethnic minority and rural populations and issues in prevention effectiveness research trials.	Continuing
Increased articles in the scientific literature on prevention effectiveness with ethnic minority and rural populations.	Continuing
Increased number of scientific presentations.	Continuing
Better understanding of processes and factors necessary to develop effective prevention programs for racial/ethnic minority and rural populations.	Continuing

1.2.3 Objective Three

Develop effective, culturally specific drug abuse prevention strategies for racial/ethnic minority populations who are at increased risk for drug abuse, such as individuals in detention or juvenile correctional facilities, the homeless, persons who have been abused or neglected, and rural populations, including persons on Indian reservations and migrants or seasonal farm workers.

1.2.3.1 Action Plan

Expand research opportunities in this area.

1.2.3.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Encourage research applications in this area.	Continuing
Require the inclusion of racial/ethnic minority issues and rural populations.	Continuing
Monitor inclusion of racial/ethnic minority populations and rural populations in studies.	Continuing

1.2.3.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies that focus on prevention with racial/ethnic minority and rural populations at higher risk for drug abuse and addiction and its consequences.	Annual increases through FY2008
Increased number of articles in the scientific literature.	Annual increases
Increased number of scientific presentations.	Annual increases
Development/refinement of prevention strategies specifically for higher risk individuals.	Annual progress

1.3 Research Area of Emphasis Three: Addressing Disparities in Treatment and Health Services Research

This is our third research priority.

NIDA currently supports several activities that focus on racial/ethnic minority groups and cultural factors in treatment for addiction. For example, the Behavioral Therapy Development Program supports several studies that are evaluating family-based treatment approaches for drug-using minority youth (based on research findings suggesting that family variables are more influential in substance use in certain minority youth). Some of these studies suggest that treatment engagement procedures may be different for Mexican American and Cuban youth. Analyses will be conducted to ascertain whether outcome differences are due to cultural factors associated with Mexican-American and Cuban families or other factors. A study was funded that is evaluating the efficacy of adding a culturally relevant, community-based community reinforcement enhancement to an existing residential treatment program for homeless, crack-using, African-American women with children. This study is using the Black church as a vehicle for implementing the intervention. To advance the current knowledge base about potential ethnic differences in nicotine dependence, NIDA is supporting a study that will design and test the efficacy of smoking cessation programs in treating Chinese American smokers.

NIDA's newly established National Drug Abuse Treatment Clinical Trials Network (CTN) will provide yet another vehicle for NIDA to ensure that minority populations are included in both NIDA's treatment research protocols and in actually conducting treatment research. The CTN will provide a much-needed national research and dissemination infrastructure to more rapidly and systematically bring new science-based addiction treatments into real-life treatment settings.

Considering the severe consequences of drug abuse and addiction on racial/ethnic populations, NIDA realizes that minority populations need to be more fully included in treatment research and clinical trials. Moreover, more attention needs to be directed at examining medical, social, and cultural factors that may influence adherence to treatment and treatment outcomes. For example, some minority populations are included in NIDA-supported clinical trials of pharmacotherapies and behavioral therapies; however, data are not completely analyzed by race/ethnicity to better understand behavior in treatment or outcomes of treatment. In some clinical research studies, there have been difficulties in enrolling and retaining adequate numbers of minorities to conduct meaningful data analyses. Other research indicates that race/ethnicity may be important in physiological responsiveness to drugs. For example, pharmacokinetic studies indicate that there are differences in some ethnic populations in their ability to metabolize different drugs.

Racial/ethnic minorities may experience more difficulties in obtaining the most appropriate health care services. Research suggests that they may be more vulnerable to gaps and lack of coordination in systems of care and that they may encounter bias in treatment assignments. The need for services appears to differ by race/ethnicity (e.g., one study suggests that Latinos may require more intensive services).

Rural populations appear to have fewer drug abuse services available to them. Moreover, service provision may be further complicated by transportation problems and issues of anonymity and confidentiality (hard to attain in rural areas), significant issues for drug abuse services.

1.3.1 Objective One

Increase the number of treatment research studies that focus on racial/ethnic minority and rural populations and improve dissemination of the study results.

1.3.1.1 Action Plan

- Ensure that all racial/ethnic minority and rural populations are fully included in NIDA's newly established National Drug Abuse Treatment CTN as clients, advisors, and research staff. Ensure that a sufficiently large sample is recruited in each study to allow for analyses by specific racial/ethnic groups.
- Develop a strategy to obtain more input from racial/ethnic minority and rural populations for the NIDA research agenda.
- Encourage research to develop and test behavioral treatments that are culturally and gender sensitive and relevant for racial/ethnic minorities, and encourage studies of behavioral treatments, alone and in combination with pharmacological treatments, for racial and ethnic minority drug abusers, including adolescents, women, and those involved with the criminal justice system.
- Encourage research to develop validated, reliable clinical screening and assessment instruments in languages other than English for use in clinical research with non-English-speaking subjects.
- Expand NIDA's intramural clinical research to address treatment issues by race/ethnicity, and further develop the program focusing on smoking cessation techniques with minority youth.

1.3.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Institute procedures for the adequate inclusion of racial/ethnic minority and rural issues and populations in the CTN.	By FY2006
Develop research opportunities through PAs, RFAs, and/or Diversity Supplements.	By FY2006
Implement strategies to solicit input from the field.	Ongoing

Implement procedures to improve assessment tools.	By FY2005
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annually

1.3.1.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies that focus on effective clinical interventions with racial/ethnic minority individuals and rural populations.	Annual increases through FY2006
Clinical tools available in languages other than English.	By FY2004
Expanded research agenda that reflects needs of the field.	Ongoing
Increased number of scientific presentations.	Annual increases
Increased number of articles in the scientific literature.	Annual increases

1.3.2 Objective Two

Determine the factors that contribute to differences, if any, experienced by racial/ethnic minority and rural populations in access to services and outcomes of treatment in managed care and other service systems.

1.3.2.1 Action Plan

- Expand the treatment and prevention services research portfolio to better understand the organization, management, financing, and delivery of services and to enhance the integration of treatment and prevention strategies and programs into existing community-level service delivery systems.
- Assess the impact of program adaptation and cultural sensitivity on substance abuse services provided to ethnic minorities, especially minority women.
- Develop research to understand the role and impact of the criminal justice system, including drug courts, on drug abuse treatment in racial/ethnic minority populations.

1.3.2.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research opportunities in this area through PAs, RFAs, and/or Diversity Supplements.	By FY2006
Increase number of studies supported.	By FY2006
Encourage and prepare the field for research in this area.	Ongoing
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annually
Provide forum/opportunities for the field to build its research agenda.	Ongoing

1.3.2.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of studies.	Annual increases
Increased number of professional presentations.	Annual increases
Expanded research agenda.	Ongoing
Better understanding of factors that contribute to disparities in drug treatment and services for each racial/ethnic minority population.	Annual progress

1.4 Research Area of Emphasis Four: Addressing Racial/Ethnic Disparities in Basic and Clinical Neurosciences

This is our fourth research priority area.

Research is needed to better understand racial/ethnic differences in genetic as well as environmental influences on vulnerability and/or resilience to drug initiation, drug abuse, and addiction; neurotoxicity; and neurobiological and behavioral processes underlying tolerance, dependence, and relapse. Pharmacokinetic studies have revealed distinct differences in some ethnic populations in the ability to metabolize different drugs, indicating a clear biological basis for response to drugs. There also may be some specific biologically based differential response to particular drugs or classes of drugs across racial/ethnic groups that might, in turn, influence such aspects as drug liking/initiation, addiction vulnerability, and neurobiological/neurobehavioral toxicity. Studies focusing on the interaction between racial/ethnic differences and the effects of drugs on underlying neural and behavioral processes will provide the basis for more targeted treatment and prevention approaches in different populations.

1.4.1 Objective One

Increase the number of neuroscience, clinical neuroscience, and basic behavioral science studies that focus on racial/ethnic differences.

1.4.1.1 Action Plan

- Provide support to key investigators to oversample underrepresented groups in their studies so that meaningful analyses and comparisons can be made across race and ethnicity.
- Encourage diversity supplements and other training opportunities for individuals from diverse groups, including minority populations, in basic and clinical neuroscience.
- Provide avenues for publication of basic research findings comparing subgroups, including NIDA-sponsored publications.
- Provide information on strategies for recruiting underrepresented groups into basic human subject-based research and clinical research.
- Expand research that directly targets minorities in the basic and clinical neurosciences and behavioral sciences, with the intent of addressing minority health disparities.

1.4.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research opportunities in this area through PAs, RFAs, and/or Diversity Supplements.	By FY2006
Increase number of studies supported.	By FY2006
Prepare the field for research in this area through technical assistance, resource materials, and meetings.	Ongoing
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annually

1.4.1.3 Outcome Measures

Major Outcome Measures	Target/Timeline
Increased number of studies.	Annual starting in FY2004
Better understanding of genetic and neurobiological factors associated with addiction.	Annual progress
Increased number of articles in the scientific literature.	Annual increases starting in FY2004
Increased number of scientific presentations.	Annual increases starting in FY2004
Better informed researchers and practitioners.	Annual progress

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

Research capacity is our first overall priority.

NIDA recognizes that conducting scientifically valid health disparities research requires a research infrastructure that includes well-informed and trained scientists, knowledgeable and cooperative communities (e.g., community-based organizations, professional associations, faith community, tribal councils), and academic institutions with competency and interest in health disparities research. NIDA has made concerted efforts to build this critical infrastructure for health disparities research. We have worked to increase the number of underrepresented scholars involved in drug abuse research and to increase our support of useful and appropriate research on drug abuse in minority communities. A number of initiatives, programs, and activities have been implemented to eliminate this underrepresentation, for example, the establishment of expert work groups on racial/ethnic populations, the strengthening of the Diversity Supplement Program, the development of an HBCU initiative, the provision of technical assistance in grants development, and the development of PAs and RFAs to build the research infrastructure of a variety of institutions. NIDA plans to build upon these already successful programs and expand them to increase training and career development opportunities for individuals from minority and other underrepresented populations. In addition, NIDA plans to increase the numbers of researchers and research studies that focus on abuse and addiction in minority communities and to, in general, stimulate interest and enhance competency in conducting research for eliminating disparities experienced by racial/ethnic populations related to drug abuse and addiction.

2.1.1 Objective One:

Increase and improve drug abuse and addiction research development and training experiences for students, especially those from minority and other underrepresented populations, as a means of attracting and preparing competent future researchers in addiction research and health disparity populations.

2.1.1.1 Action Plan

- Continue to support the Minority Recruitment and Training Program (MRTP) sponsored by the intramural program, the extramural Summer Research With NIDA program for minority high school and undergraduate students, and the Minority Supplement program. These programs were developed to address the need to build a diverse scientific workforce on drug abuse and addiction research. As noted in the introduction to this plan, the Minority Supplement Program is now the Diversity Supplement Program (note that the Summer Research Program is a part of the Diversity Supplement Program with special outreach to high school and undergraduate students). In 2005, NIDA adopted procedures to comply with the NIH Diversity Supplement Program. The MRTP, as indicated earlier will be reviewed to ensure that NIDA's need and goals of achieving diversity in the scientific workforce studying drug abuse and addiction are accomplished while conforming to NIH expectations and policies regarding equitable access to research opportunities for all population groups.
- Explore the feasibility of establishing short-term training grants (e.g., T35) from drug abuse and addiction programs particularly those involved in the National Drug Abuse CTN, to offer summer research training experiences for promising undergraduate and graduate students from minority and other underrepresented populations.

2.1.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Continued support of the Diversity Supplement Program and summer programs.	Annual
Increase budget to support these initiatives.	Annual increases
Discuss and decide feasibility of short-term training grants for this purpose.	FY2006

2.1.1.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of students pursuing careers in drug abuse research.	Annual increases
Availability of new programs to support students and faculty from minority and other underrepresented populations.	FY2006

2.1.2 Objective Two

Establish new and strengthen existing programs to provide research development and support opportunities for faculty and investigators, especially those investigators from minority and other underrepresented populations interested in minority health and health disparities research related to drug use and addiction.

2.1.2.1 Action Plan

Continue to support the Diversity Supplement Program, the Research Development Technical Assistance program, and the on-line research grants development program.

As noted in the introduction to this plan, the Minority Supplement Program is now the Diversity Supplement Program, and in 2005, NIDA adopted procedures to comply with the NIH Diversity Supplement Program.

NIDA overall offers a variety of grant development workshops and supports for all interested scholars. The participation of underrepresented scholars in these efforts has been lower than desired. The Research Development Technical Assistance Workshops were developed to ensure that underrepresented scholars were recruited and made aware of this type of training opportunity. Participation in the workshops has included scholars from all population groups. The program will be reviewed, however, to ensure that it furthers NIDA's science and scientific workforce needs and NIH expectations and policies regarding equitable access to research opportunities for all population groups.

2.1.2.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research development opportunities through PAs, RFAs, the Diversity Supplement Program, and/or	

Administrative Supplements.	FY2006
Increase budget to support these initiatives.	Annual increases
Collaborate with other Institutes and Centers and agencies on programs/activities of mutual interest.	Ongoing
Routinely monitor and discuss implementation progress, concerns and needs to determine if activities need to be modified.	Annual

2.1.2.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased number of investigators from minority and other underrepresented populations.	Annual increases
Increased number of investigators researching minority and health disparities issues in drug abuse and addiction.	Annual increases
Availability of new programs to support students and faculty from minority and other underrepresented populations.	2006

2.1.3 Objective Three

Increase the capacity of academic institutions, especially those serving individuals from minority and other underrepresented populations, to conduct health disparity research in drug abuse and addiction.

NIDA encourages all academic institutions to prepare themselves to conduct research on health disparities and to participate in NIDA activities to enhance their ability to conduct health disparities research. Efforts are taken to ensure that a variety of institutions, including HBCUs, are made aware of NIDA-sponsored meetings, workshops, and research opportunities that address health disparities concerns. In this instance, NIDA reaches out to institutions that self-identify and have been identified by other entities as institutions serving individuals from minority and other underrepresented populations.

NATIONAL INSTITUTE ON DRUG ABUSE

2.1.3.1 Action Plan

- Continue to support the Diverse Institutions Drug Abuse Research Program and the HBCU Initiative. The Diverse Institutions Drug Abuse Research Program is based on a program developed approximately 20 years ago. The current program was developed using the definition of institutions serving individuals from minority and other underrepresented populations commonly used by NIH and other Department of Health and Human Services agencies (e.g., historic designation such as HBCUs). In addition, since this is a capacity development program, consideration is given to the applicant organization's history of sponsored research in drug abuse and addiction. The program will be reviewed to ensure that it furthers NIDA's science and scientific workforce needs and NIH expectations and policies regarding equitable access to research opportunities for all population groups.
- Develop partnerships between institutions with well-established drug abuse research programs and other institutions that are interested in developing capacity in this area.
- Establish an undergraduate research development program to encourage and engage promising undergraduate students from minority and other underrepresented populations in drug abuse and addiction research.
- Support or examine the possibility of establishing Training Centers (T32s) in the basic neurosciences, behavioral sciences, and clinical neurosciences at HBCUs and other colleges and universities. Encourage the participation of minority students at already-existing centers.

2.1.3.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop research development opportunities through PAs, RFAs, the Diversity Supplement Program, and/or Administrative Supplements.	Start by FY2002
Collaborate with other Institutes and Centers and agencies on programs/activities of mutual interest.	Ongoing
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annual

2.1.3.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increased involvement of diverse institutions such as HBCUs in drug abuse research on minority	

populations and health disparities (e.g., more grants, collaboration with grantees).	Annual increases
Increased number of investigators from minority and other underrepresented populations.	Annual increases
Increased number of investigators researching racial/ethnic minority and health disparities issues in drug abuse and addiction.	Annual increases
Increased number of students pursuing careers in drug abuse research.	Annual increases
Availability of new programs to support students and faculty from minority and other underrepresented populations.	Annual increases

2.1.4 Objective Four

Involve the broader professional and lay community in addressing health disparities in racial/ethnic communities caused by drug abuse and addiction.

2.1.4.1 Action Plan

- Continue to support the various expert work groups on African American, Hispanic, Asian American and Pacific Islander, and Native American and Alaska Native communities.
- Encourage clinical minority professional organizations to create and administer clinical minority research development programs through the K12 mechanism. This can be modeled after the successful American Psychiatric Association and American Academy of Child and Adolescent Psychiatry programs to recruit and train minority clinicians interested in drug abuse and addiction research.
- Host a series of writing workshops to facilitate publications in peer-reviewed journals by minority scholars.
- Develop opportunities (e.g., forums at professional meetings) to discuss drug abuse research needs, plans, and opportunities with key stakeholder groups, to include practitioners and consumers.
- Support workshops or programs to train investigators on conducting responsible drug abuse research in racial/ethnic minority communities. Consider creating guidelines for ensuring that such research is appropriate and sensitive.

2.1.4.2 Performance Measures

Major Performance Measures	Target/Timeline
Develop research development opportunities through PAs, RFAs, the Diversity Supplement Program, and/or Administrative Supplements.	Annual
Collaborate with other Institutes and Centers and agencies on programs/activities of mutual interest.	Ongoing
Prepare the field to pursue drug abuse research in racial/ethnic minority health and health disparities areas.	Ongoing
Routinely monitor and discuss implementation progress, Concerns, and needs to determine if activities need to be modified.	Annual

2.1.4.3 Outcome Measures

Major Outcome Measures Target/Timeline

There is a certain stigma attached to drug abuse and pursuing a career in drug abuse research. The following outcomes are attempts by NIDA to measure its success in achieving its goals of increasing the field’s participation in health disparities drug abuse and addiction research and increasing the diversity of the research workforce engaged in health disparities drug abuse research. Our various programs attempt to ensure that all scientists and institutions become interested and competent in this area, and will submit applications for funding consideration. Funding decisions are based on merit.

Increased involvement of diverse institutions, such as HBCUs and others, in drug abuse research on minority populations and health disparities (e.g., more grants, collaboration with grantees).	Annual increases
Increased number of investigators from minority and other underrepresented populations.	Annual increases
Increased number of investigators researching racial/ethnic minority and health disparities issues in drug abuse and addiction.	Annual increases

Increased number of students pursuing careers in drug abuse research.	Annual increases
Availability of new programs to support students and faculty from minority and other underrepresented populations	FY2005

No new program was developed in FY05. Any programs proposed will be carefully reviewed to ensure that NIDA's need and goals of achieving diversity in the scientific workforce studying drug abuse and addiction are accomplished while conforming to NIH expectations and policies regarding equitable access to research opportunities for all population groups.

Increased participation in meetings and forums (to disseminate information on research development needs and opportunities).	Ongoing

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

This is our third overall priority.

There are special challenges and problems in creating culturally appropriate information for special populations. To meet these challenges, NIDA has organized and convened ethnic advisory panels for Latinos, Asian Americans/Pacific Islanders, and African Americans to improve our outreach to these various ethnic and minority groups. Acting upon the advice of these experts, NIDA has:

- Developed Spanish translations of our two popular marijuana pamphlets, "Marijuana: Facts for Teens" and "Marijuana: Facts Parents Should Know";
- Created a radio public service announcement campaign on marijuana abuse for African American males aged 13-25;
- Produced more than 30 fact sheets about drug abuse and addiction in Spanish as part of our fax-back system, "INFOFAX";
- Marketed the "INFOFAX" series, as well as the NIDA web site, via a Spanish art card distributed to appropriate outlets nationally;
- Given financial and editorial support to "Pro Salud," a national publication marketed to Hispanic communities; and
- Developed Spanish translations of the drug abuse Problem Oriented Screening and Assessment Instrument for adolescents.

In addition to these efforts, NIDA routinely distributes all of its press releases to media outlets designed to reach special populations.

NATIONAL INSTITUTE ON DRUG ABUSE

3.1.1 Objective One

Educate racial/ethnic minority populations about drug abuse and addiction prevention and treatment. Also, identify and improve mechanisms for dissemination of research findings within and across minority groups. NIDA is focusing on four key cultural minorities at present: Asian Americans/Pacific Islanders, Hispanics, Native Americans, and African Americans. Based on discussions with members of our cultural minority advisory panels, we have also identified some subpopulations with special needs (e.g., Vietnamese, Cambodian, Filipino, other Pacific Islander).

3.1.1.1 Action Plan

- Develop a series of radio public service announcements and educational videos targeting Hispanic women. Hispanic women have a strong influence in health and lifestyle decisions within the Hispanic community. In addition to public service announcements, a Hispanic family-targeted brochure and video highlighting specific drugs of abuse known to be a problem in various Hispanic communities (as well as among majority youth) will be provided as collateral materials. A comprehensive marketing plan to get the public service announcements aired and the brochure distributed includes forming partnerships with appropriate Hispanic organizations and persons of influence (journalists, entertainers, etc.). NIDA will work closely with the NIH Hispanic Initiative Coordinator during the preparation of all related materials.
- Create a year 2001 calendar for Native Americans that will be used to provide information about drug abuse. It will be marketed broadly in fall 2000 via appropriate organizations, the media and other venues (e.g., Native American-owned businesses; Indian Health Service clinics).
- Create television drug abuse public service announcements and videos in Spanish, which will be distributed to appropriate Hispanic outlets. The public service announcements and videos will follow the theme of NIDA's national campaign, "Addiction is a Brain Disease," in an effort to educate the Hispanic community about the disease of addiction.
- Translate and adapt other popular NIDA publications into Spanish, including "Principles of Drug Addiction Treatment." When completed, these materials will be packaged as a comprehensive set and broadly distributed to Hispanic-oriented schools, health organizations, and community groups. Provide targeted training to Hispanic substance abuse treatment providers on effective treatment methods.
- Enhance NIDA collaboration with minority professional organizations through the NIDA Constituent Conference, NIDA Town Meetings, etc.

3.1.1.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop materials specific to the audience as indicated in the plan.	Ongoing

Consult with experts on communication and racial/ethnic minority populations.	Ongoing
Routinely monitor and discuss implementation progress, Concerns, and needs to determine if activities need to be modified.	Annual

3.1.1.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Materials available in Spanish.	Ongoing
Establish ongoing relationships with various racial/ethnic minority constituent groups.	Ongoing
Dissemination plans for Hispanic and Native American populations available.	By FY2005

3.1.2 Objective Two

Put research into practice in minority communities by providing science-based prevention and treatment information to service providers serving these populations.

3.1.2.1 Action Plan

- Translate “Preventing Drug Use Among Children and Adolescents: A Research-Based Guide” and “Principles of Drug Addiction Treatment: A Research-Based Guide” into Spanish and distribute them to caregivers and service providers who work with Hispanic populations.
- Distribute to service providers working in minority communities the “NIDA Toolkit.” The “NIDA Toolkit” is a national NIDA initiative to get the latest treatment information, including a set of NIDA Treatment Manuals, to service providers across the Nation.
- Develop an outreach program to community leaders of specific special population groups that will enable them to help families understand drug abuse problems within their communities and give those families culturally appropriate tools for prevention and treatment in those communities.
- Translate the NIDA treatment manuals into Spanish and distribute them to treatment providers who work with minority populations.
- Develop a research-based prevention guide for persons working with racial/ethnic minority groups.

3.1.2.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Develop the materials as outlined in the plan.	By FY2004
Distribute the materials to service providers and community leaders working with racial/ethnic minority populations.	By FY2005
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annual

3.1.2.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Availability of guides and manuals in other languages.	By FY2005
Culturally appropriate outreach program available.	By FY2006

3.1.3 Objective Three

Educate the research and practice community about the state-of-the-art in drug abuse and addiction research with racial/ethnic minority populations.

3.1.3.1 Action Plan

- Sponsor a national conference on drug abuse and addiction research and racial/ethnic communities.
- Develop a guide and web site where information on research with specific racial/ethnic populations is available. Information such as current research, research findings, and valid measures would be available.
- Provide guidelines and training on how to conduct research with specific racial/ethnic groups, including information on cultural styles and ethical issues.
- Identify and improve mechanisms for dissemination of research findings within and across minority groups.

3.1.3.2 Performance Measures

Major Performance Measures	**Target/Timeline**
Convene the national conference.	FY2001 and 2005
Develop information sources as outlined.	Annual progress
Routinely monitor and discuss implementation progress, concerns, and needs to determine if activities need to be modified.	Annual

3.1.3.3 Outcome Measures

Major Outcome Measures	**Target/Timeline**
Increase in persons informed about drug abuse research in racial/ethnic minority populations.	Ongoing
Availability of easily accessible information on drug abuse research in ethnic minority communities (web-based information).	Ongoing
Increased interaction of NIDA staff with students, researchers, and practitioners interested in drug abuse research.	Ongoing
Better trained/prepared researchers pursuing or conducting drug abuse research in racial/ethnic minority communities.	Ongoing
Increased use of NIDA as a resource.	Ongoing

The National Library of Medicine

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

NATIONAL LIBRARY OF MEDICINE

NLM Mission/Vision Statement

Over the past half century, the nation's investment in scientific research has resulted in unprecedented revolutionary progress in biological, medical, and material sciences. Information technology holds the promise of delivering specific knowledge in a timely manner to billions of people worldwide, in ways undreamed of even a short time ago. The National Library of Medicine (NLM), in pursuit of its longstanding mission to acquire, organize, and disseminate health-related information, now has the opportunity to provide near-instantaneous reliable access to high-quality health information resources when and where decisions are made. The support of the National Institute of Health's (NIH's) efforts to understand and eliminate health disparities between minority and majority populations is an integral part of NLM's mission.

Overview of NLM Strategy for Addressing Health Disparities

NLM is directing many of its efforts toward remedying the disparity in health opportunities experienced by important segments of the American population. These efforts are based on the belief that improving access to affordable and easy-to-use health-related information (in the form of published literature, databases, and the authoritative content of others) can help solve health disparities. Collection and database development is critical to this. The advanced information products and services of the NLM are built on the foundation stone of its unparalleled collections. The Library today is seen as a principal source of biomedical information, and the NLM's many high-technology programs are infused with the confidence and competence resulting from a century and a half of experience in filling the information needs of health professionals. The Library continues to place primary emphasis on its role as acquirer, organizer, and disseminator of health-related information.

The Library is devoting considerable attention and resources to improving access by health professionals, patients, families, community-based organizations, and the general public to information, with special emphasis on rural, minority, and other underserved populations. NLM firmly believes that improved access to health information in MEDLINE, MedlinePlus, ClinicalTrials.gov, and the Library's other computerized databases will result in higher quality health care for the Nation's citizens.

In the following areas of emphasis, NLM utilizes a number of strategies to ensure access to health-related information:

- Improving the information infrastructure and communications capabilities of minority communities.
- Employing communication methods that are racially and culturally sensitive and appropriate.
- Increasing the scope of information products and services to include cultural, psychological, behavioral, social, gender-based, and environmental influences.
- Building partnerships with community-based and professional organizations.

- Strengthening the capacity of minority communities.
- Improving the infrastructure of a variety of institutions, such as Historically Black Colleges and Universities (HBCUs).

NLM incorporates public review and comment on its health disparities programs in several ways. This Strategic Plan for Addressing Health Disparities 2004-2008 is based closely on the NLM Long Range Plan 2000-2005 and follows its overall structure and content. The development of the Long Range Plan incorporated comments received from well over 100 individuals as well as members of the NLM Board of Regents and other advisory groups. The national Community-Based Outreach Symposium to be held in early December 2004 will assist in evaluating and refining NLM's health disparities programs (see section 3.1.11). Additionally, NLM's Board of Regents Subcommittee on Outreach maintains an active role in overseeing NLM's outreach activities.

1.0 AREAS OF EMPHASIS IN RESEARCH—N/A

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY—N/A

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH INFORMATION

3.1 Area of Emphasis One: Promote Use of Health Information by Health Professionals and the Public

Improved Health Information Resources

3.1.1 Objective One

Improve delivery of health information through the development of easy-to-use information resources such as MedlinePlus that are sensitive to cultural diversity issues, educational level, and language.

In 1998, NLM began to provide health information to consumers through a new web site, MedlinePlus. This was in direct response to data that showed that NLM's MEDLINE database, available free on the web since June of 1997, was being searched by members of the public seeking health information for themselves and their families. It was estimated at that time that 30 percent of searches were being done by the public. Although many members of the public are able to obtain useful information from the research literature covered in MEDLINE, it is not the most appropriate place for most citizens to seek health information. In response to this need, NLM developed MedlinePlus, guided by continuous input from its users and an NIH Advisory Group.

MedlinePlus is a resource that health professionals and especially consumers can depend on for information that is authoritative and up to date. It provides access to information produced by the NLM, such as preformatted searches of MEDLINE, plus links to information produced by the NIH and other trusted sources on over 650 diseases and conditions. Databases of full-text drug information, an illustrated medical encyclopedia, lists of hospitals and physicians, dictionaries, health information in Spanish, extensive information on prescription and nonprescription drugs, health information from the media, and links to thousands of clinical trials through ClinicalTrials.gov are also included. MedlinePlus is updated daily. Our emphasis is on organizing the full-text publications produced by the NIH Institutes and other federal government organizations.

Responses to the American Customer Satisfaction Index (ACSI) survey of MedlinePlus users indicate a higher level of satisfaction with the service than any other measured federal web site, but the service is reaching disproportionately fewer members of minority populations. In addition, activity logs indicate that most MedlinePlus en español use is from outside the United States, so more outreach is needed to the U.S. Hispanic population. Lastly, there is a need for additional health information to reach low literacy populations. Both of these are high-risk populations for health disparities, as are members of other minority and low income groups. NLM's goal is to continue to develop and test new ways of presenting the web site that will enhance its appeal and usefulness to these populations and to identify and link to additional resources that will meet their special health information needs. The intended outcome is for MedlinePlus to become a major web resource for health information for those impacted by health disparities so that they will have access to the same quality health information as the rest of the population. A key component of this strategy is to work through NLM's National Network of Libraries of Medicine (NN/LM) to reach libraries, community groups, faith-based organizations, disease support and self help groups, and others, so that the public will know where to go to find current, accurate, and understandable health information and clinical trials.

The major objectives in NLM's proposed 5-year program include:

- Conduct research into the health information needs of minority populations who are using the Internet to find information for themselves or family members;
- Identify and make available on MedlinePlus additional health information that is sensitive to culturally diverse groups;
- Work with other Institutes to increase the number of topics covered by NIHSeniorHealth to reach low-vision seniors and others.
- Investigate and test new ways of presenting the MedlinePlus web site so that it meets their health information needs;
- Work with libraries; community, faith-based, and other organizations; and consumer advocacy groups to ensure that these resources are available, known, and used; and
- Test new ways of reaching these populations and evaluate their effectiveness.

3.1.1.1 Action Plan

- Conduct studies of minority users of health resources on the Internet to assess their information needs and use patterns;

- Identify and make additional non-English resources available on MedlinePlus;
- Identify and make available on MedlinePlus additional health information that is sensitive to culturally diverse groups;
- Collaborate with NIH Institutes to identify topics needing Spanish translation and encourage increased emphasis in this area;
- Develop additional interactive tutorials aimed at reaching low-literacy and Spanish-speaking users;
- Conduct usability testing of MedlinePlus with minority and low-literacy users;
- Disseminate information about MedlinePlus to health professionals- health care organizations; libraries; and health care, community, faith-based, and other organizations who work with minority and low-income populations;
- Exhibit at national meetings of minority health professional organizations and national groups which have a minority focus; and
- Fund projects with libraries and community, faith-based, and other organizations that reach out to minority and low-income populations to improve their access to health information.

3.1.1.2 Performance Measures

- Number of focus groups with minority populations
- Number of hits to Spanish medical encyclopedia
- Number of hits to Spanish interface to MedlinePlus
- Number of usability studies conducted with minority and low-literacy populations
- Number of Spanish-language promotional materials distributed
- Number of additional links to Spanish-language materials
- Number of additional Spanish-language interactive tutorials provided
- Number of additional English-language interactive tutorials provided
- Number of additional links to materials in health disparity focus areas
- Number of projects funded that target minority groups and health disparities
- Number of exhibits at national and regional meetings that target minority groups and health disparities

3.1.1.3 Outcome Measures

- Results of focus groups translated into approaches to reaching the targeted populations
- Increased use of MedlinePlus by minority populations
- Usability study results and user feedback used to guide development of MedlinePlus
- Satisfaction levels of minority users of MedlinePlus
- Evaluations of funded projects that target minority groups and health disparities

3.1.2 Objective Two

Improve delivery of health information through the development of easy-to-use information resources such as ClinicalTrials.gov that are sensitive to cultural diversity issues, educational level, and language.

3.1.2.1 Action Plan

- Radio spots for clinical trials. The U.S. Food and Drug Administration (FDA) and NLM have collaborated to increase awareness about ClinicalTrials.gov.
- Two 60-second audio news features were prepared about ClinicalTrials.gov. Dr. Benjamin S. Carson, Director of the Division of Pediatric Neurosurgery of Johns Hopkins University, recorded one of the 60-second audio news releases about clinical trials and ClinicalTrials.gov. The feature aired on 399 radio stations across the United States and was played 762 times; more than 2.2 million people heard it. To reach Spanish-speaking consumers, Dr. Elmer Huerta, Director of the Cancer Preventorium at the Washington Hospital Center, recorded the same information in Spanish. It was broadcast on 69 Spanish language radio stations and aired 305 times.
- Three- to 5-minute radio interviews in English and Spanish were presented about clinical trials and ClinicalTrials.gov. FDA Commissioner Dr. Mark McClellan participated in 13 interviews. The interviews aired 3,148 times on radio stations and local affiliates throughout the country and were heard by more than 7.8 million listeners.
- Spanish interviews are being arranged with Amelie G. Ramirez, Dr.P.H., Professor of Medicine and Deputy Director, Chronic Disease Prevention and Control Research Center at Baylor College of Medicine. The interviews will be aired on Spanish-language stations across the United States.

3.1.2.2 Performance Measures

The number of hits/requests at ClinicalTrials.gov before and after airing of the radio spots will be used as a proxy for effectiveness.

3.1.2.3 Outcome Measures

- Increased use of ClinicalTrials.gov by minority populations.
- Increased awareness among Hispanics about the role of human research studies in supporting the practice of medicine and the use of ClinicalTrials.gov as a high-quality consumer health information site.
- Better Access to HIV/AIDS information.

3.1.3 Objective Three

Promote improved access to HIV/AIDS information to health professionals, patients, the affected community and their caregivers, as well as the general public in minority communities.

- NLM is continuing to expand efforts to improve access to HIV/AIDS information for patients, the affected community, and their caregivers, as well as the general public. A comprehensive AIDS information service is vital to enable people to combat the AIDS epidemic. Scientists, physicians, educators, and other health professionals need rapid access to the latest information on AIDS research, diagnosis, treatment, control, and prevention. Consumers require similar access to appropriate information for decision-making about their behavioral choices and treatment. Community-based organizations, clinics, and other types of service providers also need access to high quality, accurate, and timely information for their staff and clients. NLM initiated its efforts to work with consumers based upon recommendations from a joint NLM/Office of AIDS Research (OAR)-sponsored conference held in 1993 designed to elicit input from the community about needed services and resources. Since that time, interactions with representatives of AIDS community-based organizations have indicated that there is a continued need for quality information products and services, training, and funding for local efforts to improve access. As the epidemic has expanded further into minority communities, the need for resources and training has increased significantly, rather than decreased. NLM is now working with grassroots organizations that focus on the immediate needs of socioeconomically disadvantaged minorities to assist in developing infrastructure for information access. The goal is to enable organizations to provide access to quality information resources for their clients, staff, and community, as well as to incorporate the use of accurate information into the routine conduct of their business.
- The major objectives in NLM's AIDS outreach and training program include: (1) Providing an annual funding program to enable community organizations, health departments, and libraries to provide access to electronic resources, training in the use of these resources, expanding collections, Internet connections, development of locally specific information materials, town hall meetings, and opening access to collections and document delivery services; (2) Updating HIV/AIDS information resources with Spanish-language enhancements, including translations of titles and summaries of clinical trials, development of training resources and supporting materials, translation of the current glossary, and other related enhancements to make HIV/AIDS databases more useful to Hispanic communities; (3) Training courses for faculty, staff, and students at Historically Black Colleges and Universities (HBCUs), other educational institutions, and their local communities in accessing and using electronic HIV/AIDS resources.

3.1.3.1 Action Plan

- Issue Request for Quotation (RFQ) for AIDS Community Information Outreach Program.
- Publicize and promote AIDS Community Information Outreach Program and encourage proposal submissions.
- Work with community organizations to promote an understanding of the role of information and information access in fighting AIDS.
- Formalize collaboration with the United Negro College Fund Special Programs (UNCFSP), Inc. to train faculty and staff in the use of NLM's electronic information resources.

- Work with UNCFSP to develop selection criteria for faculty-initiated information projects and curricula.
- Host a meeting for faculty and staff from UNCFSP member schools about project and NLM programs and services.
- Make competitive awards as part of UNCFSP project; monitor awards; review progress; modify as appropriate.
- Expand UNCFSP program to additional schools.
- Work with diverse educational institutions, including HBCUs and other colleges and universities, and other government agencies to co-sponsor conferences with opportunities for training workshops and information dissemination.
- Conduct presentations and training sessions at meetings of minority health professionals such as the Black Nurses Association.
- Conduct training courses at HBCUs and other institutions. Invite participation in these training courses by representatives of local community organizations.

Plans for FY2004-2006 include:

- Develop selection criteria for UNCFSP projects.
- Hold meetings with UNCFSP faculty and staff.
- Solicit and award first round of funding for UNCFSP information projects.
- Monitor, evaluate, and modify UNCFSP program.
- Continue UNCFSP funding program.
- Sponsor conferences.
- Conduct presentations and training courses.
- Provide awareness opportunities and training to community organizations.
- Encourage participation in activities and programs offered.
- Issue AIDS Community Information Outreach solicitation annually.
- Encourage participation in program by community-based minority organizations.

3.1.3.2 Performance Measures

- Number of community-based organizations submitting proposals.
- Number of faculty, staff, and students trained from a variety of educational institutions, such as HBCUs.
- Number of training courses held at HBCUs and other institutions, or at minority health professional conferences/meetings.
- Number of projects funded at institutions such as HBCUs.

3.1.3.3 Outcome Measures

NLM plans to measure impact and outcomes by tracking new awards made and analyses/findings disseminated by awardees and staff.

3.1.4 Objective Four

Collaborate in Hosted Information on Treatment and Care of HIV/AIDS (HITCH) Action Plan.

HITCH is a collaboration between the NLM, the Center for HIV Information at the University of California, San Francisco and the University of KwaZulu-Natal, Nelson R. Mandela Medical School in South Africa. It is intended to assess the existing needs for HIV/AIDS medical information in the province of KwaZulu Natal and identify key issues in the adaptation and dissemination of this information. The purpose of the pilot is to assess the technical feasibility of this information dissemination model, its potential to support the work of the President's Emergency Plan for AIDS Relief (PEPFAR) in Africa, and to explore the potential role of medical libraries in its implementation.

3.1.4.1 Action Plan

The following activities are being pursued during October 2003-September 2004:

- An informal needs assessment of selected health care professionals in KwaZulu-Natal.
- The review and selection of existing HIV/AIDS care and treatment guidelines, online textbook chapters, and training materials.
- The electronic production and transfer, in collaboration with the University of KwaZulu-Natal Medical School Library, of selected HIV/AIDS information to the University of KwaZulu-Natal Medical School's HIV/AIDS Information Database.
- The creation of clinician support tools on administering antiretroviral therapy, treating opportunistic infections and preventing mother-to-child transmission of HIV.
- Establishment of a server at the University of KwaZulu-Natal, Durban to host "mirror" versions of the HIV InSite and Women, Children, and HIV web sites.
- In collaboration with the NLM, an assessment of the capacity of in-country medical libraries to play a key role in adapting and disseminating HIV/AIDS clinical information.
- A strategy for the electronic dissemination of HIV/AIDS treatment information and training materials to health care professionals in other countries participating in the President's PEPFAR initiative.

3.1.4.2 Performance Measures

Satisfactory completion of each of the above activities.

3.1.4.3 Outcome Measures

- Creation of a central Internet library that will allow PEPFAR-funded programs to benefit from materials developed by others, thereby improving access to high-quality information and avoiding duplication of effort.
- Use of HITCH education and training materials by all levels of health professionals in South Africa and, ultimately, in other countries in which the HITCH concept may be expanded.
- Enhancement of the capacity of medical libraries in Africa to provide access to HITCH content, and to participate in its development and dissemination in forms that are compatible with both the technical resources and literacy levels of African health professional users.

Better Access to Environmental Health Information

3.1.5 Objective Five

Improve delivery of health information, through the development of easy-to-use information resources, such as Tox Town, that are sensitive to cultural diversity issues, educational level, and language.

Tox Town was developed in 2003 to help users learn about potential toxins in their homes, schools, and communities. The site uses simplified graphic images to help users navigate through various locations to find information. Initial reception of the site by consumers has been very positive, and NLM has conducted focus group testing on the site as well. A text-based Spanish language version has also been developed. Future strategies include developing additional environmental scenes beyond the town and city currently available. These scenes would address populations located in other parts of the country, including a desert southwestern scene and a farm scene.

3.1.5.1 Action Plan

- Identify and make additional non-English resources available on Tox Town.
- Identify and make available on Tox Town additional health information that is sensitive to culturally diverse groups.
- Develop and test Spanish interface to Tox Town.
- Conduct usability testing of Tox Town with minority and low-literacy users.
- Disseminate information about Tox Town to health professionals, health care organizations, libraries, and health care, community, faith-based, and other organizations who work with minority and low-income populations.
- Exhibit at national meetings of minority health professional organizations and national groups that have a minority focus.
- Fund projects with libraries and community, faith-based, and other organizations that reach out to minority and low-income populations to improve their access to health information.

NATIONAL LIBRARY OF MEDICINE

Plans for FY2004-2006 include:

- Conduct minority focus groups.
- Add Spanish medical encyclopedia .
- Develop Spanish interface to Tox Town.
- Conduct usability study of Spanish interface.
- Develop Spanish language promotional materials.
- Evaluate use of Spanish language site.

3.1.5.2 Performance Measures

- Number of hits to Spanish interface.
- Number of Spanish language promotional materials distributed.
- Number of exhibits at meetings and conferences that target minority groups and health disparities.

3.1.5.3 Outcome Measures

Increased use of Tox Town by minority populations

3.1.6 Objective Six

Expand activities with HBCUs to provide information about environmental health and health disparities to include more broadly members of minority and low socioeconomic communities.

The environmental justice movement took shape in the early 1980s, questioning inequities in the distribution of toxic waste sites that activists asserted were disproportionately located in minority and other low-income areas. In 1987, the United Church of Christ published a study, *Toxic Waste and Race in the United States,* calling attention to the association between hazardous waste facilities and the racial/socioeconomic composition of the communities hosting such facilities. The study reported that while economic status played an important role in the nationwide location of commercial hazardous waste facilities, the race of the residents proved to be a more significant determinant.

In 1990, then-Governor Clinton of Arkansas organized a group of seven governors to assess the state of the environment in the Delta Region, covering 219 counties between Illinois and the Gulf of Mexico. A result of this initiative was the Mississippi Delta Project, an objective of which was to create partnerships among government, academia, private sector organizations, and community residents. Through these partnerships, efforts were made to identify key environmental hazards, promote environmental quality, and reduce and, where possible, prevent these hazards from impacting on health and the environment. Emphasis was placed on affected persons in underserved communities. The NLM was one of the federal agencies and institutes cooperating in the Mississippi Delta Project.

The initial mission of this project was to strengthen the capacity of HBCUs to train health professionals to use NLM's Toxicology and Environmental Health Information Program databases. Instructional resources were to be developed to support academic programs such as: (1) educational tools to increase awareness of information resources available; (2) instructional tools for teaching students and faculty how to use these information resources; and (3) a new mechanism to reach minority and underserved communities to increase their understanding of risks associated with exposure to toxic and hazardous chemicals.

As a result of this project, online searching has been integrated into the curricula at many of the HBCUs involved in the pilot project. Even further, several of the HBCUs have used this exposure to electronic information resources to implement programs in medical informatics. To date, more than 80 HBCUs have participated in the extended project, and training is continuing at HBCUs throughout the country. Reports from many of the HBCUs indicate that the awareness and interest generated by this training has enabled them to work collaboratively with other institutional components to bring these NLM resources as well as access to the Internet to their institutions. NLM conducted a formal assessment of TIOP which showed the profound impact that program has had on the participating schools.

To further extend the impact of this effort and to address the concerns about health disparities that may be associated with race, socioeconomic status, environmental factors, etc., this effort was expanded from the HBCUs to include more broadly members of minority and low socioeconomic communities as well as a variety of other institutions.

NLM has expanded its work with HBCUs in breadth and scope as well as in size. TIOP's name was changed to the Environmental Health Information Outreach Program (EnHIOP), and the scope broadened to include environmental health and health disparities. In addition the membership has been expanded to include 14 HBCUs and a variety of other institutions.

3.1.6.1 Action Plan

- Collaborate with HBCUs and other institutions to hold training courses for faculty, staff, and students.
- Collaborate with professional organizations of minority health professionals to hold training courses.
- Identify minority community-based organizations to collaborate with for training and information dissemination.
- Disseminate information about NLM's resources and services.
- Develop materials for use by minority organizations, institutions, and health professionals.
- Conduct presentations at conferences.
- Sponsor or co-sponsor conferences and meetings to create opportunities to raise awareness and disseminate information.

- Encourage/fund the development and implementation of local information access or information use programs and projects.

Plans for FY2004-2006 include:

- Collaborate with HBCUs and other institutions to hold training courses for faculty, staff, and students.
- Collaborate with professional organizations of minority health professionals to hold training courses.
- Identify minority community-based organizations to collaborate with for training and information dissemination.
- Disseminate information about NLM's resources and services.
- Develop materials for use by minority organizations, institutions, and health professionals.
- Sponsor or co-sponsor conferences and meetings to create opportunities to raise awareness and disseminate information.
- Encourage/fund the development and implementation of local information access or information use programs and projects.

3.1.6.2 Performance Measures

- Number of faculty, staff, students, and community members trained.
- Number of items developed.
- Number of conferences sponsored.
- Number of conference attendees.
- Number of new projects developed.

3.1.6.3 Outcome Measures

- Ongoing qualitative assessment of TIOP.
- User satisfaction with training.
- Tracking new projects supported and analyses of progress.

Improved Health Information for Specific Populations

3.1.7 Objective Seven

Develop a set of population-specific mini web sites that focus on the issues of particular populations or geographic areas.

Special populations have special needs for health information, as do the institutions and individuals who work within these communities. The NLM has created a series of web sites aimed at some of these populations. The web sites currently available are: Arctic Health site (http://arctichealth.nlm.nih.gov); Asian American Health (http://asianamericanhealth.nlm.nih.gov); and American Indian Health (http://americanindianhealth.nlm.nih.gov). Each of these sites has sections devoted to diseases and conditions important for the specific population, traditional medicine, research information, and topics of particular concern for the group such as pollution in the Arctic. NLM is developing collaborative relationships with relevant groups for the ongoing maintenance of each web site. For example, NLM is collaborating with the Asian Pacific Islander Health Forum to identify additional material for inclusion in the web site as well as for promotion of the site in the Asian American community. Other planned sites include African American health, Pacific Islander health, and Hispanic/Latino health.

In addition to web sites, there is a need to develop additional tools to support data analysis and population-based research about minority populations. Some of this information is available through the census and some embedded in other data sets. Geographic Information Systems (GIS) hold great promise to enable researchers, policymakers, and communities examine health data in community contexts along with other types of data such as toxic releases, locations of institutions, etc.

NLM’s goal includes the development of a series of web sites and other tools that will serve the needs of policymakers, researchers, health providers, and members of the communities involved. The web sites may serve as focal points for gathering into one place important information about the health care issues and research relevant to that population or area. NLM will enter into partnerships with local or other significant groups to maintain the web site and potentially expand it to serve additional needs of the constituents.

3.1.7.1 Action Plan

- Identify special populations or subpopulations (e.g., African American Seniors) as targets for these web sites.
- Develop web site.
- Identify and negotiate with local university, library, community organization, or other type of organization to maintain the web site and develop accompanying materials and outreach plans.
- Continue to monitor and assess web sites.

Plans for FY2004-2006 include:

- Identify target populations for web sites.
- Design and develop web sites.
- Negotiate with local group for web site maintenance.
- Test and evaluate sites.
- Initiate and assess pilot studies of GIS for use with data about specific population groups.

3.1.7.2 Performance Measures

- Number of page views.
- Number of unique users.
- Number of inquiries.

3.1.7.3 Outcome Measures

- Improved access to population-specific information.
- Associated projects/programs developed.

3.1.8 Objective Eight

Develop culturally and linguistically appropriate health information for refugees and their caregivers.

Each year, more than 15 million people seek political asylum or become refugees in various parts of the world. Of these, the United States welcomes the largest number. Most are displaced persons from developing countries where infectious diseases (e.g., tuberculosis, hepatitis, malaria, and various parasitic and emerging diseases) are prevalent. In addition to communicable diseases, other health problems that are specific to and characteristic of refugees include the physical after-effects of war, torture, and displacement. Refugees also are at risk for a range of mental health problems associated with their previous experience, which may have included periods of war and flight, torture, rape, witnessing violent death, and loss of friends and family. Migrants, broadly defined, require a broad range of health services. In all cases, it is important that information be culturally and linguistically appropriate for the respective consumers and their providers.

3.1.8.1 Action Plan

To improve access to quality health information, a collaborative partnership has been formed to develop an information network that will enable resettled refugees, their health care providers, and public health administrators to gain access to information relevant to refugee health. This network will include a searchable web site and database, and will be linked to existing sites specializing in refugee health, as well as medical information databases from the NLM and other credible sources of health information. The network also will facilitate communication between health professionals involved in refugee health by using e-mail and a listserv to keep all subscribed users informed and in contact with each other.

3.1.8.2 Performance Measures

- Number of individuals trained.
- Number of training sessions.
- Number of items added to the database.

- Number of languages included in database.

3.1.8.3 Outcome Measures

- Satisfaction of health care providers.
- Satisfaction of consumers.

Improved Health Information for Native Americans

3.1.9 Objective Nine

Complete, evaluate, and follow up Tribal Connection Phase IV-Four Corners.

The Four Corners Tribal Project in part extends the Tribal Connections activities into the Southwest, but also adds new features. The Four Corners Region includes the American Indian tribes and reservations located in the northwest corner of New Mexico, northeast corner of Arizona, southeast corner of Utah, and southwest corner of Colorado. The current Four Corners Project is a collaboration between three Regional Medical Libraries (RMLs) (Midcontinental, South Central, and Pacific Southwest), three Resource Libraries (Health Science Libraries at the Universities of Arizona, New Mexico, and Colorado), and NLM. The focus in the current phase is on: conducting needs assessments on selected reservations, with emphasis on health providers serving tribal communities; developing a list of key tribal contacts in the region (and including them in a database); gathering information on key tribal health and health information services in the region (for inclusion in a regional MedlinePlus Go Local web site); and identifying lessons learned from this and the prior Tribal Connections projects (for inclusion in a publicly accessible repository). The project includes a strong evaluation component. Additionally, the Resource Libraries will be conducting some direct outreach to tribes as a parallel effort. Further outreach and special projects are anticipated in a prospective TC Four Corners Phase V.

3.1.9.1 Action Plan

- Complete Tribal Connections Phase IV-Four Corners, in collaboration with the Midcontinental RML and others.
- Evaluate Tribal Connections Phase IV-Four Corners, including possible follow-up in this geographic region.
- Implement Tribal Connections Phase V-Four Corners follow-up.

3.1.9.2 Performance Measures

- Number of planning meetings or activities, and number and geographic spread of participants.
- Number of needs assessments conducted.
- Number of tribal site visits conducted.

- Number and type of tribal participants in site visits.
- Participation of evaluators in needs assessments and site visits.

3.1.9.3 Outcome Measures

For Tribal Connections Four Corners Phase IV:

- Number and quality of needs assessments completed.
- Quality of tribal participation in needs assessment.
- Nature and comprehensiveness of needs identified.
- Number and quality of follow-up projects identified.
- Number of tribal contacts identified and entered into database.
- Lessons learned and submitted to community outreach clearinghouse.
- Tribal health sources and services identified and included in Regional GoLocal.
- Quality of collaboration among project participants.

For Tribal Connections Four Corners Follow-On outreach and special projects:

- Number of tribal health providers trained.
- Results of training (and other interventions).
- Number and type of special projects implemented.
- Number of current tribal sites engaged in intensive follow-up.
- Number of new tribal sites engaged in tribal connections program.
- Number of new or enhanced tribal connections partnerships.
- Number of new or enhanced computer access terminals, local and wide area networks, and Internet connections.
- Levels of tribal awareness of web-based health information resources relevant to tribal health concerns.
- Levels of satisfaction with and efficacy of the tribal connections consultation and planning process—as viewed by the relevant tribal staff and leadership.
- Levels of satisfaction with and efficacy of the tribal connections-related web sites, training, and special activities--as viewed by the participants.
- Changes in the quality and performance of the tribal technical infrastructure including web sites needed to support access to and use of health information.
- Changes in health information seeking behavior of participants in training sessions and special activities.
- Changes in health behavior and, to the extent measurable, health decisions and outcomes of participants in training sessions and special activities.
- Changes in overall capacity of the participating tribal communities to make use of health information resources to enhance the health of the community.

3.1.10 Objective 10

Complete, evaluate, and follow up Native American Listening Circles.

NLM learned, in the initial phases of Tribal Connections, that community-based consultation was an essential part of successful tribal outreach. On the advice of NLM's tribal advisors, in particular Dr. Ted Mala, NLM extended the tribal community consultation to include the concept of "Listening Circles." These circles are well known to Native Americans as a process of open dialog between individuals to build understanding and trust, and share perspectives of respective needs, visions, and capabilities. The first round of Listening Circles includes circles in three diverse locations—the Dakotas (American Indians); Hawaii (Native Hawaiians); and Alaska (Alaska Natives). The first two circles have been completed, and the third is pending. Based on evaluation and related follow-up associated with the first three circles, a determination will be made as to the need and value-added of conducting additional circles in other parts of the country.

3.1.10.1 Action Plan

- Complete initial round of Listening Circles—Dakotas (American Indians), Hawaii (Native Hawaiians), Alaska (Alaska Natives).
- Evaluate Listening Circles and possible follow-up.
- Plan and implement select Listening Circles follow-up project(s).
- Determine need for further Listening Circles, and implement as needed.

3.1.10.2 Performance Measures

- Number and timing of circle planning activities.
- Participation of Native Americans from host area in circle planning.
- Extent of collaboration planning process.

3.1.10.3 Outcome Measures

For the Listening Circles (including any additional Listening Circles conducted):

- Quality of circle participation by Native Americans and by NLM.
- Level of shared understanding achieved.
- Number and type of associated complementary site visits and cultural activities.
- Number, type, and quality of follow-up ideas generated.
- Overall value-added of circle and related activities.
- Number, timing, and quality of circle follow-up activities implemented.
- Number of current tribal sites engaged in intensive follow-up.

- Number of new tribal sites engaged in tribal connections program.
- Number of new or enhanced tribal connections partnerships.

For Listening Circle Follow-Up Outreach and Special Projects:

See performance measures listed earlier under Tribal Connections Phase IV outreach and special projects.

3.1.11 Objective 11

Implement and follow up Native American Outreach Evaluation at Community-Based Outreach Symposium.

In collaboration with two RMLs (Midcontinental and Middle Atlantic), NLM is hosting a national Community-Based Outreach Symposium in early December 2004. The symposium idea emerged in part from the realization, during Tribal Connections Phases I and II, that community-based outreach was an essential ingredient of effective tribal outreach. Or put differently, successful tribal outreach is likely to be community-based outreach. The symposium is co-funded by NLM and the NIH National Center on Minority Health and Health Disparities. A subtheme is evaluation of NLM's Native American outreach program. With about 7 years of relevant outreach activities, NLM concluded that the timing was right for an evaluation. The symposium includes several Native American speakers and panelists, and a special post-symposium work session that will focus solely on evaluating NLM's Native American outreach. It is anticipated that the symposium and special work session will develop ideas for refinement of NLM's Native American outreach program and will identify varied follow-up possibilities.

3.1.11.1 Action Plan

- Implement Community-Based Symposium with subtheme on evaluating NLM's Native American outreach.
- Plan and implement select community-based organization symposium follow-up projects.

3.1.11.2 Performance Measures

- Number and quality of symposium planning activities.
- Quality of collaboration among symposium planners.
- Number of Native Americans included on program and as invited guests.

3.1.11.3 Outcome Measures

- Quality and diversity of Native American participation in the symposium
- Quality of post-symposium Native American outreach evaluation work session.

- Number and type of tribal outreach "lessons learned" identified at the symposium and work session.
- Suggestions for refinements and enhancements to NLM's Native American outreach.
- Number and type of follow-up ideas identified.
- Number and type of follow-up ideas actually implemented.

3.1.12 Objective 12

Continue, evaluate, and extend Native American Powwow Initiative.

Another outgrowth of the original Tribal Connections is the NIH Native American Powwow Initiative. This initiative began in the offices of the NIH Acting Deputy Director and NIH Director's Equal Employment Opportunity Officer, who both realized that the Tribal Connections Pacific Northwest and Southwest might be relevant closer to NIH's home base in Bethesda, Maryland. NIH and NLM collaborated on the initial formulation of the powwow initiative. The initiative is now in its third year, with several institutes participating. To date, NLM headquarters has participated in about 18 powwows, all but one in the greater mid-Atlantic region (states of North Carolina, Virginia, Maryland, Delaware, New Jersey, and Pennsylvania). The NLM involvement includes the Office of the Director (OD)/Office of Health Information Programs Development (OHIPD), OD/Office of Administration (OA), OD/Office of Communications and Public Liaison (OCPL), and Office of Computer and Communications Systems (OCCS). The NLM powwow exhibit includes wireless "live" demonstrations of MedlinePlus and other web sites, when electric power and wireless cell connections are available at the powwow location.

3.1.12.1 Action Plan

- Complete Year Three of the NIH Native American Powwow Initiative.
- Evaluate powwow initiative, and develop future extension plan, in collaboration with the NIH OD and others.
- Implement powwow extension plan on a phased basis.

3.1.12.2 Performance Measures

- Number and quality of powwow planning activities.
- Number of pre-powwow staff training activities.
- Efficient powwow scheduling and logistical arrangements.

3.1.12.3 Outcome Measures

- Number, geographic spread, and diversity of powwows selected for inclusion.
- Estimated powwow attendance and percentage of attendees visiting the NIH/NLM exhibit tables.

- Number of persons watching or participating in online computer searching demos at the powwows.
- Anecdotal evidence of the powwow attendees' interest in NIH/NLM exhibits and prospective (or actual) use of health information from exhibited web sites.
- Overall value added of powwow participation, as compared with other types of outreach and with the associated financial and staff costs and logistical arrangements.
- Lessons learned for effective powwow participation and implications for future powwow activities in the Mid-Atlantic region and other regions.

3.1.13 Objective 13

Continue, evaluate, and enhance Tribal Connections-related web sites.

Over the last 7 years, NLM has developed or sponsored several web sites that focus on health and other information relevant to Native Americans. Perhaps the first was the original Tribal Connections.org web site, originally developed specifically to support Tribal Connections Phase I. This web site has gradually transitioned to a broader focus. Then came the Native American Health page on MedlinePlus, followed by several specialized web sites (see earlier discussion), including the Arctic Health web site, with coverage of Alaska Natives and Arctic health research; the American Indian Health site; and a Pacific Islander site (to include Native Hawaiians) still in development. Also, a Tribal Health Connections web site was developed in connection with a Gates Foundation-supported project in parallel with Tribal Connections Phase II Pacific Southwest. It would seem timely to conduct an evaluation of all of these web sites to help discern the optimal strategy going forward for NLM's Native American web presence.

3.1.13.1 Action Plan

- Develop plan for evaluating and upgrading of Tribal Connections web site.
- Implement web site evaluation and upgrade plan.
- Evaluate web site upgrade.

3.1.13.2 Performance Measures

- Major web site planning and development activities.
- Levels of staff and resource commitments to web site development.
- Level and extent of Native American involvement in and feedback on web site design and content.

3.1.13.3 Outcome Measures

- Number and results of usability testing, by web sites.
- Number and results of user surveys, by web site.

- Clarity of statements of web site missions and content priorities.
- Native American views on efficacy and relevancy of web sites.
- Level of cross-site collaboration on rationalization of web site missions and content.
- Clarification of relationships of web sites to each other and to other Native American web sites, and to GoLocal web sites with Native American content.
- Extent of coverage of and links to relevant Indigenous Peoples web sites.
- Specific follow-up ideas for web site improvements and enhancements.
- Changes in usage levels for the upgraded web sites by participants in training sessions and special activities.

3.1.14 Objective 14

Participate in Sacred Breath tribal diabetes project.

A disproportionately high percentage of American Indians, Alaska Natives, and Native Hawaiians suffer from diabetes. Many of them live in remote, isolated areas where quality health care is not accessible. The prevalence of diabetes has more than tripled since 1990 in some communities, and it now affects about 17 million Americans. Native Americans are about three times more likely than Whites to have the disease, according to the Agency for Healthcare Research and Quality.

3.1.14.1 Action Plan

MyCareTeam is an interactive health information technology application developed by the Imaging Science and Information Systems (ISIS) Center at Georgetown University, with support from the Department of Defense. It has been designed as a tool to help individuals with diabetes better manage their illness. The objective of the Sacred Breath initiative is to deploy MyCareTeam into a number of clinical environments to improve the effectiveness of various diabetes management programs for Native communities.

Although the bulk of this project is being carried out by Georgetown University, NLM will participate by providing training in the use of MedlinePlus and other electronic health information resources at each site where the MyCareTeam is deployed.

3.1.14.2 Performance Measures

- Number trained.
- Number of training sessions.

3.1.14.3 Outcome Measures

Improved access to information.

Improved Health Information for Hispanics

3.1.15 Objective 15

Assess the benefits of MedlinePlus with Hispanic patients in a diabetes care clinic.

3.1.15.1 Action Plan

In collaboration with the Upper Cardozo Health Center in Washington, DC, and George Washington University, undertake a controlled field experiment with patients enrolled in the Diabetes Health Disparities Collaborative wherein diabetes patients will receive an information technology-based intervention to complement their regular patient education program. It will consist of: (a) one-on-one health educator counseling on how to use the Internet and acquire good information about diabetes and related illnesses; (b) group computer classes that are offered to stimulate searching on the Internet for self-management on diabetes; (c) waiting room health educator, clerks, and medical assistants who assist patients in utilizing computers for searching NLM's MedlinePlus, resource which is available in English and Spanish for this largely Hispanic patient population. Additionally, health center physicians will be trained in the use of electronic-based information resources and their integration into daily practice, with special emphasis on diabetes resources.

Timeline

Eighteen months beginning in October 2004.

3.1.15.2 Performance Measures

Increase number and proportion of patients who report use of MedlinePlus since their last appointment, identify MedlinePlus as a high quality Internet-based resource for diabetes information, and report that using MedlinePlus has positively affected their understanding of the disease and ability to self-manage their diabetes. Measure frequency and duration of use of medical services and adherence with appointments or medication regimens. Measure evidence of improved patient-provider communication in diabetes self-management.

3.1.15.3 Outcome Measures

Changes, relative to control group, in hemoglobin A1C, blood glucose, cholesterol, and use of specialty services (e.g., retinal exam, foot exam, nutrition education class, diabetes education class).

3.1.16 Objective 16

Improve the usability of home telemedicine systems with minority and senior diabetic patients.

3.1.16.1 Action Plan

In collaboration with the Columbia University Department of Medical Informatics, undertake an outreach evaluation research project to reduce barriers to diabetes care using a home telemedicine system. The research will: (a) analyze patient training sessions and identify aspects that contribute to successful outcomes; (b) characterize cognitive and non-cognitive factors that preclude or limit sustained use; (c) understand how health literacy plays a mediating factor in patients' use of the system; and (d) develop a system design framework so that participants with a wide range of skills can better manage their chronic illnesses. The patient population consists of both Hispanic and senior persons who have had little exposure to computer-based systems.

Timeline

Twelve months beginning October 2003.

3.1.16.2 Performance Measures

Number and characteristics of patients trained to system performance criteria, and those who are not, with emphasis on those cognitive and other skill sets hypothesized to be relevant to seniors and Hispanic patients. Cognitive and usability measures include varying levels of computer literacy; complexity of graphical user interfaces for novice users; physical limitations such as poor eyesight; and variability in literacy, numeracy, and basic health literacy levels.

3.1.16.3 Outcome Measures

Define alternative training strategies and protocols capable of reducing barriers to patients' productive use of current and next-generation home telemedicine systems

Regional and National Networking

3.1.17 Objective 17

Ensure continued coordination of regional NN/LM services, which include providing equal access to health information by members of the general public and health professionals.

3.1.17.1 Action Plan

The NN/LM National Network Office will prepare the Request for Proposals (RFP) for the 2006-2011 NN/LM contracts. The purpose of these contracts is to achieve at a minimum the following goals: (a) develop collaborations among NN/LM libraries to improve access to and sharing of biomedical and electronic health information resources; (b) promote awareness of and access to biomedical and electronic health information resources for health care providers, the public health workforce, and the public; and (c) develop, promote, and improve access to electronic health information resources among Network member libraries, health care providers, the public health workforce, and organizations that provide health information to the public.

3.1.17.2 Performance Measures

Award NN/LM contracts to eight health science institutions.

3.1.17.3 Outcome Measures

- Number of activities with a focus on minority groups and health disparities areas.
- Number of training sessions in which half or more than half of participants were from minority populations.
- Number of projects funded targeting minority and underserved groups.
- Number of exhibits at national health professional and consumer-oriented meetings that target minority and underserved populations.

3.1.18 Objective 18

Expand partnerships among various types of libraries and community-based organizations with the goal of forming community coalitions to improve access to health information for members of minority and underserved populations as well as health professionals serving these populations.

3.1.18.1 Action Plan

The NN/LM contracts direct considerable resources and effort at the development, implementation and evaluation of outreach programs. The major focus of the outreach program is outreach to health care providers and consumer health information services. The program encourages and supports collaborations and partnerships with Network member libraries through funded projects and agreements. The projects are designed to target:

1. Special populations.
2. Health care providers and public health workers serving special populations.
3. Minority institutions and those whose objective is to train minority health practitioners or those who serve minority populations.

3.1.18.2 Performance Measures

- Fund projects with libraries and community, faith-based, and other organizations that work with minority and low-income populations to improve their access to health information.
- Develop programs that focus on reaching minorities and underserved populations.
- Develop programs to expand the awareness and use of NLM’s resources.

- Train members of the target populations.
- Sponsor technology fairs.
- Exhibit at health professional and consumer-oriented national meetings that target minority and underserved populations.
- Enhance the Internet access capabilities of Network member libraries.

3.1.18.3 Outcome Measures

- Increase the number of individuals introduced to NLM's resources and services.
- Increase the number of partnerships formed.
- Evaluate funded projects that target minority and underserved populations.

3.1.19 Objective 19

Develop a plan to provide opportunities for organizations and institutions serving individuals from minority and other underrepresented populations to enhance their competitiveness in seeking NLM funding.

NLM offers various funding opportunities through many of its divisions (i.e., Extramural Programs, Specialized Information Services, Telemedicine initiatives, and the NN/LM). NLM plans to increase its efforts to provide assistance to organizations and institutions serving individuals from minority and other underrepresented populations in applying for NLM funding and responding to RFPs. The 5,215 health sciences libraries in the NN/LM, which are a key component in NLM's outreach efforts to address the health disparities in minority and underserved populations, provide valuable assistance in these efforts. The NN/LM provides technical assistance workshops that provide attendees with opportunities to enhance their proposal writing skills.

3.1.19.1 Action Plan

- Identify organizations to approach with offers of providing technical assistance workshops.
- Assist in the development of materials for the workshops.
- Assist in the promotion of the workshops.
- Conduct technical assistance workshops prior to the issuance of RFPs.
- Develop materials based on the program areas issuing RFPs.
- Disseminate information on workshops to targeted organizations.
- Develop a mechanism to track which targeted organizations/institutions apply for NLM funding following attendance at workshops.

3.1.19.2 Performance Measures

- Number of targeted organizations/institutions participating in workshops.

- Number of individuals trained.
- Number of workshops held.

3.1.19.3 Outcome Measures

- Increased number of targeted organizations/institutions receiving training in proposal writing.
- Increased number of targeted organizations/institutions applying for NLM funding.

3.2 Area of Emphasis Two: Strengthen the Informatics Infrastructure for Biomedicine and Health Through Training Health Professionals and the Public in the Use of NLM and Other Health Information Resources

3.2.1 Objective One

Train health professionals from minority and other underrepresented populations, information professionals, and community members to use NLM and other quality health information resources.

NLM recognizes that it is critical to establish relationships with health professionals, information professionals, and members of organizations that encourage and foster communication and information access in local communities and with different segments of the population. It is of particular interest to ensure that the government is meeting the needs of minorities and underserved communities.

Access to the latest and best information is essential to medical decision-making for patients and their providers. Despite its tremendous potential, many members of minority communities do not have access to electronic information resources. Many minority health professionals serve in their own communities and also may lack access to or knowledge of these important resources.

NLM is approaching this program on a number of fronts. The five ethnic caucuses of the American Library Association (ALA) (the American Indian Library Association, the Asian Pacific American Library Association, the Black Caucus of the American Library Association, the Chinese American Library Association, and Reforma), the Office of Literacy and Outreach Services (OLOS), the ALA, and the NLM will offer a program session on minority health information at the 2004 ALA Annual Meeting in Orlando, Florida. The session will provide attendees with information that will increase their awareness of NLM's resources and services and skills that will allow them to better serve diverse populations in the area of health information. The five ethnic caucuses, OLOS, and the NLM believe that the sharing of health information and knowledge within communities of color will result in improved health outcomes for diverse populations. The session will serve as the first step in building awareness of health information for minority librarians. Future projects will arise from needs identified at this conference.

Another mechanism that NLM is using to identify needs is through the librarians at the health sciences libraries of minority educational institutions. These librarians and their libraries service minority health professionals, students, and their communities and are uniquely situated to provide this input to NLM. NLM then uses this information to create products, programs, and services.

To facilitate access to and delivery of health science information through computers and telecommunication technology for health care providers, NLM is initiating a training program with the National Medical Association (NMA). Improving the ability of NMA's members to use quality health information resources, including those from NLM, will enable them to remain current in their area of specialty, conduct medical research, improve patient care, involve their patients in clinical trials, and provide consumer-level information for their patients. The initial plan is for NLM to provide training courses at NMA regional meetings to introduce physicians and their staffs to health information databases and other electronic resources and services. Later phases of this project will include working with additional health professional organizations.

3.2.1.1 Action Plan

- Collaborate with the ALA ethnic caucuses to provide conference support for health information programming.
- Plan and carry out an ALA program on minority health information resources and services.
- Collaborate with the NMA to plan and conduct training activities at regional meetings.
- Identify additional health professional groups and associations with which to collaborate.
- Conduct presentations or training activities at meetings of health professionals and health information professionals.
- Assess progress, barriers, and outcomes of pilot minority consumer health outreach projects and refine program.
- Provide funding opportunities for local information access projects in minority communities.

Plans for FY2004-2006 include:

- Collaborate with the NMA to plan and conduct training activities at regional meeting.
- Conduct presentations or training activities at meetings of health professionals and health information professionals.
- Provide funding opportunities for local information access projects in minority communities.

3.2.1.2 Performance Measures

- Number trained.
- Number of training sessions.
- Feedback from pre- and post-training surveys.
- Number and types of projects funded.

3.2.1.3 Outcome Measures

- Strategies for information dissemination in minority communities.
- Improved access to information.

3.2.2 Objective Two

Train scientists and students in medical informatics research.

3.2.2.1 Action Plan

The Lister Hill National Center for Biomedical Communications (LHNCBC) conducts an Informatics Training Program (ITP) for training in informatics science at the NLM. Students from HBCUs, students of Hispanic origin, and students from Tribal Colleges and Universities are eligible and encouraged to participate. The students work on informatics research projects in areas such as consumer health informatics, image processing, and language processing. The students work closely with senior staff at the Center and present what they have learned at the end of the summer in a seminar to the NLM community. LHNCBC advertises its ITP at its public web site, in mailings to professional schools, and in advertisements in a representative set of professional journals. LHNCBC participates in conference recruitment fairs. The Center actively participates in the National Association for Equal Opportunity in Higher Education (NAFEO), Hispanic Association of Colleges and Universities (HACU), and Washington Internships for Native Students (WINS) programs every summer.

3.2.2.2 Performance Measures

Number of students and scientists trained.

3.2.2.3 Outcome Measures—N/A

3.2.3 Objective Three

Develop an internship program for tribal leaders.

To develop and implement an internship program for representatives from Native American tribes (including Native Alaskans and Native Hawaiians) to learn: (1) about NLM's programs and services; (2) how to use information resources and integrate them into their programs; (3) information technology; and (4) information dissemination. The interns would study successful community-based projects funded by NLM and develop ideas on how to involve their communities in this process.

NLM's experience with Native American tribes and communities indicates that they may not only be unfamiliar with health information resources, but equally unfamiliar with the process of obtaining funding and implementing programs in information access. They are not likely to have the expertise to provide training in the use of information resources and services. An information internship for staff from tribal groups may provide the needed experience and understanding to enable them to take advantage of government programs and resources.

The objective for this program is to provide an opportunity for representatives from American Indian tribes, Alaska Native tribes or villages, and Native Hawaiian communities to learn about the NLM, the NN/LM, and successful information projects currently under way. This project will not only provide training in the use of information resources, instruction in managing information outreach projects, and information about potential opportunities, but most importantly, connection with people and programs that might provide support and assistance in the future.

3.2.3.1 Action Plan

- Plan curriculum for internship.
- Identify first participants.
- Conduct internship.
- Continue to monitor and assess progress.
- Adjust curriculum based upon feedback.
- Identify methods and criteria for selecting new interns.

3.2.3.2 Performance Measures

- Attendance at scheduled sessions.
- Positive feedback from interactions.

3.2.3.3 Outcome Measures

- Successful project proposal for NLM funding.
- Successful local projects.

Conduct and Support Informatics Research

3.3.1 Objective One

Genetics Home Reference (GHR): Conduct Studies of Users of Health Resources on the Internet to assess their information needs and use patterns.

3.3.1.1 Action Plan

The LHNCBC at NLM has created and is continually expanding, improving and updating the Genetics Home Reference (GHR), a web site designed to help members of the public understand genetic conditions and the genes that cause them. The LHNCBC, in collaboration with the Genetic Alliance, conducted a survey to assess the site's usefulness and navigation. The customer satisfaction survey was conducted with 374 persons. Because the survey did not gather information about race or ethnicity, we cannot provide statistics about the number of minority group members who participated. However, the Genetic Alliance is the largest genetics coalition representing more than 600 affiliated organizations and through them millions of members, some of whom are members of minority populations.

3.3.1.2 Performance Measures

Analyzed results of the survey.

3.3.1.3 Outcome Measures

Improve the usability, organization, and navigation of the site for consumers.

3.3.2 Objective Two

Conduct health literacy research.

3.3.2.1 Action Plan

LHNCBC conducts readability and health literacy research to develop metrics to match consumers with appropriate health text for various tasks. Starting with readability formulas as a baseline approach, the project will explore and incorporate various linguistic and non-linguistic (e.g., graphical) factors from documents, reader factors (e.g., health and general literacy), and contextual/task-oriented goals (e.g., instructional vs. informational tasks). The goal is to develop, evaluate, and validate algorithmic approaches to predicting accessibility of documents for various consumer audiences for different tasks.

3.3.2.2 Performance Measures

Readability metrics.

3.3.2.3 Outcome Measures

Improved readability and understanding of consumer health web sites.

3.3.3 Objective Three

Develop an automated system for machine translation-based cross-language information retrieval.

3.3.3.1 Action Plan

Research on developing an automated system for helping Spanish speakers use machine translation and natural language processing technologies. A native Spanish-speaking consultant with a Ph.D. in linguistics and extensive experience in machine translation of medical texts is leading this initiative.

3.3.3.2 Performance Measures

Promising results of an initial cross-language information retrieval study to be presented at national and international conferences. Next phase: explore retrieval of Spanish-language protocol record abstracts in ClinicalTrials.gov.

3.3.3.3 Outcome Measures

It is hoped that further research in this area will lead to improved health information access by Hispanics.

The NIH Clinical Center

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

CLINICAL CENTER

MISSION/VISION STATEMENT

The National Institutes of Health (NIH) Clinical Center (CC) is the research hospital of the NIH. Through clinical research, scientific discoveries in the laboratory are translated into new and better medical treatments and therapies.

Clinical research is at the heart of the CC's mission. Natural history studies, often in patients with rare diseases, make up about half of the clinical research conducted at the CC in Bethesda, Maryland. Understanding the basis for rare diseases often leads to new approaches to common problems. Most of the other clinical research studies are early (Phase 1 and 2) trials that are the first applications of basic, bench-side research into new treatments and therapies in people. Approximately one thousand protocols are under way at the CC.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The NIH CC is the clinical research facility of the NIH. It provides patient care, services, training, and the environment in which NIH clinician-scientists creatively translate emerging knowledge into better understanding, detection, treatment, and prevention of human diseases for the health of a diverse nation.

The NIH CC will serve as a premier center for clinical research. A model of collaborative excellence, the NIH CC will lead through innovation in the design, conduct, training, and impact of clinical research.

Attached, in priority order, are the areas of emphasis from the CC Strategic Plan on Reducing Health Disparities. The substance of the plan is consistent with the CC mission of *support* for rather than *conduct* of clinical research. The priorities outlined in this plan fall into the categories of Infrastructure and Public Information/Outreach.

OBJECTIVES

Priority 1: Infrastructure and Cross-Cutting Issues

Goal: Tailor Aspects of the Patient Recruitment and Referral Process to Facilitate Minority Participation in Clinical Trials

Improve Patient Recruitment and Referral Process

The NIH CC established a Patient Recruitment and Public Liaison Office (PRPL) in 1997 to support the Institutes in their individual efforts at recruitment of patients, including minorities, to clinical research protocols. The office, which serves as the CC's central location for the dissemination of protocol information, is responsible for ensuring easy and equitable access to the organization and its services.

Actions

- Maintain ethnically diverse staff in the PRPL to deal with cultural differences sensitively and appropriately.

Completion Date: FY2002 ongoing through FY2008.

- Evaluate minority recruitment strategies by tracking the number of members of minority groups who contact the PRPL annually and are referred and enrolled in a protocol.

Completion Date: FY2002 through FY2008

Completion Date: FY2008

Priority 2: Ensure Needs of Minority Patients Are Met Through Increased Recruitment of Minority Blood and Marrow Donors

Individuals of non-Caucasian ancestry have tissue antigen types (HLA or human leukocyte antigens, also known as transplantation antigens) that are substantially different from the HLA types of Caucasian persons of European descent. HLA compatibility is important in obtaining compatible platelet transfusions for patients who are alloimmunized, and in finding HLA-matched unrelated bone marrow donors for patients awaiting hemotopoietic transplantation. In particular, persons of African American or Asian ancestry are much more likely to find a matched blood or marrow donor among individuals of the same ancestry. This is one of the highest proportions of minority donors in any National Marrow Donor Program Center in the country.

Similarly, the red cell phenotype (characteristic antigens on the surface of the red blood cell) of African Americans differs substantially from that of Caucasians. For transfusions in people of African ancestry, frequently it is only possible to find compatible red cell units from donors of the same ethnic background. The National Bone Marrow Program recognized the CC for outstanding results in recruitment of minority donors.

Completion Date: FY2003 ongoing through 2008

Outcome

- Establish a recruitment program targeting HLA-typed plalteletpheresis donors of minority background.
- To increase the number of transplants performed on minority patients awaiting transplantation.

- To increase the percentage of minorities participating in the plalteletpheresis donor program.

Priority 3. Limited English Proficiency (LEP) Program/Service Center

The CC Volunteer Interpreters Program has exceeded its ability to address the needs of Spanish-speaking and other LEP patients. Current services provided by 32 Spanish-speaking volunteers and one Hispanic Association of Colleges and Universities student include: assistance with admissions, orientation to the CC and NIH, interpreting during family and medical team meetings with patients, and assistance during medical procedures. The need is most pressing for interpreting informed consent documents and in fulfilling STAT requests for services. The provision of a dedicated program will ensure that informed consent and equal access rights of patients are addressed and the accompanying liability and ethical concerns are alleviated. In addition, patient confidentiality issues expressed and substantiated by the CC Patient Advisory Group about family members and other patients interpreting for the medical team will be addressed.

Increased resources to this program will ensure attention to multiple issues faced by the CC such as:

- Hire two interpreters. **Completion Date: FY2002.**
- Address minority and health disparity issues and services to meet federal LEP requirements and uphold the NIH mission regarding recruitment of women and minorities. **Completion Date: FY2002.**
- Provide a systematic process for analyzing the interpreting service needs for languages not currently met (such as Romance, Slavic, and Arabic languages). **Completion Date: FY2002.**
- Ensure the translation of protocol, informed consent, and other written documents. **Completion Date: Spring FY2003**.
- Ensure appropriate bilingual/trilingual signage in new Clinical Research Center. **Completion Date: FY2004.**
- Annually, bilingual students are recruited for internships to assist with interpreters' services. **Completion Date: FY2003 ongoing through 2008.**

Outcome

- Improve response time for requirement for interpretive services.
- Appropriate documentation of Informed Consent forms (for most frequently requested languages).

Priority 4. Establish a Hospital Environment in Which the Diverse Needs of Minority Patients Are Recognized and Addressed.

In the health care industry, there remains a history of underrepresentation of minorities in professional positions. To successfully address this disparity, the number of health care providers of diverse backgrounds must increase so that the needs of patients are appropriately met through individual interactions with health care providers with whom they are easily able to identify. Once the number of minority employees in professional positions increases, there must be a plan to retain them and provide equal access to educational and career opportunities.

Actions

Recruit and retain a workforce that represents the diversity of our nation by:

- Building relationships with academic and professional organizations to recruit a diverse workforce. **Completion Date: FY2003 ongoing through FY2008**
- Development a targeted recruitment plan for occupations with significant underrepresentation of minorities and other health disparity populations. **Completion Date: FY2003 ongoing through 2008.**

Completion Date: FY2003

Outcome

- Diverse workforce accomplished as reported by labor/statistics/census data.
- Establishment of a referral mechanism to the CC for minority professional and academic organizations.

Priority 5. Public Information/Outreach

Goal: Continue Active Public Information/Outreach Program About the NIH CC and Participation in Clinical Trials.

Initiative A: Increase awareness of the CC among minority patients and referring physicians.

Initiative B: Enhance community involvement in minority outreach.

Actions

- Continue information meetings with professional organizations such as the National Medical Association and Hispanic Medical Association.

Completion Date: FY2002 ongoing through 2008.

Outcome

- Improve awareness of CC and NIH as a referral source for educational, community, and professional organizations.

Priority 6: Enhance Community Involvement in Minority Outreach

Actions

- Establish a network of community advocates through the development of a Community Leadership Alliance, consisting of leaders from minority organizations, to assist the NIH CC in reaching out to and understanding the needs of minority populations.
- Conduct presentations at minority community organizations to address issues of concerns related to participation in research.
- Disseminate information about the NIH CC and participation in clinical research to corporations who employ a diverse workforce; minority businesses; and minority education and church groups.
- Establish ongoing working relationships with minority professional health care organizations such as the National Medical Association.

Completion Date: FY2002 ongoing through 2008.

Outcome

- Increased referral of minority patients by organizations such as the National Medical Association and self-referral as a result of outreach to community organizations and churches.

Priority 7. Design Outreach Effort to Provide the Lay Community With an Understanding of How Clinical Research Is Addressing Health Disparities.

Actions

- Plan “Medicine for the Public” lecture series in collaboration with the Institutes to target lectures to areas of research in health disparities.
- Distribute “Medicine for the Public” information to minority schools, community groups, health fairs, and health care facilities.

Completion Date: FY2002 ongoing through 2008.

Outcome

- To make available the “Medicine for the Public” lecture series via video tape and teleconferencing to minority health schools, community groups, etc.

Priority 8. Public Information/Outreach

Goal 1: Establish an Active Public Information/Outreach Program About the NIH CC and Participation in Clinical Trials.

Focus group research conducted by the NIH CC demonstrated that national and local awareness about the NIH CC, especially among minorities, is low. People are unaware that the NIH CC is a research hospital or they are under the impression that research is conducted only on rare or terminal illnesses. Additionally, members of minority groups have many negative perceptions regarding participation in clinical research. An outreach and education effort, employing multiple outlets (community presentations, Internet, and the media) is critical to increase public awareness about the NIH CC, correct misinformation, and foster positive perceptions.

Initiative A: Enroll Minorities in Education and Training Programs in Clinical Research

Research on health disparities requires increasing numbers of minority physicians leading clinical trials. To facilitate this goal, the NIH CC will make a concerted effort to enhance enrollment of minorities and other health disparity populations in its clinical research curriculum. Since 1995, the NIH CC has offered a training program in clinical research, *Introduction to the Principles and Practice of Clinical Research*. Throughout the past 5 years, the scope of the curriculum has expanded, and participants now attend the program both in person and via satellite broadcasts (with five locations including the University of Puerto Rico [UPR]). Enrollment has increased exponentially each year. In addition, three other courses are now sponsored by the NIH CC. An experiment in distance learning designed to strengthen training opportunities in clinical research is a degree-granting collaboration between the NIH CC and Duke University. In its fourth year, this course is designed primarily for clinical fellows and other health professionals who are training for careers in clinical research. A second course, the *Principles of Clinical Pharmacology*, also in its fourth year, is based on a series of lectures covering the scientific basis of the discipline of clinical pharmacology. This course is teleconferenced to three sites. The third course, *The Ethical and Regulatory Aspects of Human Subjects Research,* offers education and training in research ethics for intramural scientists and research staff.

Action

- A partnership with the Medical Sciences Campus at the UPR has allowed videoconferencing of this course to 87 students in San Juan. Traditionally, the Medical Sciences Campus at the UPR has been a teaching and service-providing institution. Efforts are being redirected to further develop clinical research at the UPR, and this videoconference allowed investigators to focus on clinical research training. This collaboration is planned to continue with expanded enrollment, as determined by UPR faculty.
- The faculty from Meharry Medical College and Morehouse School of Medicine have participated and plan to continue enrollment in distance learning programs sponsored by the CC.

Completion Date: FY2002 through 2008

Outcome

- To increase the number of minority medical students involved in the *Introduction to the Principles and Practice of Clinical Research.*

The Office of AIDS Research

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

OFFICE OF AIDS RESEARCH

MISSION/VISION STATEMENT

The National Institutes of Health (NIH) Office of AIDS Research (OAR), located within the Office of the Director (OD), coordinates the scientific, budgetary, legislative, and policy elements of the NIH acquired immunodeficiency syndrome (AIDS) research program and serves as the principal liaison with the Department of Health and Human Services (HHS), other federal agencies, and domestic and international governmental and non-governmental organizations on behalf of NIH AIDS-related research. The NIH represents the largest and most significant public investment in AIDS research in the world. Our response to the epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of all the NIH Institutes and Centers (ICs). This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently. This is recognized in the unique role given the OAR in its authorizing legislation, the NIH Revitalization Act of 1993. That law establishes OAR as a model for trans-NIH coordination, vesting it with primary responsibility for overseeing all NIH AIDS-related research, and thus allowing NIH to pursue a united research front against the global AIDS epidemic.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

The OAR's legislative authority requires OAR to develop an annual strategic plan for all NIH AIDS research activities, including those relating to racial and ethnic minorities. To achieve this end, the OAR has established a unique and effective model for developing a consensus on scientific priorities for the annual comprehensive *NIH Plan for HIV-Related Research*. Each year, Planning Groups for each section of the NIH plan for human immunodeficiency virus (HIV)-related research with the previous year's plan (to establish specific priorities, scientific objectives, and the strategies for attaining these objectives). The Planning Groups include public and private sector members, who represent a diverse membership: scientists, academicians, representatives of community-based organizations, foundations, industry, public think tanks, and people living with HIV infection. Utilizing their knowledge of the science and the progress made during the course of the last year to address these objectives and strategies, the group updates the Plan. In the case of racial and ethnic minorities and HIV-related health disparities, these updates are based upon the continuing evolving epidemiology, eliminating those strategies where research is no longer necessary; adding new objectives and strategies where research has uncovered new questions; and reprioritizing the objectives as necessary where the science has changed. In this way, the planning process serves to monitor and assess scientific progress on an annual basis.

The resulting draft Plan is then provided to each NIH IC Director and AIDS Coordinator for additional recommendations and comments. In addition, the Plan is reviewed by the Office of AIDS Research Advisory Council (OARAC). OAR continues to reassess the planning process and make refinements to better capture the broadest range of scientific expertise and community participation and to facilitate the identification of specific scientific priorities.

The Plan serves several important purposes:

- As the framework for developing the NIH AIDS research budget.
- For determining the use of NIH AIDS-designated dollars and for tracking and monitoring those expenditures. The Plan thus defines those research areas for which AIDS-designated funds may be allocated.
- As a document that provides information to the public, the scientific community, Congress, and AIDS-affected communities about the NIH AIDS research agenda. OAR distributes the annual comprehensive Plan to a wide audience, and it appears on the OAR web site: http://www.nih.gov/od/oar.

The OAR**,** as indicated in the 1993 NIH revitalization act, fosters and coordinates trans-NIH HIV/AIDS research activities. Through its unique, trans-NIH planning, budgeting, and portfolio assessment processes, OAR ensures that research dollars are invested in the highest priority areas of scientific opportunity. As such, the OAR represents the roadmap for NIH AIDS research, allowing NIH to pursue a united research front against the pandemic.

1.0 AREAS OF EMPHASIS IN RESEARCH

More than 20-plus years into the HIV epidemic, HIV infection among racial and ethnic minorities continues to be a formidable health challenge, with little sign of abating. The disproportionate impact of HIV infection and transmission among these populations has altered the social construction of these communities, affected their oldest institutions, and destroyed families across several generations, making HIV one more among many existing health disparities. Despite the increased number of agents in the therapeutic armamentarium, the introduction of a new class of agents, and a novel class of agents under investigation, urban centers continue to reflect HIV transmission rates that rival resource-poor settings internationally.

The reasons for this disproportionate impact, as well as the high rates of transmission, are complex and represent a confluence of social, economic, and historical factors. Social apathy, poverty, racism, homophobia, unequal access to health care resources, disproportionate impact of substance and alcohol abuse, marginalization of subpopulations within these communities (e.g., gay, bisexual, and transgendered persons), and the health impact of co-morbid conditions that disproportionately affect this population (e.g., sexually transmitted infections [STIs] and hepatitis) underscore that a range of interventions will be necessary. Exploring each of these factors will be time consuming and labor intensive. However, the current HIV transmission rates mandate a more extensive and intensive effort in all areas.

Social, economic, and historical factors are complexly interwoven; the legacy of slavery, internment camps, and reservations has led to racial and ethnic minorities in the United States experiencing a disproportionate amount of poverty, as well as the associated social ills. HIV infection (as well as HIV-hepatitis C virus [HCV] co-infection) is at the intersection of these factors given that substance abuse, survival sex, and commercial sex are associated with blood borne pathogens and STIs.

HIV infection among racial and ethnic minorities occurs against a backdrop of a number of other co-morbid diseases, including but not limited to hypertension, diabetes, cardiovascular disease, STIs, the hepatitides and tuberculosis.

Unequal access to health care resources continues to drive the epidemic and limit the potential for decreased transmission. Unequal access to health care means that fewer members of racial and ethnic minority groups receive treatment, and as such they may continue to facilitate HIV transmission. Limited health care access also means less exposure to health education messages, including prevention. Finally, limited access to health care means perpetuating the inadequate enrollment of racial and ethnic minorities within NIH-sponsored HIV clinical trials. As the epidemic reaches further into racial and ethnic minority communities, this failure leaves important questions about the impact of race and ethnicity upon treatment, treatment adherence, prevention, and disease progression.

The history of the treatment of domestic racial and ethnic minority populations within the health care system, as well as health care delivery, is at best a checkered one. Whether it is the legacy of Tuskegee and African Americans, or the introduction of smallpox into the blankets of Native Americans, these experiences have left a legacy of distrust in racial and ethnic minority communities of the organized systems providing health care, health messages, or conducting research. This mistrust affects not only health care-seeking behavior, but also treatment adherence, as well as incorporating/utilizing health promotion messages. Although this remains a complex and multifaceted problem, it will be essential to tease apart the myriad sources that contribute to these disparities and to identify ways to modify or eradicate them. Bias, prejudice, stereotyping, unequal access to care, and low levels of health literacy only compound these challenges. Given the routes of transmission, HIV infection adds a new level of disparity, because of the impact of cultural norms and stigma associated with sexual and drug using behaviors. Just as the Institute of Medicine report demonstrated structural determinants that globally influence racial and ethnic disparities in health, similar evaluations are necessary to further identify the impact of these structural determinants upon treatment outcomes in HIV infection. Despite the advent of antiretroviral therapy, there remains a difference between the treatment outcomes (such as survival) in Caucasians and African Americans or Latinos.

Objective One

Identify and examine the sociocultural and structural determinants, pathways, and mechanisms that enhance, sustain, or perpetuate health disparities.

Strategies:

- Design clinical trials with sufficient power to detect racial, ethnic, and gender differences.
- Encourage basic research and its clinical application to elucidate the impact of culture-, race-, and gender-related influences upon the response to HIV infection and treatment.
- Design and conduct studies to determine the factors that promote and/or preclude early access to care and treatment.
- Examine the impact of traumatic stressors such as acculturative stress, discrimination, racism, and homophobia upon health outcomes.
- Explore the impact of economic and educational inequities among understudied populations such as Native Americans and mixed-race individuals and observed health disparities in HIV infection.
- Explore the impact of race/ethnicity, poverty, language, and lack of education upon the observed disparity in HIV infection among border communities, as well as among documented and undocumented immigrants.
- Study the impact of race/ethnicity and gender upon those cultural contexts and social norms that may influence HIV transmission as well as disease progression.
- Study the multiple factors that disproportionately impact racial and ethnic minorities (such as racism, poor education, poverty, homelessness) and their role in creating the observed health disparities at the individual and community levels.
- Promote and sustain interagency research to:
  - Determine the impact of criminal justice, economic, and educational disparities in the health outcomes of racial and ethnic minorities with HIV infection.
  - Conduct research on the role of health care disparities and public policy factors in sustaining the disparities in the health outcomes of racial and ethnic minorities with HIV infection.

Objective Two

Conduct clinical research that includes numbers of racial and ethnic minorities that reflect the current incidence and epidemiological trends in the HIV/AIDS epidemic domestically.

Strategies:

- Conduct research to examine the effects of HIV infection upon the physiologic, immunologic, hormonal, and neuropsychological development of racial and ethnic minority adolescents.
- Conduct appropriately powered clinical trials to explore differential responses to treatment, metabolic toxicities, and immune responses to HIV infection in racial and ethnic minorities.
- Maintain representation of racial and ethnic minorities in trials designed to prevent and reduce HIV transmission in numbers that reflect the local (or regional) epidemiology.
- Enhance collaboration across ICs that jointly conduct clinical trials in racial and ethnic minorities to:
    - Promote consistent and timely sharing of trial data with these communities;

    - Expedite the production of reports, consensus conferences, or other materials emanating from these trials; and
    - Enhance opportunities for the translation of trial results to the actual needs of racial and ethnic minority communities.
- Develop, test, and support clinical research methodologies that prospectively examine racial/ethnic/gender/sexual orientation differences in transmission, pathophysiology, and treatment outcomes.
- Encourage academic-community partnerships to enhance clinical trial participation by racial and ethnic minorities.
- Continue to conduct trials on the impact of alcohol and drug use on the success of clinical interventions in racial and ethnic minorities, as well as disease progression and treatment.
- Promote awareness and understanding of the ethics of clinical research, as well as the protections required for research participants in racial and ethnic minority communities and the community-based organizations that serve them.
- Encourage the exploration of proteomics and genomics to determine the effects of race, gender, and age upon immune response to HIV infection.
- Continue the study of the biology of HIV infection among racial and ethnic minorities including:
    - The effect of race/ethnicity and gender upon immune dysfunction and the development of opportunistic infection.
    - The effect of race/ethnicity and gender upon p-glycoproteins and their role in HIV drug resistance.
    - The impact of pre-existing health conditions that disproportionately affect racial and ethnic minorities, such as diabetes, hypertension, and cardiovascular disease, upon HIV infection.

Objective Three

Explore the natural history of HIV disease and its consequences in racial and ethnic minority communities.

Strategies:

- Study the impact of other co-morbid diseases including the hepatitides, tuberculosis, mental illness, diabetes, alcohol use and abuse, substance abuse, and STIs upon HIV-related morbidity, mortality, and disease progression in minority communities.
- Support research that explores factors that promote or prevent HIV transmission, including:
    - The role of extended and nuclear family and caregivers;
    - The role of traditional and nontraditional organizations upon social structure and norms;
    - The role of peer and social networks; and
    - The individual, as well as community, interface with institutionalized care delivery systems.
- Study the impact of alcohol and other substance abuse treatment as an approach to HIV prevention.

- Determine the impact of alcohol use and abuse, substance abuse, and mental health disorders upon HIV disease in racial and ethnic minority communities.
- Determine the impact of mental health and substance abuse disorders upon the co-morbidities associated with HIV disease.
- Explore the intersection of poor health indicators, co-morbid diseases, and HIV disease progression in racial and ethnic minorities to identify multiple points for intervention.
- Determine the impact of race-related factors upon disease progression, if any, in understudied populations such as Native Americans, Alaska Natives, Pacific Islanders, and Native Hawaiians.
- Determine the impact of structural factors within health-related organizations, such as insurance status and institutional racism, upon when racial and ethnic minorities present for HIV-related care and its impact upon disease outcome in these populations.
- Identify the factors that influence HIV transmission among racial and ethnic minorities
- Continue to expand research to identify specific mechanisms of transmission in racial and ethnic minorities:
    - Enhance and expand research on the potential impact of vaccines and microbicides upon HIV transmission among racial and ethnic minority communities.
    - Conduct research on the impact of rapid testing for HIV infection upon transmission.
    - Promote research to explore the impact of access to treatment and services in HIV transmission.
    - Conduct research on HIV infection among older individuals and its impact upon HIV transmission in minority communities.

Objective Four

Develop and test innovative models, research methods, and measures of risk behavior in racial and ethnic minority communities.

Strategies:

- Develop, pilot, test, and evaluate new measures of HIV risk behavior that are culturally and contextually appropriate for racial and ethnic minorities.
- Develop new models of HIV behavioral interventions that incorporate common stresses for racial and ethnic minorities, such as racism and poverty.
- Encourage the development of novel sampling methods to enhance the representation of racial and ethnic minorities in clinical trials, with attention to sampling adequately from national origin subgroups.
- Identify resiliency and protective factors in racial and ethnic minority communities, and test them for impact upon decreasing HIV transmission.
- Study HIV risk behaviors of underrepresented racial and ethnic minorities, such as American Indians/Alaska Natives and Asians/Pacific Islanders.
- Fund the development and testing of new sampling methodologies in racial and ethnic minority communities.

- Encourage the study of intergenerational trauma and its impact upon HIV risk behavior in racial and ethnic minority communities.
- Validate existing measures for translational, cultural, and linguistic equivalents for each of the communities in which they are to be used.

Objective Five

Study the impact of treatment and adherence upon the health outcomes of HIV infection in racial and ethnic minority communities.

Strategies:

- Continue to study the short- and long term effects of non-adherence in racial and ethnic minority communities.
- Determine the impact of short- and long term non-adherence upon drug-resistant HIV infection, multidrug-resistant tuberculosis, and HIV disease progression.
- Conduct research into the role of racial, ethnic, sexual orientation, and gender differences upon adherence, as well as non-adherence.
- Identify factors at the individual, societal, and community levels that promote adherence.
- Study the impact of chronic and traumatic stress upon health outcomes, adherence, and non-adherence.
- Study the role of provider-patient interactions that negatively and positively affect adherence.
- Determine the impact of provider decision-making upon patient adherence.
- Conduct research on community-based multi-level interventions to promote adherence.
- Continue to study the role of complementary therapies upon treatment for HIV infection, its complications, and quality of life (such as symptom relief).
- Define the role and impact of health beliefs upon treatment acceptance and adherence in racial and ethnic minority communities.
- Continue to explore novel therapeutic regimens for HIV infection and associated co-infections.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

Minority investigators remain significantly underrepresented among HIV investigators. Despite a sprinkling of minority investigator development programs across NIH and the country, the bulk of minority investigators do not participate in these programs. Those located at minority-predominant and minority-serving institutions often are challenged by lack of mentoring, large teaching loads, administrative duties, or little protected research time. Expanded funding for allocated research infrastructure development at these institutions would help provide the skeleton upon which a program of minority investigator development could be built. This would include, but not be limited to, the development of basic science capacity at various institutions such as Historically Black Colleges and Universities (HBCUs), with bench-to-bedside applications as part of the capacity development. Diverse institutional research partnerships with equitable and equal distribution of resources across all participating entities also would assist with not only capacity building but also minority investigator development. These partnerships would contribute to the bidirectional exchange of information important to inform the research agenda in racial and ethnic minority communities and become part of the development of self-sustaining, comprehensive HIV/AIDS research agendas at various institutions. However, minority investigators are only part of a multidisciplinary effort; minority community-based organizations and institutions are also essential components. Minority community-based organizations include institutions such as HBCUs. The involvement of minority communities is completed when these institutions can develop academic-community partnerships in minority communities, addressing research questions that are of importance and interest to all participating entities.

There are inherent limitations and difficulties with this approach without a sustained and ongoing effort. Successful mentorship of investigators from minority and other underrepresented groups cannot be accomplished without a commitment to sustained funding not only for pilot projects, but also for recruiting and retaining senior investigators as mentors. Offering incentives for senior investigators to not only identify investigators from minority and other underrepresented groups with research potential, but also to mentor these investigators, will begin to address the challenge of mentoring without financial resources. These incentives are needed for both the extramural and intramural programs at NIH.

Incentives at the institutional level for the development, recruitment, and retention of minority investigators will be critical components of the approach. Some of these institutions will need to evolve from a mandate of primarily teaching (based upon their history and the reason for their existence) to research as well as teaching. A number of grant mechanisms exist to facilitate the development of these institutions; however, these need to be reviewed and tracked by their outcomes to determine those that are the most (and the least) effective.

The development of minority investigators also provides an opportunity to develop additional opportunities for routine exchanges between racial and ethnic minority communities and the research community. Community constituency groups and community advisory boards are just one aspect of the bidirectional exchange needed between minority communities and those who come into the community to conduct research. These bidirectional exchanges are not optional; they are essential to the development of research questions of mutual interest to the investigator and the communities within which such research is to be conducted. When questions are jointly identified, the issue of recruitment and retention of adequate numbers of members of racial and ethnic minority groups to explore specific findings unique to that subgroup will cease to be a challenge. When minority communities can perceive that the findings from a research agenda have particular relevance to them, their interest and participation will increase.

Investigators, clinicians, policy makers, and communities will need to work together to identify, test and implement novel strategies to identify and remedy the ongoing gap in health outcomes in HIV infection. In this area, community-based interventions and efforts will be essential, requiring academic-community partnerships. These partnerships will require an investment of resources that may be greater than those for university-based clinical trials; however, the investment from the community will be essential. In addition to health disparities, economic and educational disparities affect racial and ethnic minorities. Continued research to explore the interactions between these disparities is needed for all racial and ethnic minorities, but especially those significantly underrepresented in clinical studies, including Native Americans, Alaska Natives, and individuals of mixed race.

Incorporation of racial and ethnic minorities in increased numbers in prevention interventions will also require a new and creative mode of thinking. Despite two decades of prevention research and intervention, significant segments of the minority community are missing prevention messages, ignoring prevention messages, or failing to incorporate these messages into their lifestyles. In addition, a number of racial and ethnic minorities are underrepresented in these behavioral trials: Native Americans, Alaska Native, and Asians/Pacific Islanders. Despite the success of specific research instruments and methodologies in other population groups affected by the HIV epidemic, there is a powerful argument for the development of novel survey instruments and methodologies that are culturally and contextually appropriate for minority communities. In order to develop, test, and evaluate such novel approaches, a more broad-based approach to HIV prevention in minority communities will be necessary.

The translation of prevention research findings into practice, especially in racial and ethnic minority communities, is long and arduous, particularly given the multiple factors listed above that affect these communities. The barriers to effective prevention in these communities include, but are not limited to: need for organizational infrastructure development, limited opportunities for routine exchanges between prevention researchers and front-line community providers, different definitions of effective prevention interventions between researchers and front-line community service providers, a paucity of minority investigators, and prevention methods that have little to no cultural relevance to the target population.

Organizational infrastructure development is an overarching need in racial and ethnic minority communities. Lack of organizational development, as well as the pervasive lack of significant and consistent infrastructure, limit the ability of racial and ethnic minority organizations to develop and maintain effective partnerships with academic and research entities through which prevention interventions (from behavioral to therapeutic) are delivered. Moreover, without this infrastructure, there is no institutional memory for development and expansion of preliminary efforts to continue work that was initiated in these communities. This continued need to start from the beginning presents challenges and frustrations to the academic and research communities, as well as community organizations. Sustained and consistent long-term investment in the organizational infrastructure of minority community organizations is a key component of the continued development and application of appropriate prevention interventions in this population.

OFFICE OF AIDS RESEARCH

The OAR plays a unique role at NIH, establishing a roadmap for the AIDS research program. OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Our response to the AIDS epidemic requires a unique and complex multi-institute, multi-disciplinary, global research program. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of the NIH ICs. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently.

OAR oversees the development of the annual comprehensive trans-NIH AIDS-related research plan and budget, based on scientific consensus about the most compelling scientific priorities and opportunities that will lead to better therapies and prevention strategies for HIV disease. The Plan serves as the framework for developing the annual trans-AIDS research budget; for determining the use of AIDS-designated dollars; and for tracking and monitoring those expenditures. The annual *Trans-NIH Plan for HIV-Related Research* is developed in collaboration with the ICs; non-government experts from academia, foundations, and industry; and community representatives. The Plan and the unique processes instituted by OAR to ensure its implementation allow NIH to pursue a united research front against the global AIDS epidemic. The Plan includes a separate section devoted to racial and ethnic minorities. To develop the plan, OAR has established trans-NIH Coordinating Committees for each of the major areas of the Plan, including a committee for racial and ethnic minorities. These committees, composed of representatives of the ICs with major research portfolios in that area, provide an ongoing mechanism for collaboration, coordination, and information exchange. The planning process serves to monitor and assess scientific progress on an annual basis, eliminating strategies where research is no longer necessary; adding new strategies where research has uncovered new questions; and reprioritizing objectives when the science has moved or changed. It is in this context that the recommendations to the Health Disparities report for the National Center for Minority Health and Health Disparities (NCMHD) were developed and provided.

Objective One

Enhance and increase the capacity for multidisciplinary NIH-funded HIV research, through expanding the pool of investigators and institutions to include underrepresented minority investigators, institutions, and communities. Minority is defined as any racial and ethnic group other than Caucasian. As the HIV/AIDS epidemic in the United States disproportionately affects minority communities, and research on AIDS in these communities requires candor and trust about culturally and contextually sensitive behaviors such as sexual contact and drug use, increasing the number of minority investigators and institutions conducting this research is essential.

Strategies:

For the investigator:

- Expand the pool of applicants and strengthen existing programs designed to increase the awareness of underrepresented minority investigators of NIH funding mechanisms for HIV/AIDS research.
- Conduct a review to determine the number of minority scientists produced as a result of existing NIH programs (such as K awards, diversity biomedical research supplements, and the NIH Program Announcement (PA-05-015) entitled "Research Supplement to Promote Diversity in Health-Related Research.") to support the transition from trainee to independent investigator. In past reviews, the number of minority investigators conducting HIV/AIDS research remained at less than 5 percent of the investigators who reported their race/ethnicity in a voluntary report on the status of their grant. This is in marked contrast to the demographics of the population at risk for HIV infection, in which 80 percent of the new cases of HIV infection among women, for example, are women of color.
- Convene an outside expert review panel to review the NIH success in recruiting, retaining, and developing minority intramural and extramural investigators to make recommendations to the Director of the NIH for program improvement.
- Review incentives, through existing funding mechanisms, for the development, recruitment, and retention of a diverse pool of investigators in intramural and extramural research.

For the institution:

- Expand funding allocated for research capacity and infrastructure development at HBCUs as well as other institutions serving the specific diverse populations at risk for HIV/AIDS in the United States.
- Partner institutions with shared research interests for research program and infrastructure development through the use of funding incentives and grant mechanisms.
- Expand the diverse pool of investigators conducting basic science on HIV/AIDS through mentored training awards, infrastructure development, and institutional partnerships and collaborations.
- Expand training opportunities for a diverse pool of investigators by enhancing existing mechanisms to provide personnel necessary for the successful conduct of HIV/AIDS research, for example, through Intergovernmental Personnel Agreements and other mechanisms.
- Provide financial support through existing mechanisms to strategic planning efforts designed to develop an HIV/AIDS research agenda at institutions conducting research in communities with high rates of HIV infection.

For the community:

- Increase minority representation on community advisory boards for HIV research to reflect their current incidence and trends in the epidemic.
- Enhance and expand technology transfer programs to expedite transfer of state-of-the-art information from the bench to the bedside.

- Disseminate effective prevention interventions to racial and ethnic minority communities through: community-based organizations, providers of HIV-related care and services, and minority-predominant and minority-serving institutions.
- Facilitate the establishment of research partnerships between institutions and the communities they serve by enhancing and expanding initiatives that support research in diverse communities.
- Establish mechanisms to include community consultations in NIH-funded extramural research from study development to the dissemination of study results.
- Expand information dissemination and regional technology transfer programs in regions with high rates of HIV transmission within racial and ethnic minority communities.
- Share study results with research participants promptly through existing information dissemination mechanisms, as well as through community organizations.
- Fund community-driven participatory research to facilitate the bidirectional transfer of knowledge and observations.
- Fund training of community-based organization staff, as well as community participants, to increase their knowledge about clinical trials and the clinical trial process, with the goal of enhancing both the participation and retention of racial and ethnic minorities.
- Develop, test, and promote successful strategies linking community organizations with NIH research performance sites through the use of Internet resources, such as AIDSinfo.nih.gov.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

Effective and efficient information dissemination and exchange are important tools in the effort to control and end the AIDS epidemic. The NIH has responsibility for disseminating information to support research, treatment, and prevention related to HIV and AIDS. Progress in these areas depends on the transfer of information to researchers, health care and service providers, HIV-infected individuals and their families, policymakers, and the public. These audiences have varying needs for information that is critical in the fight against HIV/AIDS. The changing demographics of the epidemic provide challenges to disseminating HIV research results to communities at risk in the United States, including women and minorities, as well as those at risk in developing countries. An additional challenge is providing information in formats that are useful to both health care providers and patients. The flow of information among researchers, health care providers, and the affected communities represents new opportunities to rapidly translate research into practice and to shape future research directions.

Community Outreach Programs

Providing accurate and up-to-date HIV/AIDS prevention and treatment information to communities at risk, especially women and minorities, is a critical challenge. The NIH has a number of ongoing projects to address HIV/AIDS in minority and underserved communities. Since FY1994, the NIH, through the National Library of Medicine, has made annual awards of up to $50,000 (or $10,000 for simplified express awards) to enable community-based organizations and public and health science libraries to design their own programs for improving access to AIDS information for targeted groups, including people living with HIV/AIDS, their caregivers, communities at risk, and the general public. These awards support activities such as purchasing equipment and telecommunications services, implementing Internet access, training in the use of sophisticated information tools, and developing language- and culture-specific materials.

Curriculum-based AIDS information programs and modules are made available nationwide, including through the HBCUs and other educational institutions, as well as groups of minority health professionals, such as the National Association for Equal Opportunity in Higher Education (NAFEO) and the National Medical Association. Training is also carried out in conjunction with the HHS Office of Minority Health Resource Center.

Regional Information Dissemination Programs

OAR sponsors a series of regional information dissemination programs to bring current research findings to community health professionals, particularly in minority communities, and to populations with the least access to information. This is accomplished through regional workshops, exhibit displays, and collaborative programs with other agencies and organizations.

Regional Workshops

OAR sponsors regional workshops targeted to Hispanic, Native American, Asian and Pacific Islander, and African American communities. Events have focused on issues relating to women, children, and injecting drug users. These 2-day events provide a forum for the presentation of research information. To ensure that the meetings are culturally appropriate and effective, they are planned in collaboration with scientists, researchers, community leaders, people living with HIV/AIDS, and care providers in the community.

Conferences

OAR, in collaboration with the Health Resources and Services Administration, provides support to the National Minority AIDS Council (NMAC) for a series of conferences held in locations with the highest rates of HIV infection among minority populations in the United States. The purpose of these conferences is to help community-based organizations and leaders in case management and treatment meet the wide range of challenges in HIV treatment and adherence in communities of color. These conferences are unique opportunities for health care workers to receive critical research updates that contribute to the quality of care and life for infected individuals. This program has been in operation for 6 years.

Exhibit Displays

OAR has developed two exhibits that are displayed at events in the United States and abroad. These exhibits offer insight into the HIV/AIDS research programs at the NIH:

- *The NIH AIDS Research Program Exhibit* provides information on the HIV/AIDS research programs conducted and supported by the NIH. The exhibit provides publications, fact sheets, treatment guidelines, information about NIH web sites, including AIDS information, and order forms for information from the ICs. The exhibit provides this critical information about the NIH AIDS research program to scientists, health care workers, social workers, community-based workers, patients, and the public at domestic and international scientific and community-oriented events.

- *The Children's Art Exhibit* was designed by OAR in collaboration with the Pediatric HIV Working Group of the National Cancer Institute (NCI). To help individuals better understand the challenges and triumphs of living with HIV and AIDS, this exhibit presents artwork created by children, adolescents, and young adults participating in the clinical trials of the Pediatric HIV Working Group of the NCI. The pictures in the exhibit are created by these young people, and in some cases their uninfected siblings, who are using this art to give form to their psychological experiences and tell the story of their journey of living with HIV and AIDS.

Collaboration with National/Community-Based Organizations

OAR collaborates with a number of organizations addressing HIV/AIDS issues in racial and ethnic minority communities. OAR supports approximately 10 regional conferences each year focusing upon treatment issues. These meetings are held in locations with the statistically highest HIV/AIDS rates in the United States.

OAR has developed AIDS information kiosks that have been placed in strategic locations for access by at-risk populations, including in community college settings, at the University of Puerto Rico, through grassroots organizations working with youth, and with faith-based organizations. These computer kiosks allow directed searching through the Internet to learn more about HIV and AIDS. The home page and links created for this site direct the user through information on topics they query in English or Spanish.

Objective One

Support the effective dissemination, communication, and utilization of HIV/AIDS information to all constituent communities of the NIH, domestically and internationally.

Strategies:

- Rapidly disseminate new research findings, including information on the potential implications for prevention, care, and treatment of HIV-infected individuals, using existing and innovative methods.
- Utilize computer and other information dissemination technology (including use of the Internet) to disseminate up-to-date information about HIV therapeutic, vaccine, and prevention trials and information about HIV training programs.
- Expand access to and education about current state-of-the-art treatment and patient management guidelines, including information on clinical trials, using multiple technologies such as online access and voice access (AIDSinfo).
- Improve outreach and support access to HIV/AIDS information resources (including computers) by community groups, health care providers, and community-based HIV/AIDS service organizations, including those serving minority communities.
- Support dissemination of information, including to constituent communities, in culturally and linguistically appropriate ways.
- Develop and disseminate educational information to enhance the understanding of HIV and basic and clinical research processes by health care providers, community-based HIV/AIDS service organizations, social service organizations, policymakers, and persons with HIV/AIDS.
- Develop and disseminate information resources about HIV vaccine clinical trials and the importance of potential HIV vaccines.

Objective Two

Support research to identify existing gaps in communication approaches, identify and evaluate existing strategies, and develop and test new and innovative communication strategies that will improve access to and use of state-of-the-art HIV information by all relevant target audiences, domestically and internationally.

Strategies:

- Identify obstacles to information dissemination and develop, test, and evaluate possible ways to overcome these obstacles.
- Develop, test, and evaluate innovative strategies for effectively reaching specific audiences (e.g., minority communities, adolescents, drug users, other hard-to-reach populations, and health care providers) with relevant HIV information.
- Work to reduce communication gaps between academic researchers, treatment providers, and community-based organizations so that research results are more effectively disseminated to providers and that research agendas reflect the needs of practicing clinicians.

The Office of Behavioral and Social Sciences Research

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

OFFICE OF **B**EHAVIORAL AND **S**OCIAL **S**CIENCES **R**ESEARCH

MISSION/VISION STATEMENT

The Office of Behavioral and Social Sciences Research (OBSSR) was established by Congress in the Office of the Director (OD), National Institutes of Health (NIH), in recognition of the key role that behavioral and social factors often play in illness and health. The OBSSR mission is to stimulate behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into others of the NIH health research enterprise, thereby improving our understanding, treatment, and prevention of disease. The major responsibilities of the office and its director are to:

- Provide leadership and direction in the development, refinement, and implementation of a trans-NIH plan to increase the scope of and support for behavioral and social sciences research;
- Inform and advise the NIH Director and other key officials of trends and developments having significant bearing on the missions of the NIH, the Department of Health and Human Services (HHS), and other federal agencies;
- Serve as the principal NIH spokesperson regarding research on the importance of behavioral, social, and lifestyle factors in the causation, treatment, and prevention of diseases; and advise and consult on these topics with NIH scientists and others within and outside the federal government;
- Develop a standard definition of “behavioral and social sciences research,” assess the current levels of NIH support for this research, and develop an overall strategy for the uniform expansion and integration of these disciplines across NIH Institutes and Centers (ICs);
- Develop initiatives designed to stimulate research in the behavioral and social sciences arena, integrate a bio-behavioral perspective across the research areas of the NIH, and encourage the study of behavioral and social sciences across NIH’s ICs;
- Initiate and promote studies to evaluate the contributions of behavioral, social, and lifestyle determinants in the development, course, treatment, and prevention of illness and related public health problems;
- Provide leadership in ensuring that findings from behavioral and social sciences research are disseminated to the public; and,
- Sponsor seminars, symposia, workshops, and conferences at the NIH and at national and international scientific meetings on state-of-the-art behavioral and social sciences research.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Scientific research supported by the NIH has been of great benefit to the health of the population in the United States. Research to improve diagnosis, treatment, and prevention of disease has led to improvements in health care for most Americans, and to significant declines in morbidity and mortality from numerous diseases. As a result, the population can expect not only to live longer but also to be more productive and to enjoy a higher quality of life. However, these gains have not benefited all segments of the population equally. For example, minority populations in the United States, as well as those residing in rural areas and those with a low socioeconomic status (SES), continue to experience substantial disparities in the burden of disease and death when compared to the majority population. Because the existence of racial and ethnic health disparities is to a large extent due to the influence of behavioral and social rather than biological factors, the OBSSR is committed to developing better knowledge of their specific causes and participating in finding solutions.

OBSSR staff reviewed the 511 pages of public comments received from government agencies, academia, health care associations, and other professional associations and from the general public. A number of general themes emerged from these comments. They include a desire to:

1. Produce an accurate and uniform definition of health disparities to improve the quality of data on health disparities;
2. Increase the scope of research to include more behavioral and social influences on health; sponsor programs to mentor, educate, and provide grant support to minorities to pursue health care opportunities; and
3. Support research that will increase our understanding of various population groups, among them underserved minorities including underrepresented subpopulations.

In the fall of 2002, at the request of Dr. Elias Zerhouni, Director of the NIH, and Dr. John Ruffin, Director of the National Center for Minority and Health Disparities (NCMHD), the NIH Committee on Minority Health and Health Disparities was established and charged with determining operational definitions and developing a methodology that would form the basis for future reporting on all NIH activities related to minority health and health disparities.

OBSSR staff participated in the meetings of the new committee through January 2004 and provided input in the development of an operational definition for *minority health and health disparities* at the NIH. The committee produced a detailed report with definitions and methodology that will serve as the basis for all minority health and health disparities reporting at the NIH. The new definition of health disparities includes members of minority populations, plus those who are of low SES and those residing in rural areas. This definition will be applied consistently across all ICs at the NIH, and will provide more accurate data on minority health activities as well as health disparities activities.

Between Fiscal Years 2004 and 2008, OBSSR plans to participate in a number of activities in the behavioral and social sciences that support the NIH effort on minority health and health disparities. The Office also plans to participate in activities to mentor, educate, and provide grant support to minorities to pursue health care opportunities. In addition, the OBSSR plans to participate in a variety of projects to increase scientific understanding of the health status of various population groups, to lead to more effective interventions and services for diverse populations, among them underrepresented minorities.

The projects discussed in this report represent directions that OBSSR would like to pursue in the next 5 years as funding allows. The projects fall into broad categories of areas of emphasis in research, areas of emphasis in research capacity, and areas of emphasis in community outreach, information dissemination, and public health education, and are not listed in priority order. In addition, the OBSSR may pursue projects not identified here if opportunities for collaboration with the NIH ICs arise.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Pathways Linking Education and Health

Education, along with income and occupation, has been used repeatedly to define the social gradient in health that persists despite marked improvement in the health of the American population over the last hundred years. Generally individuals with lower income, less education, and lower-status occupation/employment, requiring less education and/or providing less income, have poorer health. Greater understanding of the nature of the independent (non-income) relationships between education and health depends on increasing knowledge about the mechanisms and pathways that explain the association between education and health.

Better scientific understanding of the causal pathways between education and health could lead to additional and improved prevention and therapeutic intervention strategies for important health problems. To better understand these pathways, validation of specific measures of abilities crucial to educational attainment, such as level of cognitive or language skills, may be needed. Further exploration is needed of intervening neuro- or psychobiological mechanisms, such as impact on frontal lobe structure or function or psychological characteristics, and how these relate to a significant health outcome or important health-related behavior or expected outcome. In addition, it will be necessary to explore what components or dimensions of education are important to health. The association or pathway between formal education and either important health behaviors or diseases may not be causal. Instead it may reflect the influence of confounding or co-existing determinants or may be bi-directional.

1.1.1 Objective One: Support Research on Education and Health

The OBSSR has developed an initiative that will lead to an increase in the level and diversity of research directed at elucidating the causal pathways and mechanisms that may underlie the association between education and health.

1.1.1.1 Action Plan

- Co-sponsor a Request for Applications (RFA) with the National Institute on Aging (NIA), National Cancer Institute (NCI), and National Institute of Child Health and Human Development (NICHD) focusing on the relationship between education and health.
- Support research on the pathways linking education to health.

Timeline: Fiscal Years 2004-2006

1.1.1.2 Performance Measures

- Issue the RFA entitled Pathways Linking Education to Health.
- Support research projects on the pathways linking education to health.

1.1.1.3 Outcome Measures

- Support high-quality research on the pathways linking education to health.
- Research outcomes and publications on the pathways linking education to health.

1.1.2 Objective Two: Understanding and Promoting Health Literacy

Healthy People 2010 defines health literacy as the “degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Many factors affect individuals’ ability to comprehend, and in turn use or act on, health information and communication. Proficiency in reading, writing, listening, interpreting, oral communication, and visual analysis is necessary, as the modern health system typically relies on a variety of interpersonal, textual, and electronic media to present health information. Individuals and families both must be able to: communicate with health professionals; understand the health information in mass communication; understand how to use health-related print, audiovisual, graphical and electronic materials; understand basic health concepts (e.g., many health problems can be prevented or minimized) and vocabulary (e.g., about the body, diseases, medical treatments, etc.); and connect this health-related knowledge to health decision-making and action-taking. Access to and understanding of health information and services is a reciprocal process among health professionals, communication professionals, and patients. For instance, these professionals must use science-based strategies and tactics, develop resources and materials, and understand communication interactions between providers and patients.

Research on health literacy should assist NIH in its mission of communicating scientifically based health information to the public and to the health care providers and related professionals who serve the public. The application of scientific knowledge from health literacy research may also strengthen the health information knowledge and communication skills of the public, and further one of the national goals of Healthy People 2010, to improve health literacy by the decade’s end.

1.1.2.1 Action Plan

- Co-sponsor with other NIH ICs a Program Announcement (PA) with Special Review to invite investigators to submit R01 and R03 research grant applications on health literacy. The goal of this PA is to increase scientific understanding of the nature of health literacy and its relationship to healthy behaviors, illness prevention and treatment, chronic disease management, health disparities, risk assessment of environmental factors, and health outcomes, including oral and

mental health. Such knowledge will help enable health care and public health systems to communicate effectively across different health literacy levels, and to employ strategies that reduce health disparities in the population.
- Fund or co-fund high quality research projects on health literacy.

Timeline: Fiscal Years 2004-2007

1.1.2.2 Performance Measures

- Develop and co-sponsor the Health Literacy PAR with other NIH ICs.

.

1.1.2.3 Outcome Measures

- Issue the Health Literacy PAR in collaboration with NIH ICs.
- Support high-quality research on health literacy.

1.1.3 Objective Three: Support Community-Based Participatory Research (CBPR) on Health Promotion, Disease Prevention, and Health Disparities

The promise of community participation in all aspects of the research process is that better-informed hypotheses will be tested, more effective interventions will be developed, and the translation of the research results into practice will be enhanced. OBSSR is working with NIH ICs to develop a program that would support research on health promotion, disease prevention, and health disparities that is jointly conducted by communities and researchers.

CBPR is defined as scientific inquiry conducted in communities in partnership with researchers in which community members; persons affected by the health condition, disability, or issue, under study; or other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work (from conception through design, conduct, analysis, interpretation, conclusions, and communication of results). In this program, community refers to populations that may be defined by: geography, race, ethnicity, gender, sexual orientation, disability, illness, or other health condition, or to groups that have a common interest or cause, such as health or service agencies and organizations, health care or public health practitioners or providers, policy makers, or lay public groups with public health concerns. Community-based organizations refer to organizations that may be involved in the research process as members or representatives of the community.

1.1.3.1 Action Plan

- OBSSR will develop and co-sponsor with other NIH institutes a PA with Special Review focusing on CBPR. OBSSR is working with the NCI, Office of AIDS Research in the OD, NICHD, National Institute of Environmental Health Sciences (NIEHS), Agency for Healthcare Research and Quality (AHRQ), and Centers for Disease Control and Prevention (CDC) in developing and drafting this announcement. The PAR will likely be completed in FY2005 and hopefully will have additional IC support. The working title of this PAR is "Community Participation in Health Promotion and Disparities Research." This PAR will use NIH research project grant (R01) and exploratory/developmental grant (R21) award mechanisms. Research projects are encouraged both to tackle specific health problems and to improve the research methodology of CBPR. The CBPR working group is a subcommittee of the Interagency Task Force on CBPR, which is chaired by NIEHS.

- To include various community groups in the development of this PAR. CBPR is characterized by substantial community input in the development of the grant application. Although not an exhaustive list, organizations as varied as Tribal governments and colleges, independent living centers, other educational institutions such as junior colleges, advocacy organizations, health delivery organizations, health professional associations, non-governmental organizations, and federally qualified health centers are possible community partners.

Timeline: Fiscal Years 2005-2008

1.1.3.2 Performance Measures

- Develop and co-sponsor with NIH ICs the PAR on community-based participatory research.
- Inclusion of community groups in the development of the PAR.

1.1.3.3 Outcome Measures

- Draft and Issue a PAR on CBPR.
- Support high-quality research projects on CBPR.

1.2 Area of Emphasis Two: Interrelation Between Work, Family, and Well-Being

The mismatch between the demands of family and work are larger in families with fewer social and economic resources. This research program will evaluate specific workplace interventions to reduce these mismatches. These interventions should be designed to improve employees' abilities to more successfully meet work and family demands, thereby improving worker and family health. OBSSR is developing a research program to evaluate interventions designed to improve the health and well-being of children and adult family members resulting from conflicts between family and work demands.

1.2.1 Objective One: Support Research on Work and Family

OBSSR will develop and co-sponsor an RFA to support the development of research plans focused on the interrelations between work, family, health, and well-being that are state-of-the-art in conceptualization and measurement techniques. The model protocols that are developed from this program will serve as the basis for a future U01 initiative to support a set of multi-site interventions to evaluate which types of workplace policies and practices are the most beneficial for the health and well-being of workers, their families (including their children and other dependents), and workplaces.

1.2.1.1 Action Plan

- In preparation for the RFA, OBSSR has worked with NICHD to organize three meetings in FY2003 and FY2004. The first meeting was in FY2003 and involved 300 researchers and subject matter experts. OBSSR contributed $50,000 in support of the project, which led to the development of a book yet to be published.
- The second and third meetings will occur within FY2004. It will involve both researchers and representatives of the private and public sector work sites where this type of research may occur.
- The third meeting is a workshop to review the best research practices for this type of research.

Timeline: Fiscal Years 2004-2005

1.2.1.2 Performance Measures

- Establish agreement with other NIH ICs to co-sponsor the RFA.
- Conduct the second meeting, involving both researchers and representatives of the private and public sector.
- Plan and conduct workshop to review the research in this area.

1.2.1.3 Outcome Measures

- Develop initiatives collaboratively with NIH ICs.
- Support high-quality research projects on work and health.

1.3 Area of Emphasis Three: Mind-Body Interactions and Health

"Mind-body interactions and health" refers to the relationships among cognitions, emotions, personality, social relationships, and the physiological processes linking them with health. Research supported by the Public Health Service has documented that many of the leading causes of morbidity and mortality in the United States are attributable to social, behavioral, and lifestyle factors. OBSSR has led efforts at the NIH to develop a mind-body initiative to: (a) further understanding of underlying processes linking behavioral and social factors with health; (b) develop interventions to prevent illness and treat disease based upon this knowledge; and (c) research the origins of social and behavioral factors affecting health. The mind-body initiative calls for and supports research on cultural and socioeconomic processes involved in the relationships among cognitions, emotions, social relationships, and health that may contribute to health inequalities.

1.3.1 Objective One: University of Michigan Center on Social Inequalities, Mind, and Body

Through grants to the University of Michigan, OBSSR is supporting the Michigan Interdisciplinary Center on Social Inequalities, Mind, and Body (MICSIMB). This research center is seeking to elucidate interactions of psychosocial states (beliefs, attitudes, affective states, values, and social relationships), their determinants, stress, and pathophysiologic markers of stress, in the development of physical and mental disorders, in child development, and in aging. The MICSIMB includes a focus on socioeconomic and racial inequalities in health, and on life-course and community determinants in population-based samples of children and adults, men and women, Whites and minorities.

The study in progress at MICSIMB is based on the assumption that inequalities in adult health represent the multifaceted accumulation of disadvantage over the life course. Thus, it concentrates on the roles of economic factors, neighborhood characteristics, and the biology of stress from birth to old age. Research projects underway at the Center include: Pathways to Child Health and Function; Social Context, Social Inequality, Mind, Body, and Health; and Health of Women Under Economic Stress.

1.3.1.1 Action Plan

Support research encouraging interdisciplinary collaboration and innovation toward understanding the processes underlying mind-body interactions and health, and socioeconomic and racial inequalities in health, as well as toward the application of such basic knowledge into interventions and clinical practice in the promotion of health and the prevention or treatment of disease and disabilities.

Timeline: Fiscal Years 2004-2008

1.3.1.2 Performance Measures

Support various mind-body research centers.

1.3.1.3 Outcome Measures

Support research on socioeconomic and racial inequalities in health.

1.4 Area of Emphasis Four: Social and Cultural Dimensions of Health

Social scientists have made significant strides in shedding light on the basic social and cultural structures and processes that influence health. Social and cultural factors influence health by affecting exposure and vulnerability to disease, risk-taking behaviors, and the effectiveness of health promotion efforts, and by affecting the availability of and access to quality health care. Social and cultural factors also play a role in shaping perceptions of and responses to health problems and the impact of poor health on individuals' lives and well-being. In addition, such factors contribute to understanding societal and population processes, such as current and changing rates of morbidity, survival, and mortality. Consequently, social science research should be integrated into interdisciplinary, multi-level studies of health. Linking research from the macro-societal levels, through the behavioral and psychological levels, to the biology of disease will provide the integrative health research necessary to fully understand health and illness.

Advances in social science research on health depend on a foundation of basic theory and knowledge that describes social structures, the dynamics of social and cultural processes, and the ways in which individuals are located in and interact with the environment, social structures, and cultural factors. Several key sociodemographic constructs, including race, ethnicity, gender, age, and SES, are widely used in studies of the etiology of health and disease and in research that describes and monitors the distribution of disease across social categories, geographic areas, and time. However, the meanings of such constructs depend on their cultural, geographical, and historical context, and their utility in health research depends on their use in ways that are theoretically and historically grounded. In addition, the concept of "culture" requires careful theoretical grounding in health studies. Most social scientists agree that the concept of culture is complex and implies a dynamic and ever-changing process.

OBSSR continues to sponsor research to explore the implications of different conceptualizations and measurements of social stratification systems and processes, such as SES and social class, age, gender, and race/ethnicity, for understanding health at the individual and higher levels of aggregation (e.g., community). Activities in this area will include research to improve the monitoring and understanding of inequalities in health and disease among diverse groups, and the implications for monitoring of strategies used to measure basic constructs, such as SES and social class, age, gender, race, and ethnicity.

1.4.1 Objective One: Support Research on Social and Cultural Dimensions of Health

OBSSR plans to support research that will help: (a) elucidate basic social and cultural constructs and processes used in health research; (b) clarify social and cultural factors in the etiology and consequences of health and illness; (c) link basic research to practice for improving prevention, treatment, health services, and dissemination; and (d) explore ethical issues in social and cultural research.

1.4.1.1 Action Plan

- Revise and re-issue the PA on social and cultural dimensions of health.
- Support high-quality research projects on the social and cultural dimensions of health.

Timeline: Fiscal Years 2004-2007

1.4.1.2 Performance Measures

Re-issue the PA on "Social and Cultural Dimensions of Health" in collaboration with NIH ICs.

1.4.1.3 Outcome Measures

- Revise and re-issue the PA.
- Support high-quality research projects on the social and cultural dimensions of health.

1.4.2 Objective Two: Research on the Behavioral and Social Aspects of Health and Illness

The OBSSR is committed to supporting research that will increase scientific understanding of the health status of various population groups and lead to more effective health interventions and services for individuals within those groups. High priority is placed on research with groups that appear to have distinctive health risk profiles but thus far have received insufficient attention from investigators.

1.4.2.1 Action Plan

The OBSSR, in collaboration with the National Institute of Mental Health (NIMH), is revising a PA that will increase research on behavioral and social aspects of health and illness with particular attention to minority and diverse populations. OBSSR is co-sponsoring the PA entitled "Behavioral, Social, Mental Health, and Substance Abuse Research with Diverse Populations."

Timeline: Fiscal Years 2004-2007

1.4.2.2 Performance Measures

- Co-sponsor with the NIMH the PA entitled "Behavioral, Social, Mental Health, and Substance Abuse Research with Diverse Populations."
- Support research projects on behavioral and social aspects of health and illness.

1.4.2.3 Outcome Measures

- Support high-quality research projects on behavioral and social aspects of health and illness.

1.4.3 Objective Three: Social and Behavioral Research in Health Disparities

The NIH Behavioral and Social Sciences Research Coordinating Committee, with sponsorship by OBSSR, plans to convene one or more symposia on social and behavioral research contributions to understanding the origins of health disparities and to the design and implementation of interventions to reduce health disparities. The symposia will focus on current research and interventions at either the individual or societal levels. In addition, the symposia will consider needed future directions for behavioral and social research.

1.4.3.1 Action Plan

Plan and convene symposia: Understanding and Reducing Health Disparities: Behavioral and Social Science Perspectives

Timeline: Fiscal Years 2004-2005

1.4.3.2 Performance Measures

- Plan and hold meeting.

1.4.3.3 Outcome Measures

- Develop a trans-NIH initiative on understanding and reducing health disparities using a behavioral and social science approach.
- Support high-quality research projects on social and behavioral research as it relates to health disparities.

1.4.4 Objective Four: Health Disparities and Chronic Disease

OBSSR is developing a series of scientific reports that would analyze the magnitude of the health disparities and the social and behavioral causes of several of the most important chronic diseases, such as coronary artery disease. The first report, *The Prevalence of Multiple Chronic Disease Risk Factors: 2001 National Health Interview Survey*, has been accepted for publication. This study found that men under the age of 65 with a high school education or less had a significantly higher rate of behavioral risk factors for several chronic diseases.

1.4.4.1 Action Plan

- Research the relevant topics and draft reports.
- Publish reports.

Timeline: Fiscal Years 2004-2006

1.4.4.2 Performance Measures

- Support the planning and implementation of research projects on health disparities and chronic diseases.
- Publish a series of scientific reports.

1.4.4.3 Outcome Measures

- Support research on health disparities and chronic diseases.

1.4.5 Objective Five: Effect of Racial and Ethnic Discrimination/Bias on Health Care Delivery

Racial/ethnic minorities suffer disproportionate morbidity and mortality from chronic diseases such as cancer, heart disease, diabetes, and stroke. Although racial/ethnic differences in morbidity and mortality can be partially explained by differences in lifestyle, health-seeking behavior, and financial access to care, these factors do not entirely explain differences in incidence, treatment, or outcomes. Research is needed to provide insight into how and why racial/ethnic disparities occur and to test interventions and strategies to eliminate them, including research that provides further elucidation on: (1) patient, provider, and institutional contributions to health care disparities; (2) the relative contributions of provider bias, stereotyping, prejudice, and uncertainty to racial/ethnic disparities in diagnosis, treatment, and outcomes of care; and (3) the role of non-physician health care professionals, pharmacists, allied health professionals, and non-professional staff in contributing to health care disparities.

OBSSR is co-sponsoring a PA to encourage research to reduce the prevalence of racial/ethnic health disparities through a better understanding of the role that racial/ethnic discrimination plays and through the development of interventions to reduce the influence of racial/ethnic discrimination in health care delivery systems. This PA will focus on examining overt as well as subtle racial/ethnic discriminatory behavior and processes perceived or experienced by historically disadvantaged racial/ethnic minority groups and their contribution to the persistent disparities in the receipt of quality health care and disease outcomes that have been observed among these populations.

1.4.5.1 Action Plan

- Co-sponsor with other NIH ICs a PA to invite investigators to submit R01, R21, and R03 research grant applications on the effect of racial and ethnic discrimination on health care delivery. The goal of this PA is to improve the measurement of racial/ethnic discrimination in health care delivery systems through improved instrumentation, data collection, and statistical/analytical techniques. This PA also will enhance understanding of the influence of racial/ethnic discrimination in health care delivery and its association with disparities in disease incidence, treatment, and outcomes among disadvantaged racial/ethnic minority groups.

- Fund or co-fund high-quality research projects on the effect of racial and ethnic discrimination on health care delivery

Timeline: Fiscal Years 2005 - 2010

1.4.5.2 Performance Measures

- Co-sponsor the PA on the effect of racial and ethnic discrimination on health care delivery

1.4.5.3 Outcome Measures

- Support high quality research projects on the effect of racial and ethnic discrimination/bias on health care delivery

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Training Minority Students

The NIH has established numerous research-training programs in response to the call to improve the diversity of the research workforce in the health professions. Although the NIH currently provides opportunities for students from underrepresented groups and disadvantaged backgrounds through the traditional research grant programs and through special initiatives supported by various components of the NIH, there is no evidence that the need for increased representation has changed.

The OBSSR recognizes the need to prepare a new generation of scientists for careers and leadership roles in health sciences research working toward eliminating health disparities. Therefore, the OBSSR has continued its efforts to establish a diversified workforce by increasing the number of individuals from underrepresented groups actively participating in health sciences research. Ultimately, the OBSSR will continue its strong commitment to aid in expanding and intensifying research relating to the sources of health disparities, and to recruit from a diverse pool of scientists and research professionals.

2.1.1 Objective One: Kellogg Scholars in Health Disparities

In conjunction with the Kellogg Scholars Program in Health Disparities and the Center for the Advancement of Health, OBSSR coordinated and hosted a meeting of health disparities scholars as part of their orientation at the NIH. The goal of the Kellogg Scholars program is to prepare a new generation of scientists for careers and leadership roles in health disparities research and in health policy and practice to:

1. Research questions that relate to the understanding of health disparities by race/ethnicity, gender and income/SES,
2. Study mechanisms and pathways by which social, economic, political, environmental, and educational factors and discrimination affect health, and
3. Develop private sector and public policy frameworks and programs to eliminate health disparities.

2.1.1.1 Action Plan

- Coordinate and sponsor another meeting of the Kellogg Scholars in Health Disparities.

Timeline: Fiscal Year 2004

2.1.1.2 Performance Measures

- Coordinate and sponsor meeting.

2.1.1.3 Outcome Measures

- Participants are informed about NIH's health disparities related research programs.

2.1.2 Objective Two: Undergraduate Scholarships for Disadvantaged Students

In an effort to further address the continued need for an increased number of minority researchers, the OBSSR supported the NIH Undergraduate Scholarship Program (UGSP), Sec. 487D of the Public Health Service Act, as amended, which offers competitive scholarships to students from disadvantaged backgrounds who are committed to pursuing careers in biomedical, behavioral, and social science research.

The program offers scholarship support, paid research training at the NIH during the summer, and paid employment and training at the NIH after graduation. The UGSP is a highly competitive program, awarding approximately 15 scholarships each year to promising undergraduate students from disadvantaged backgrounds, one to three of which are completely funded by OBSSR.

2.1.2.1 Action Plan

- Support 1-3 UGSP scholars.

Timeline: Fiscal Years 2004-2008

2.1.2.2 Performance Measures

- Support UGSP scholars.

2.1.2.3 Outcome Measures

- Support undergraduate students from disadvantaged backgrounds pursuing careers in biomedical, behavioral, and social science research.

2.1.3 Objective Three: Linking Scientists, Including Those From Underrepresented Groups, With Mentors

OBSSR designed a web site to expand the promotion efforts of the NIH research supplement training program. This web site is open to all individuals interested in learning about mentoring opportunities. Furthermore, the OBSSR seeks to ensure a concentration of researchers who will address behavioral and social factors that are important in improving the public's health, especially among underrepresented populations. This web site creates a link between students interested in finding mentors and faculty eligible for support through the NIH Research Supplements to Promote Diversity in Health-Related Research program (see http://grants.nih.gov/grants/guide/pa-files/PA-05-015.html). In addition, it establishes a central resource for students and faculty, as well as researchers, seeking information on NIH research training opportunities in the behavioral and social sciences. The creation of this site also is in line with Congressional interest in increasing the number of behavioral science training opportunities available to minority students (U.S. House Report 105-635).

2.1.3.1 Action Plan

- Link students, including those from groups that have been shown to be underrepresented in science, and faculty with NIH-funded researchers at their home institution who are in a position to offer students the opportunity to join a research team of leading behavioral and social scientists to aid them in building a research career in the behavioral and social sciences.
- Link NIH-funded researchers with students, including those from groups that have been shown to be underrepresented in science, and faculty allowing researchers to offer their expertise and assist the OBSSR in building a diverse cadre of scientists in the behavioral and social sciences.

Timeline: Fiscal Years 2004-2008

2.1.3.2 Performance Measures

- The web site provides a mechanism for students, including those individuals from groups that have been shown to be underrepresented in science, and faculty to find NIH-funded researchers at their home institutions.

2.1.3.3 Outcome Measures

- Provide invaluable research training opportunities for students, including those from groups that have been shown to be underrepresented in science, and faculty.
- Provide the opportunity for aspiring researchers, including those from groups that have been shown to be underrepresented in science, and established NIH-funded researchers to form a mutually beneficial mentor/mentee relationship.

2.2 Area of Emphasis Two: Research and Evaluation Designs and Methods in Health Disparities Intervention Research

To understand and address health disparities, it is critical that we build a cadre of scientists who possess a thorough understanding of the influence of behavioral and social sciences factors on health and illness. Further, this new cadre of scientists must also possess the necessary tools to develop and implement research projects utilizing various methodologies such as randomized clinical trials to evaluate behavioral interventions. They must understand how the most common psychosocial models have been combined in recent research studies and the applicability of research and evaluation designs and methods in intervention research. OBSSR has developed a series of programs to fully equip health disparities researchers with the necessary tools to conduct high-quality research in this important area.

2.2.1 Objective One: Training for Conducting Behavioral Randomized Clinical Trials

The relevance of behavioral and social processes and interventions to health research has become increasingly clear over the past 3 decades. Research findings are now at the level where evaluation of interventions through Randomized Clinical Trials (RCTs) is becoming more and more necessary. However, behavioral RCTs present unique challenges (e.g., the identification and implementation of proper "placebo" or control groups), and few behavioral scientists have training or experience in conducting RCTs.

In consultation with experts, OBSSR developed and fully financed a 12-day Summer Training Institute for Randomized Clinical Trials Involving Behavioral Interventions, which it held in 2001, 2002, and 2003. Each year, more than 400 scientists have expressed interest in the course, and more than 200 submitted applications for the 30 fellowships. The annual RCT course consistently has approximately 25 percent minority attendees. The participants rated the training experience as "excellent."

2.2.1.1 Action Plan

- With the goal of creating a cadre of behavioral and biomedical scientists trained in evaluating behavioral interventions, OBSSR has awarded a competitive contract to Mt. Sinai Medical School and Columbia University to conduct the Summer Training Institutes for 5 years and to expand the number of fellows to 35-40 per summer.

- In addition, OBSSR organized a well-received series of symposia to provide similar training to NIH staff starting in FY2003.

Timeline: Fiscal Years 2003-2008

2.2.1.2 Performance Measures

- Conduct the annual summer institute training.

2.2.1.3 Outcome Measures

- Support research projects utilizing randomized clinical trials to evaluate behavioral interventions.

2.2.2 Objective Two: Planning Meeting on Health Disparities and Work

A social gradient in health disparities for many physical and mental disorders has been well established. However, the pathways linking low SES and poor health outcomes are not adequately understood. The pathways likely involve several domains including work. However, there is no uniform methodology for measuring SES. Studies measuring the social gradient approach the measurement of SES in a variety of ways. And, the work domain includes a variety of factors such as the psychosocial work environment, work organization, family-work conflicts, wages and fringe benefits, access to information and technology (e.g., the Internet), job/employment security, labor market status (student, unemployed, not in the labor market, retired), employer characteristics (size, sector, market position, etc.), racial-gender segregation, experiences of discrimination or harassment, and contingent/precarious employment, as well as physical and chemical exposures.

The characterization of these work sub-domains can be done with varying levels of specificity, for example using broad industry or occupation classification systems, using job exposure matrices, using questionnaire surveys, or using detailed methodologies for the assessment of physical and chemical hazards. Health disparity research that examines the social gradient of health among working-age adults and their families may benefit from a more detailed consideration of work-health relationships.

The OBSSR in collaboration with the CDC organized a half-day workshop or planning meeting in April 2004 to plan a research agenda workshop for FY2005. The following questions were discussed at the workshop:

1. What are the most influential pathways by which work experiences may explain the observed social gradient in health?

2. What is the added value of measuring work sub-domains in research studies where the social gradient is the primary independent variable in the study of specific health endpoints?

3. Given the variety of potentially salient work sub-domains and the multiple levels at which each work sub-domain could be measured, what focus and level of detail are appropriate when including the work domain in health disparity studies?

The workshop participants were both from academia and several of the NIH ICs. The workshop recommended proceeding with the planning of a research agenda conference around the three questions above. OBSSR is seeking the participation of a few ICs to proceed with such a workshop in FY2005.

2.2.2.1 Action Plan

The OBSSR and CDC are considering either of the following options as next steps:

- *Organize a methodological workshop aimed at developing specific information and recommendations around research methods*. An example of the type of methodological issues a workshop might address is a detailed review of how the most common psychosocial models such as the demand/control and effort/reward models have been combined in recent research studies. Another methodological topic could be the identification of the specific work variables that are correlated most strongly with the social gradient, such as job content, job structure, and job security. Workshop products could include general recommendations and information on specific methods/questionnaires.
- *Organize a workshop to develop a broad research agenda useful to CDC and NIH*. Such a workshop typically involves presentations of research studies and suggestions of future high-priority research topics. A key focus of such a research agenda workshop might be discussion of the specific sub-domains of work and their potential role in contributing to the social gradient.

Timeline: Fiscal Year 2005

2.2.2.2 Performance Measures

- Conduct the workshop.

2.2.2.3 Outcome Measures

- Develop a research initiative in collaboration with NIH ICs and the CDC on health disparities and work.

2.2.3 Objective Three: Research and Evaluations Designs and Methods for Health Care Quality Improvement Interventions: Exploring the Tradeoffs

The OBSSR conducted on May 4-5, 2004, a workshop entitled Research Designs for Complex, Multi-level Health Interventions and Programs. This workshop was co-sponsored by NIH, CDC, and the AHRQ. The learning objectives of the presentations offered during this activity were as follows:

1. Understand how opportunities and challenges in effectiveness and translational research (related to the research questions, setting, availability of resources, etc.) lead to a consideration of a variety of research designs.

2. Recognize key tradeoffs between alternative research designs.

3. Identify one or more useful research designs for effectiveness and translational studies.

Further, the issues covered during the 2-day workshop included: Prevention of Type 2 Diabetes and Childhood Obesity, and Promotion of Physical Activity.

The three co-sponsors and Robert Wood Johnson have decided, based on the success of the most recent meeting, to organize a similar workshop focused on interventions within the health care system designed to promote the translation of evidence-based treatments. It is anticipated that this workshop will be held in July 2005. The new topic is Research and Evaluations Designs and Methods for Health Care Quality Improvement Interventions: Exploring the Tradeoffs.

2.2.3.1 Action Plan

- This new meeting will use similar program format and involve a similar approach of intensive pre-meeting planning process and work with the meeting presenters. There will be careful development of case examples and other instructional material.
- Develop peer-reviewed publication for the *Journal of Preventive Medicine* based on the series of three conferences: lessons learned and unanswered questions.
- Prepare summaries of the 18 conference calls that will guide the development of the presentations and case studies.
- Prepare edited final copies of presentations and case studies using the submissions of the presenters.
- Develop a final brief report on lessons learned from the January and March meetings and suggestions for the third meeting.

Timeline: Fiscal Years 2004-2006

2.2.3.2 Performance Measures

- Conduct the workshop.

2.2.3.3 Outcome Measures

- Develop research publications for submission to peer-reviewed journals.
- Develop final report.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Support CBPR on Health Promotion, Disease Prevention, and Health Disparities

The OBSSR seeks to support research on health promotion, disease prevention, and health disparities that is jointly conducted by communities and researchers. The promise of community participation in all aspects of the research process is that better-informed hypotheses will be tested, more effective interventions will be developed, and the translation of the research results into practice will be enhanced.

3.1.1 Objective One: Support CBPR on Health Promotion, Disease Prevention, and Health Disparities

The promise of community participation in all aspects of the research process is that better-informed hypotheses will be tested, more effective interventions will be developed, and the translation of the research results into practice will be enhanced. OBSSR is working with NIH ICs to develop a program that would support research on health promotion, disease prevention, and health disparities that is jointly conducted by communities and researchers.

CBPR is defined as scientific inquiry conducted in communities in partnership with researchers in which community members; persons affected by the health condition, disability, or issue under study; or other key stakeholders in the community's health have the opportunity to be full participants in each phase of the work (from conception through design, conduct, analysis, interpretation, conclusions, and communication of results). In this program, community refers to populations that may be defined by: geography, race, ethnicity, gender, sexual orientation, disability, illness, or other health condition, or to groups that have a common interest or cause, such as health or service agencies and organizations, health care or public health practitioners or providers, policy makers, or lay public groups with public health concerns. Community-based organizations refer to organizations that may be involved in the research process as members or representatives of the community.

3.1.1.1 Action Plan

- OBSSR will develop and co-sponsor with other NIH institutes a PA with Special Review focusing on CBPR. OBSSR is working with the NCI, Office of AIDS Research in the OD, NICHD, NIEHS, AHRQ, and CDC in developing and drafting this announcement. The PAR will likely be completed in FY2005 and hopefully will have additional IC support. The working title of this PAR is “Community Participation in Health Promotion and Disparities Research.” This PAR will use NIH research project grant (R01) and exploratory/developmental grant (R21) award mechanisms. Research projects are encouraged both to tackle specific health problems and to improve the research methodology of CBPR. The CBPR working group is a subcommittee of the Interagency Task Force on CBPR, which is chaired by NIEHS.
- To include various community groups in the development of this PAR. CBPR is characterized by substantial community input in the development of the grant application. Although not an exhaustive list, organizations as varied as Tribal governments and colleges, independent living centers, other educational institutions such as junior colleges, advocacy organizations, health delivery organizations, health professional associations, non-governmental organizations, and federally qualified health centers are possible community partners.

Timeline: Fiscal Years 2005-2008

3.1.1.2 Performance Measures

- Develop and co-sponsor with NIH ICs the PAR on CBPR.
- Inclusion of community groups in the development of the PAR.

3.1.1.3 Outcome Measures

- Draft and issue a PAR on CBPR.
- Support high-quality research projects on CBPR.

3.1.2 Objective Two: Social and Behavioral Research in Health Disparities

The NIH Behavioral and Social Sciences Research Coordinating Committee, with sponsorship by OBSSR, plans to convene one or more symposia on social and behavioral research contributions to understanding the origins of health disparities and to the design and implementation of interventions to reduce health disparities. The symposia will focus on current research and interventions at either the individual or societal levels. In addition, the symposia will consider needed future directions for behavioral and social research.

3.1.2.1 Action Plan

- Plan and convene symposia: Understanding and Reducing Health Disparities: Behavioral and Social Science Perspectives.

Timeline: Fiscal Years 2004-2005

3.1.2.2 Performance Measures

Plan and hold meeting.

3.1.2.3 Outcome Measures

- Develop a trans-NIH initiative on understanding and reducing health disparities using a behavioral and social science approach.
- Support high-quality research projects on social and behavioral research as it relates to health disparities.

3.1.3 Objective Three: Health Disparities and Chronic Disease

OBSSR is developing a series of scientific reports that would analyze the magnitude of the health disparities and the social and behavioral causes of several of the most important chronic diseases such as coronary artery disease. The first report, *The Prevalence of Multiple Chronic Disease Risk Factors: 2001 National Health Interview Survey*, has been accepted for publication. This study found that men under the age of 65 with a high school education or less had a significantly higher rate of behavioral risk factors for several chronic diseases.

3.1.3.1 Action Plan

- Research the relevant topics and draft reports.
- Publish reports.

Timeline: Fiscal Years 2004-2006

3.1.3.2 Performance Measures

- Support the planning and implementation of research projects on health disparities and chronic diseases.
- Publish a series of scientific reports.

3.1.3.3 Outcome Measures

- Support research on health disparities and chronic diseases.

3.2 Area of Emphasis Two: Community Outreach to Facilitate the Training of Minority Students

The NIH has established numerous research-training programs in response to the call for an increase in the number of underrepresented minority scientists participating in the health professions. Although the NIH currently provides opportunities for students from minority and other underrepresented groups through the traditional research grant programs and through special initiatives supported by various components of the NIH, there is no evidence that the need for increased minority representation has changed.

The OBSSR recognizes the need to prepare a new generation of scientists from minority and other underrepresented populations for careers and leadership roles in health sciences research, working toward eliminating health disparities. Therefore, the OBSSR has continued its efforts to establish a diversified workforce by increasing the number of individuals from minority and other underrepresented groups actively participating in health sciences research. Ultimately, the OBSSR will continue its strong commitment to aid in expanding and intensifying research relating to the sources of health disparities, and to recruit from a diverse pool of scientists and research professionals.

3.2.1 Objective One: Linking Minority Scientists with Mentors

OBSSR designed a web site to expand the promotion efforts of the NIH research supplement training program. This web site is open to all individuals interested in learning about mentoring opportunities. Furthermore, the OBSSR seeks to ensure a concentration of researchers who will address behavioral and social factors that are important in improving the public's health, especially among underrepresented populations. This web site creates a link between students interested in finding mentors and faculty eligible for support through the NIH Research Supplements to Promote Diversity in Health-Related Research program (see http://grants.nih.gov/grants/guide/pa-files/PA-05-015.html). In addition, it establishes a central resource for students and faculty, as well as researchers, seeking information on NIH research training opportunities in the behavioral and social sciences. The creation of this site also is in line with Congressional interest in increasing the number of behavioral science training opportunities available to minority students (U.S. House Report 105-635).

3.2.1.1 Action Plan

- Link students, including those from groups that have been shown to be underrepresented in science, and faculty with NIH-funded researchers at their home institution who are in a position to offer students the opportunity to join a research team of leading behavioral and social scientists to aid them in building a research career in the behavioral and social sciences.

- Link NIH-funded researchers with students, including those from groups that have been shown to be underrepresented in science, and faculty allowing researchers to offer their expertise and assist the OBSSR in building a diverse cadre of scientists in the behavioral and social sciences.

Timeline: Fiscal Years 2004-2008

3.2.1.2 Performance Measures

- The web site provides a mechanism for students, including those individuals from groups that have been shown to be underrepresented in science, and faculty to find NIH-funded researchers at their home institutions.

3.2.1.3 Outcome Measures

- Provide invaluable research training opportunities for students, including those from groups that have been shown to be underrepresented in science, and faculty.
- Provide the opportunity for aspiring researchers, including those from groups that have been shown to be underrepresented in science, and established NIH-funded researchers to form a mutually beneficial mentor/mentee relationship.

The Office of Intramural Research

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

OFFICE OF **I**NTRAMURAL **R**ESEARCH

MISSION/VISION STATEMENT

The Office of Intramural Research (OIR) is responsible for oversight and coordination of intramural research, training, and technology transfer conducted within the laboratories and clinics of the National Institutes of Health (NIH). NIH's intramural facilities are located on the main campus in Bethesda, Maryland, as well as in Research Triangle Park, North Carolina (National Institute for Environmental Health Sciences [NIEHS]); Baltimore, Maryland (National Institute on Drug Abuse [NIDA] and National Institute on Aging [NIA]); Frederick, Maryland (National Cancer Institute [NCI]); Hamilton, Montana (National Institute of Allergy and Infectious Diseases [NIAID]); and Phoenix, Arizona (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK]). Organizationally, the individual laboratories and sections answer to the 27 Institutes and Centers that conduct applied and basic biomedical research in particular disease or subject areas. OIR's responsibility is to develop and implement NIH-wide projects, policies, standards, and review for intramural research, training, and technology transfer. OIR also includes the following: Office of Intramural Training and Education (OITE), Office of Loan Repayment and Scholarship (OLRS), Office of Animal Care and Use, Office of Human Subjects Research, and Office of Technology Transfer.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

Since 1994, OIR has created discrete research training programs within the Intramural Research Program (IRP) to address emerging needs for a sound future for biomedical research. Among these needs is that of increasing the diversity within the health sciences community by training future biomedical research scientists and other health professionals that can ultimately help reduce domestic health disparities. These programs are (FY started): the NIH Academy (FY00), the Graduate Partnerships Program (FY00), the Undergraduate Scholarship Program (FY96) and the Intramural Clinical Research Loan Repayment Program (FY94).

1.0 AREAS OF EMPHASIS IN RESEARCH—N/A

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Research Training

Expand opportunities in research training and career development for research investigators from racial and ethnic minority populations and other health disparity populations.

2.1.1 Objective One: Diversification of the Biomedical Workforce

To increase the representation of ethnic minority populations and other health disparity populations (e.g., the economically disadvantaged) in biomedical research and other health professions that could assist in the reduction of health disparities (e.g., health professionals who serve the underserved).

OFFICE OF **I**NTRAMURAL **R**ESEARCH

2.1.1.1 Action Plan

The NIH Academy, OITE, OIR

The NIH Academy is a 1- to 2-year post-baccalaureate training program for recent college graduates who have an interest in research leading to the elimination of domestic health disparities. Implemented in the fall of 2000, the program is intended to contribute to the elimination of domestic health disparities through the development of a diverse cadre of biomedical researchers and other health professionals. While in the program, trainees work side-by-side with some of the world's leading scientists in the IRP and, in addition, participate in a series of seminars, journal clubs, and workshops on topics related to health disparities. Among the topics covered in the 2003-2004 curriculum were: infectious diseases, infant morbidity/mortality, cancer, mental health, and diabetes. NIH Academy trainees also participate in a series of outside community activities including, for example, a Hispanic Community Health Fair in Langley Park, Maryland, and the annual Black Family Reunion, held annually on the Mall in Washington, DC. To foster a spirit of community, NIH Academy participants are required to reside in apartments located adjacent to the main NIH campus in Bethesda, Maryland. During their tenure in the Academy, trainees are expected to initiate the application process for admission to graduate or medical school, aided by group discussions on identifying the best programs to meet their goals and tips on applying for these opportunities. Upon completion of the program, it is anticipated that Academy graduates will resume their education and ultimately pursue careers in research and health care that will allow them to contribute to the elimination of domestic health disparities. To date, 57 post-baccalaureate students have been accepted into the NIH Academy.

Graduate Partnerships Program, OITE, OIR

In July 2000, the Graduate Partnerships Program (GPP) was implemented to formally link the NIH IRP with universities in the training of pre-doctoral graduate students in biomedical sciences. This program strengthens and expands the IRP's role as a key provider of excellent graduate training and offers universities the opportunity to develop new, or expand, Ph.D. programs by providing additional faculty and funds. For graduate students at NIH, the GPP provides the academic infrastructure needed to ensure and track student progress and graduate student community services.

To date, 483 graduate students representing more than 55 universities have been enrolled in the GPP. The number is projected to grow to about 500 in the next several years through the establishment of multiple NIH-University partnerships in diverse and multidisciplinary biomedical areas. Students usually spend their initial years of training at the university in course work and laboratory rotations and then move to the NIH IRP for dissertation research. In many NIH-University partnerships, students work in a collaborative project between a university advisor and an NIH intramural scientist.

Present NIH-University Partnerships are: Boston University, George Washington University, Georgetown University, Johns Hopkins University, Karolinska Institute (Sweden), New York

University, University of Cambridge (United Kingdom), University of Maryland, University of North Carolina at Chapel Hill, University of Oxford (United Kingdom), University of Pennsylvania, and Brown University.

Undergraduate Scholarship Program, Intramural Loan Repayment and Scholarship Program (ILRSP), OITE, OIR

The NIH Undergraduate Scholarship Program (UGSP) for students from a disadvantaged background was authorized by statute in 1994 and established in 1996. The UGSP participants, as mandated under section 487D of the Public Health Service Act, receive up to $20,000 in scholarship support to defray educational expenses. Scholarship recipients are required to be employees at the NIH IRP for 10 weeks during the summer for each year of scholarship support, and to complete 1 year of research employment for each year of scholarship support after their graduation. The 1-year service payback can be deferred until the receipt of a terminal degree (Ph.D., M.D., M.D./Ph.D., etc). The aim of the program is to provide students from disadvantaged backgrounds the opportunity to be trained and hired as employees in the NIH Intramural Research Program. To date, 102 students have been awarded scholarships.

The Intramural Clinical Research Loan Repayment Program, ILRSP, OITE, OIR

Public Law 103-43 Section 487E (42 USC 288-5) established a program of educational loan repayment to attract physicians or dentists from disadvantaged backgrounds to conduct clinical research. The NIH Intramural Clinical Research Loan Repayment Program's (CR-LRP) mission is to recruit highly qualified health professionals from disadvantaged backgrounds to serve as clinical researchers in the IRP, using loan repayment as an economic incentive. The intramural CR-LRP was implemented in FY1994. There have been 134 participants to date.

2.1.1.2 Performance Measures

The diversity of the enrolled participants is the principal initial performance measure for each program with respect to expected impact on health disparities.

The NIH Academy, OITE, OIR

To date, 57 students have been enrolled in the NIH Academy. The overall demographics are as follows: 56 percent female, 44 percent male; 31 percent African American, 21 percent Hispanic, 19 percent White, 16 percent Asian, 5 percent Pacific Islander, 7 percent Native American, and 1 percent other.

The mission of the NIH Academy is to enhance research dedicated to the elimination of domestic health disparities through the development of a diverse cadre of biomedical researchers and other health professionals who will help reduce health disparities. The NIH Academy efforts to recruit talented individuals who evidence these aspirations are completely aligned with the efforts to reduce health disparities. To date, more than 80 percent of the participants have been minority students from populations in which health disparities have been documented.

Graduate Partnerships Program, OITE, OIR

To date, 483 graduate students have been enrolled in the GPP. The overall demographics are: 54 percent female, 46 percent male; 8 percent African American, 5 percent Hispanic, 18 percent Asian/Pacific Islander and 69 percent White. Through its goal to strengthen and expand the IRP's role as a key provider of excellent graduate training leading to the Ph.D. degree, the GPP's recruitment of talented individuals who aspire to careers in biomedical research is completely aligned with the efforts to reduce health disparities. To date, 31 percent of these graduate students have been minority students from populations in which health disparities have been documented.

Undergraduate Scholarship Program, ILRSP, OITE, OIR

To date, 102 students have been awarded scholarships. The overall demographics are as follows: 54 percent female, 46 percent male; 33 percent African American, 33 percent Hispanic, 17 percent White, 12 percent Asian, 3 percent Pacific Islander, and 2 percent Native American.

The UGSP mandate is to provide opportunities in biomedical, behavioral, and social science research for students from disadvantaged backgrounds. Our efforts to recruit talented individuals who aspire to careers in biomedical research are completely aligned with the efforts to reduce health disparities. To date, more than 80 percent of the participants have been minority students from populations in which health disparities have been documented.

The Intramural Clinical Research Loan Repayment Program, ILRSP, OITE, OIR

To date, there have been 134 participants. The overall demographics are as follows: 47 percent female, 53 percent male; 34 percent African American, 14 percent Hispanic, 13 percent Asian/Pacific Islander, 1 percent Native American and 35 percent White.

The intramural CR-LRP has been successful in recruiting clinical researchers from diverse backgrounds to the NIH IRP. Sixty percent of the participants come from populations that are affected by health disparities, and all are from disadvantaged backgrounds.

2.1.1.3 Outcome Measures

In addition to continued recruitment of the diverse target populations as a measure of each program's success, individual outcomes will be measured in a step-wise manner along the career path of each participant. The first outcome is successful completion of the program. For example, for the GPP, that would be receipt of the Ph.D. For the NIH Academy, it would be admission into a doctoral or terminal degree program in a biomedical science. Ultimate success will be measured further along the participants' biomedical career paths, with the mission or mandate of the specific program as the principal measure.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION—N/A

The Office of Research on Women's Health

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

MISSION/VISION STATEMENT

MISSION

The Office of Research on Women's Health (ORWH) was established in September 1990 within the Office of the Director (OD), National Institutes of Health (NIH), to serve as a catalyst and focal point for women's health research at NIH.

The ORWH: (a) advises the NIH Director and staff on matters relating to research on women's health; (b) strengthens and enhances research related to diseases, disorders, and conditions that affect women; (c) ensures that research conducted and supported by NIH adequately addresses issues regarding women's health; (d) ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; (e) develops opportunities for and supports recruitment, retention, re-entry, and advancement of women in biomedical careers; and (f) supports research on women's health issues. The ORWH works in partnership with the NIH Institutes and Centers (ICs) to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

ORWH was given the mandate to:

- Strengthen, develop, and increase research into diseases, disorders, and conditions that affect women; determine gaps in knowledge about such conditions and diseases; and then establish a research agenda for NIH for future directions in women's health research;

- Ensure that women, including those from underrepresented or disadvantaged populations, are appropriately represented in biomedical and biobehavioral research studies, especially clinical trials, that are supported by NIH; and

- Develop and implement initiatives to increase the number of women in biomedical careers and to facilitate their advancement and promotion.

The Office is responsible for establishing NIH-wide goals and policies for research related to women's health and coordinating NIH activities undertaken in performing such research.

With the participation of the biomedical, public policy, and advocacy communities, the ORWH developed a research agenda that addresses the ways in which biologic characteristics, including sex, gender, age, and race/ethnicity; economic status; geographic location such as rural or inner city living; and other factors influence the health of women. The *Agenda for Research on Women's Health for the 21st Century*[xlviii] (http://orwh.od.nih.gov/pubs/agenda_book_1.pdf) is based upon several general principles and the expanded definition of women's health. The published report serves as the foundation on which research priorities and programmatic direction are established. The members of the NIH Advisory Committee on Research on Women's Health, composed of nonfederal representatives, further review the recommendations that are utilized to determine priority research areas.

In the development of women's health research and programmatic priorities, the following four overarching themes are currently recommended:

1. **Sex/Gender Determinants.** Women are characterized by both sex and gender as highlighted in the ORWH *Agenda for Research in Women's Health for the 21st Century* and the Institute of Medicine report entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter*?[xlix] Sex factors that contribute to the biological differences include chromosomes, reproduction, and hormones. The effects of gender on psychological, social, and behavioral perspectives are important considerations in most areas of research. Consideration of these variables is critical to the accurate interpretation and validation of research affecting women's health. Moreover, these variables determine how similar or different health or disease processes may be between women and men.

2. **Health Disparities/Differences and Diversity.** Women are disproportionately affected by some conditions and diseases in terms of incidence, diagnosis, course, and response to treatment. Some populations of women may be at higher risk for adverse disease outcomes because of factors such as biology, environment, race/ethnicity, culture, education, access to care, and quality of care. Therefore, the need exists for opportunities for inclusion of diverse populations of women as volunteers in clinical studies. Thus, clinical research should include, but not be limited to, population-specific characteristics such as cultural diversity, race, ethnicity, immigrant status, rural or inner-city residency, poverty, sexual orientation, and physical or mental disabilities.

3. **Lifespan.** The health of girls and women is affected by developmental, physiological, and psychological age. Women's lives are marked by continuum from intrauterine life to the elderly years: infancy, childhood and adolescence, menarche, reproductive life, the menopausal transition, the postmenopausal years, the elderly, and the frail elderly. Many women's lives and health status are influenced by factors such as work inside and outside the home, caregiving roles such as childcare and elder care responsibilities, reproductive influences, and chronic illness. Each of these may influence health, disease, treatment choices, and response to therapy. Researchers should consider these variables in designing studies related to women's health.

4. **Interdisciplinary Research.** With increasing understanding of the interrelatedness and complexity of disease, the nature of scientific investigation is shifting to an interdisciplinary collaborative approach. Advances in women's health can be better achieved by promoting partnerships in cross-disciplinary research from basic, clinical, and translational research that involves collaborative interactions among investigators in all areas of academic, private industry, and federal settings, and provides access to the latest scientific tools and technologies.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

Research from many perspectives is needed in women's health, including integration of knowledge from disparate sources, as well as teams with multiple areas of scientific expertise. Interdisciplinary research can facilitate the integration of basic science, clinical research and translational research, population studies, behavioral and social research, and outcomes research. An additional focus on bioengineering and biomedical informatics, genomics, proteonomics, imaging, industry, and metabolomics is increasingly relevant to research on women's health.

VISION

The ORWH at the NIH seeks to enhance and expand research and programs based upon science-driven initiatives that can, then, redress inequities in prevention, detection, and treatment of illness among women of diverse races, cultures, and circumstances. In its policies and programs, the ORWH emphasizes the need to consider not only influences of sex and gender, but other biologic and social bases for differences between men and women in health and disease. In addition, emphasis is placed on designing research studies to determine racial and ethnic influences. The ORWH leads the trans-NIH efforts to ensure that all components of the NIH comply with the guidelines requiring the inclusion of women and minority members in human subjects research. A trans-NIH Tracking and Inclusion Committee convened by ORWH and co-chaired by a senior IC official monitors the adherence of ICs to the NIH policy and procedures for inclusion of women and minorities in clinical research funded by NIH. This committee also tracks data on the numbers of women and minorities participating in clinical research.

In concert with the ICs of the NIH, the ORWH develops and/or supports research and initiates programs to implement the recommendations of the *Agenda for Research on Women's Health for the 21st Century* to address the gaps in knowledge about diverse populations of girls and women. The ORWH also undertakes activities designed to foster the participation of diverse populations of women in biomedical research as study subjects and as investigators, to redress disparities in the health status and health outcomes of diverse populations of women and to provide career development opportunities to diversify the pool of biomedical researchers with an interest in addressing health disparities.

The ORWH will continue to pursue these mandates in conjunction with the scientific, professional, and advocacy communities of women and men. In expanding and enhancing these visionary goals, particular attention will be given to new and evolving factors that influence our understanding of health as well as innovative directions for improving health status, especially among disparate and minority populations. Emphasis will be given to collaborative efforts to enhance interdisciplinary research and career development, the clinical translation of the results of research, and the creation of a cadre of new investigators prepared for emerging scientific challenges. ORWH contributions should and would enhance knowledge about the health of women, and men, of diverse racial, ethnic, social, geographic, and other characteristics in the global environment.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

To ensure that the health and career concerns of specific groups of underrepresented and minority women and men are adequately and appropriately addressed, the ORWH has given priority to the initiation of new research studies that address health and health disparities including sex/gender factors. The ORWH has initiated programs to increase opportunities for women of all races in biomedical careers. Further, the ORWH is addressing issues to increase the participation of diverse populations of women and minorities in clinical research through monitoring the implementation of the NIH inclusion policy, as well as through efforts to help investigators recruit and retain diverse populations in their clinical studies. The ORWH will develop and expand programs to increase and encourage opportunities for a diverse pool of women to enter and successfully advance in biomedical careers. The ORWH will continue in its collaborative efforts with the Office of Extramural Research (OER) and the ICs to ensure that the inclusion policy requiring women and minorities in clinical research is continually addressed and recognized as part of the scientific review within the grant application process.

Specific policies and programs have been implemented to ensure that minority women benefit from NIH-sponsored research. Through a broad-based effort involving clinicians, researchers, community leaders, health activists, psychologists, social scientists, and citizens, the ORWH developed the *Agenda for Research on Women's Health in the 21st Century*. Volume 6 of the agenda series, *Differences Among Populations of Women*[l] (http://orwh.od.nih.gov/pubs/agenda_book_6.pdf), focuses on the specific health needs of minority women, women in rural areas and inner cities, and other groups that traditionally have been underserved by the medical research and health care communities. Critical issues addressed include the importance of delineating factors that contribute to disparities in health status and health outcomes among diverse populations of women. These include biological, genetic, racial, cultural, ethnic, psychosocial, and behavioral factors; educational influences; traditional and alternative health practices; environmental influences; poverty and socioeconomic status; access to health care; and occupational issues.

The ORWH also publishes a lay version of the *Agenda for Research on Women's Health for the 21st Century*, in English, Volume 7[li] (http://orwh.od.nih.gov/pubs/agenda_book_7.pdf) and in Spanish, Volume 8[lii] (http://orwh.od.nih.gov/pubs/agenda_book_8.pdf), to provide information about the importance of research and help educate the lay public about research addressing health disparities as well as current and future priorities.

Additionally, the ORWH generates and distributes several professional and lay publications related to women's health research and minority/disadvantaged women, such as the *Women of Color Health Data Book,*[liii] available in hard copy and online in both English and Spanish (http://orwh.od.nih.gov/pubs/wocSpanish.pdf). This publication will continue to be updated with current research findings related to the health of many different populations of women and incorporates new and useful data and statistics from research.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

It is important and scientifically appropriate for women and minorities to be included in human subjects research so that differences in response to interventions can be determined and all populations can benefit from the outcomes of research. The findings of biomedical and behavioral research provide the scientific basis for improving standards of care, formulating public health policy, changing individuals' health-related behaviors and expectations of their health, modifying health care delivery systems, and creating strategies for overcoming cultural and economic barriers to health care.[liv] The continuing challenge is to confront the recruitment and retention of women, minorities, and other participants to ensure that clinical research is representative, relevant, and targeted to address scientific questions important to the public health.

The ORWH recognizes that to succeed in recruiting and retaining diverse populations of women in clinical research, it is necessary to enlist the help of community-based individuals and organizations and health professionals who are on the front lines of health care delivery. Several important factors in overcoming barriers that often limit the participation of ethnic minorities in research include:
(a) cultural competence on the part of researchers regarding the intended study population;
(b) collaboration with and participation of communities and community groups of the targeted population in the planning, implementation, and evaluation of such research; and (c) utilizing researchers who are themselves from the communities they seek to include in studies.

The ORWH will continue to expand the number of efforts to assist in the recruitment and retention of women and minorities in NIH funded clinical research. The *Outreach Notebook for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research*[lv] (http://orwh.od.nih.gov/pubs/outreach.pdf) is and continues to be widely disseminated throughout the scientific and advocacy communities. This document contains practical guidance, examples and advice on recruiting minority women in clinical studies as well as a list of resources for investigators as they seek to comply with the NIH inclusion guidelines. The implementation of these guidelines is a partnership between the ORWH and other components of the NIH and the broader scientific community. The publication assists investigators and public health policy makers to address the continuing challenges confronting the recruitment and retention of women, men, and minorities, so that clinical research is representative, relevant, and targeted to address scientific questions important to the public health.

A report of a recent workshop, *Science Meets Reality: Recruitment and Retention of Women in Clinical Studies and the Critical Role of Relevance,*[lvi] provides innovative and proven methods for the inclusion of women and minorities. This report, which is based on the experiences of many accomplished and successful researchers in conducting clinical research with women and minorities, will continue to be used as a resource providing advice to investigators, information to potential volunteers, and examples for program development efforts. A summary of this meeting is available on the ORWH web site at http://orwh.od.nih.gov/pubs/SMR_Final.pdf.

Recognizing that research is essential to providing the scientific basis for improvements in health status and health care, the ORWH is dedicated to fostering and supporting efforts to improve the health of all Americans, especially those whose health concerns have not been adequately addressed by the biomedical research community in the past.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Sex/Gender Determinants and Health Disparities/Differences and Diversity

ORWH employs a deliberative process annually to review and revise the NIH-wide Research Priorities for Women’s Health. Since its establishment, ORWH has been fostering greater awareness of the study of sex/gender differences in all areas of health and disease, and the importance of including sufficient numbers of minorities and individuals from underrepresented or disadvantaged populations, including subpopulations of girls and women, to obtain valid research results and address health disparities. Because the ORWH does not have direct funding authority, ORWH collaborates with the NIH Institutes and Centers to fund or co-fund meritorious research grants.

1.1.1 Objective One: Increase Awareness of the Need for Sex/Gender and Race/Ethnicity Analysis Components in Proposed Research Studies

Create greater awareness among extramural scientific reviewers of the need for research applications under review to include sex/gender analysis as well as analysis by race/ethnicity, as part of the proposed research studies.

1.1.1.1 Action Plan

Working with the Office of Extramural Research (OER), expand and update current scientific review guidelines for extramural scientists involved in Center for Scientific Review (CSR)-directed reviews.

1.1.1.2 Performance Measures

Continue to create and disseminate clearer criteria to extramural scientists participating in CSR peer review groups to follow in reviewing grant applications and proposals, specifying requirements as to sex, race, and ethnicity of study participants, and the importance of evaluating sex/gender differences.

Continue to partner with extramural resources to foster the evaluation of sex/gender research, especially innovative methods for analyses.

Continue to publicize research findings that showcase sex/gender analysis, and continue to encourage journal publishers to emphasize the importance of sex/gender analysis.

1.1.1.3 Outcome Measures

Increased number of research grants that address sex/gender factors in health and disease.

Increased collaboration with NIH Institutes and Centers in the development, implementation, and support of innovative approaches in the design of research studies that address sex/gender differences.

1.1.2 Objective Two: Stress Inclusion of Minority Populations and Subpopulations of Minority Women and Girls in Research Grants

Communicate the scientific relevance and importance of including minority populations, including subpopulations of minority girls and women, in NIH-supported research grants in order to address health disparities.

1.1.2.1 Action Plan

In collaboration with the NIH Institutes and Centers, encourage and foster innovative approaches and methodologies to study health problems, risk factors, and protective factors among minority girls and women in order to address health disparities.

1.1.2.2 Performance Measures

Encourage greater awareness among scientific reviewers of the requirement for and the scientific reasoning for investigators to include diverse populations and subpopulations of minority girls and women as study participants.

In collaboration with OER, promote a more comprehensive review of all grant applications, ensuring investigators clearly document their inclusion/exclusion, if scientifically relevant, of minority girls and women as study participants in research studies.

In collaboration with OER, promote the development of culturally appropriate instrumentation and outcome measures for minority populations, especially subpopulations of minority girls and women.

In collaboration with OER, encourage the development of research models that include and define the provision of subpopulations of underrepresented or disadvantaged populations, girls and women.

Incorporate the use of a qualitative models as well as quantitative models so that researchers can better facilitate studies in different minority populations and subpopulations of minority girls and women.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

1.1.2.3 Outcome Measures

Increased collaboration with NIH Institutes and Centers in the development, implementation, and support of innovative approaches in the design of research studies that address health disparities in minority girls and women.

1.1.3 Objective Three: Improve Study of and Communication to Minority Communities

Improved data collection, analysis, and reporting of information to minority communities.

1.1.3.1 Action Plan

Continue to monitor the inclusion of women and minorities, especially those who have previously been excluded from clinical studies, and to stress the importance of the resulting differential data, and conveying those differences to the scientific and consumer communities.

1.1.3.2 Performance Measures

Continue examination and identification of the cultural and financial barriers for minority girls and women to participation in clinical studies.

Foster the design of additional or new research studies to specifically address health disparities of various populations, especially of minority girls and women.

Promote greater communication and dissemination of culturally appropriate and sensitive information to minority girls and women.

Promote collaboration with faith-based and community-based organizations in the design and implementation of research studies.

1.1.3.3 Outcome Measures

Increased compliance with the requirement for inclusion of women and minorities and the number of NIH-funded investigators who include minority girls and women as participants in clinical studies, at the time of initial grant application.

Monitor the increase in publications on this subject from local and national organizations.

1.1.4 Objective Four: Stress Study of Diseases and Conditions Disparately Affecting Minority Groups

Encourage investigators to study diseases and conditions in underrepresented or disadvantaged populations by focusing on girls and women who are at higher risk for specific diseases or conditions.

1.1.4.1 Action Plan

In collaboration with NIH Institutes and Centers, encourage and foster innovative research on diseases and disorders prevalent in underrepresented or disadvantaged populations.

1.1.4.2 Performance Measures

Increased attention to gaps in knowledge related to diseases and conditions specific to minority girls and women, or that have a higher prevalence in these populations.

Consistent planning and designing of research studies leading to better appreciation of the health problems and risk factors within the minority female population.

Involvement of investigators from underrepresented or disadvantaged populations in research, especially those who have access to distinct resources within their community.

Improve partnerships between investigators and communities in the design and conduct of the research, and in recruitment of study participants.

Develop and expand research collaborations with academic institutions such as Hispanic-serving institutions (HSIs), Historically Black Colleges and Universities (HBCUs), and Tribal Colleges and Universities (TCUs); and state organizations serving women in the respective communities of underrepresented or disadvantaged communities.

1.1.4.3 Outcome Measures

Increased knowledge about diseases and conditions that are more prevalent or may affect populations and subpopulations of girls and women from underrepresented or disadvantaged populations.

Increase the scientific bases for studies focusing on diseases and conditions more prevalent among or affecting populations and subpopulations of girls and women from underrepresented or disadvantaged populations.

1.1.5 Objective Five: Promote Participation of Minority Women Investigators in Clinical Research

In collaboration with NIH Institutes and Centers, encourage the participation of women from underrepresented or disadvantaged populations as investigators in the planning, design, and scientific review of clinical studies.

1.1.5.1 Action Plan

In collaboration with OER, profile career development awards for women investigators, including those from underrepresented or disadvantaged populations, throughout the NIH.

In collaboration with OER, determine innovative ways to overcome the barriers for women from underrepresented or disadvantaged populations as investigators and/or participants in research.

1.1.5.2 Performance Measures

Examine specific barriers to participation in clinical research and access to health care from the perspective of women from underrepresented or disadvantaged populations, both as investigators and as study participants.

Promote active participation of women and underrepresented or disadvantaged populations in research projects, especially as it relates to problem identification, selecting appropriate recruitment strategies, methods of data collection, and participating in the analysis and interpretation of study results.

1.1.5.3 Outcome Measures

In collaboration with OER, increase the number of NIH-funded investigators who include women from underrepresented or disadvantaged populations in the planning and designing of clinical studies, as co-investigators and as study participants.

1.1.6 Objective Six: Increase Understanding of Contributions and Needs of Minority Women in Science

Promote a better understanding in the biomedical and behavioral research community of the potential contributions and special needs of women from underrepresented or disadvantaged populations in science.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

1.1.6.1 Action Plan

In collaboration with the NIH Institutes and Centers, identify successful models of women scientists including scientists from underrepresented or disadvantaged populations across the extramural funding portfolios.

1.1.6.2 Performance Measures

Encourage greater awareness and acceptance of the uniqueness of women scientists from underrepresented or disadvantaged populations in all areas of the biomedical and research community.

Implementation of programs that encourage diversity and increased cultural sensitivity for women from underrepresented or disadvantaged populations in all facets of the academic and professional environment.

Collaboration with organizations to ensure that the environmental, linguistic, and physical access needs of women from underrepresented or disadvantaged populations are addressed.

Inclusion of women from underrepresented or disadvantaged populations in the planning and implementation of NIH-sponsored events directed to special populations of women.

1.1.6.3 Outcome Measures

Increased participation of women from underrepresented or disadvantaged populations, as investigators and study participants, in both biomedical and behavioral research.

Increased participation of women from underrepresented or disadvantaged populations in leadership roles in both biomedical and behavioral research.

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY

2.1 Area of Emphasis One: Career Development and Research Training

The ORWH's mandate includes the development of opportunities for the recruitment, retention, reentry, and advancement of women in biomedical careers. A wide variety of career development programs has been implemented over the years, including the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program, an innovative K-12 program to support the training of junior faculty researchers in a mentored environment in women's health research. Because ORWH does not have direct funding authority, all projects are funded or co-funded through the NIH Institutes and Centers.

Expansion and continuation of programs such as these is part of the overall plan for career development and research training in ORWH.

2.1.1 Objective One: Promote Educational and Professional Development of Special Populations

Foster education, training, and professional development of women and underrepresented or disadvantaged populations in biomedical careers.

2.1.1.1 Action Plan

Expand and continue to develop programs such as the ORWH Re-entry Program and the BIRCWH Programs, which strongly encourage the involvement of women and underrepresented or disadvantaged populations.

Develop and expand programs to support special populations of women interested in pursuing careers in science at the middle school, high school, undergraduate, and graduate levels.

Promote continued collaboration with NIH Institutes and Centers, as well as other agencies, to utilize ORWH career development and research training programs and initiatives.

Encourage collaboration between Institutes and Centers to provide awards for students from underrepresented or disadvantaged populations interested in scientific careers.

Foster programs that can help to increase the success rate of grant applications for minority women investigators.

2.1.1.2 Performance Measures

Increase in the number of applications submitted requesting participation in ORWH sponsored/cosponsored programs such as the BIRCWH and the Re-entry program.

- The BIRCWH program seeks to increase the number of researchers working on women's health issues by pairing junior researchers with senior investigators in mentored, interdisciplinary scientific settings. ORWH leads the BIRCWH initiative. Several NIH Institutes, the Office of Dietary Supplements, and the Agency for Healthcare Research and Quality co-sponsor this program.

- The ORWH Re-entry Program was developed in 1992 as a pilot program to help fully trained scientists (women and men) reestablish careers in biomedical or behavioral science after taking time off to care for children or parents, or to attend to other family responsibilities. This program is now supported by all NIH Institutes.

Increase in the number of materials on biomedical careers requested by community organizations, students, teachers, and health professionals.

- ORWH continues to provide support to the Office of Education and the Office of Science Education to develop programs that enhance opportunities for students and intramural research fellows. Programs include video and poster series aimed at middle school and college students, career development workshops, science communication courses, and the Fellows Award for Research Excellence (FARE). Future plans include adding a video on dentistry highlighting minorities and women professionals.

- The ORWH supports ongoing projects and has initiated specific training projects that include opportunities for students from underrepresented or disadvantaged populations, high school students, and college faculty and students to obtain research experience or exposure to current scientific concepts through the NIH. The ORWH also develops and supports a number of programs for the advancement of girls and women in science through collaboration with the NIH Office of Science Education, including a video series featuring minority women surgeons, researchers, and pathologists and an on-line curriculum designed to spark interest in biomedical sciences among middle-school and high-school students.

- ORWH/Foundation for the Advanced Education in Sciences (FAES)/NIH High School Student Summer Program. This summer the program had 24 new high school students and 17 returning students. There were 26 women and 15 men, including 11 from underrepresented or disadvantaged populations, coming from both public and private schools in Maryland, Virginia, and the District of Columbia to spend time at the NIH in intramural labs.

- The Office of Loan Repayment and Scholarships (OLRS). The Office of Intramural Research (OIR) is responsible for the development and management of the Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds (UGSP). The UGSP provides scholarships to undergraduate students who have been competitively selected from a nationwide pool of candidates. An average of 15 scholarships is awarded each year.

- The objective of the Health Disparities Research Loan Repayment Program (HDR-LRP) is the recruitment and retention of highly qualified health professionals to research careers that focus on minority health or other health disparities issues. The program provides for the repayment of educational loan debt of qualified health professionals who agree to conduct minority health or health disparities research for 2 years. The program provides for the repayment of the principal and interest of the educational loans, up to a maximum of $35,000 per year.

2.1.1.3 Outcome Measures

Increase in the number of career development awards and fellowships to women students from underrepresented or disadvantaged populations at the graduate level.

Increase in the number of women, individuals from underrepresented or disadvantaged populations, and middle and high school students considering future biomedical careers.

Increase in the number of women investigators and investigators from underrepresented or disadvantaged populations who are successful applicants for NIH funding.

2.1.2 Objective Two: Support Career Development and Research Training Through Mentoring

Continue to support and facilitate mentoring of women scientists and scientists from underrepresented or disadvantaged populations.

2.1.2.1 Action Plan

Continue to work with professional societies, groups, and associations in defining, generating, and publicizing successful models of mentoring.

Continue to provide special training, rewards, and recognition for mentors of special populations of women scientists.

Continue to provide opportunities for women and individuals from underrepresented or disadvantaged populations to participate in scientific conferences and the peer review process.

2.1.2.2 Performance Measures

Increase in the number of professional societies, groups, and associations with which the ORWH works to develop mentoring models.

Increase in requests for information on mentor training programs.

Increase in the number of women and individuals from underrepresented or disadvantaged populations requesting information on participation in scientific conferences and the peer review process.

2.1.2.3 Outcome Measures

Increased understanding of women investigators and investigators from underrepresented or disadvantaged populations about how to navigate the channels for academic advancement.

Increased availability of investigator role models who are women or are from underrepresented or disadvantaged populations; and increased understanding of the role of being mentors.

Greater recognition of the potential scientific contributions of women investigators and investigators from underrepresented or disadvantaged populations and appreciation of their value in the scientific arena.

2.1.3 Objective Three: Institutional Encouragement and Support of Career Advancement

Encourage institutions to develop programs and mechanisms that allow women scientists and scientists from underrepresented or disadvantaged populations to advance in their careers without sacrificing family and community responsibilities.

2.1.3.1 Action Plan

Collaborate with independent and government institutions to develop programs that address the participation and advancement of women, especially women of underrepresented or disadvantaged populations, in biomedical careers.

Facilitate programs sponsored and/or co-sponsored by the ORWH that enable special populations of women scientists to meet family, work, and community responsibilities while pursuing biomedical career interests.

Provide opportunities for re-entry of women scientists and scientists from underrepresented or disadvantaged populations into biomedical careers and career redirection.

2.1.3.2 Performance Measures

Increase in the number of institutions with which the ORWH collaborates to develop programs for the participation and advancement of women in biomedical careers, especially for women of underrepresented or disadvantaged populations.

Increase in the number of women scientists and scientists from underrepresented or disadvantaged populations participating on study sections and advisory boards of independent institutions.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

2.1.3.3 Outcome Measures

Increase in the number of institutions that have implemented programs to encourage the career development of women of special populations in biomedical careers.

More diverse representation of women and individuals from underrepresented or disadvantaged populations participating on institutional study sections, advisory boards, and the peer review process.

2.1.4 Objective Four: Professional Society, Group, and Organization Support of Career Advancement

Encourage professional societies, groups, and organizations to develop programs, models, and other mechanisms to foster the advancement of women and persons from underrepresented or disadvantaged populations in biomedical research.

2.1.4.1 Action Plan

Continue to expand AXXS (Achieving Xxcellence in Science) efforts.

Expand collaboration and partnerships with underserved community organizations and scientific/professional societies, especially those focused on special populations of female scientists at all levels of the career pipeline.

Support workshops and opportunities to stimulate appropriate professional societies to develop management and leadership training programs.

Facilitate ways for professional societies, groups, and organizations to formalize networking opportunities for special populations of women scientists.

Improve mechanisms for disseminating information to professional societies, groups, and organizations on new and existing funding support for grants and training programs.

2.1.4.2 Performance Measures

Increase in the number of requests for information on AXXS programs.

Increase in the number of professional societies, groups, and organizations with which the ORWH collaborates to develop programs, models, and other mechanisms to foster the career development of women scientists and scientists from underrepresented or disadvantaged populations.

Increase in the number of requests for information on career development programs co-sponsored and sponsored by the ORWH.

2.1.4.3 Outcome Measures

Increase in the number of participants in the AXXS program.

Greater opportunities for women and individuals from underrepresented or disadvantaged populations interested in pursuing biomedical careers through collaboration with the NIH/ORWH and professional societies, groups, and organizations.

2.1.5 Objective Five: Build Community Awareness of Women and Minority Scientists

Foster appreciation in the community for the contributions and needs of women and individuals from underrepresented or disadvantaged populations in science.

2.1.5.1 Action Plan

Support programs that encourage diversity and heightened cultural sensitivity in all facets of the academic and medical environment.

Celebrate the uniqueness and promote the acceptance of special populations of women scientists in all areas of the scientific community.

2.1.5.2 Performance Measures

Increase in requests for materials or information recognizing the contributions and needs of women and individuals from underrepresented or disadvantaged populations in science.

2.1.5.3 Outcome Measures

Greater understanding of the contributions and needs of women and individuals from underrepresented or disadvantaged populations in science.

2.2 Area of Emphasis Two: Interdisciplinary Research

2.2.1 Objective One: Sponsor Programs that Support Interdisciplinary Research on Women's Health

ORWH has developed, implemented, and funded new and innovative interdisciplinary research centers and interdisciplinary research training programs. These programs benefit both women's and men's health through sex and gender research, interdisciplinary scientific collaboration, and support for young investigators in a mentored environment to become independent investigators doing research in women's health.

2.2.1.1 Action Plan

Continue implementation of the BIRCWH and SCOR.

Expand the knowledge base of women's health research related to sex and gender factors using an interdisciplinary approach

Encourage an interdisciplinary approach to research on the role of sex and gender related health effects.

2.2.1.2 Performance Measures

Increased attention to the BIRCWH and SCOR programs and the expansion of these or the development of similar programs.

Increase in the number of women and individuals from underrepresented or disadvantaged populations receiving K and other NIH awards.

2.2.1.3 Outcome Measures

Greater knowledge of women's health derived from interdisciplinary research on sex and gender differences.

Increased number of young investigators who pursue interdisciplinary biomedical research careers in women's health.

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION

3.1 Area of Emphasis One: Outreach, Information Dissemination, and Public Health Education Targeted at the Community

3.1.1 Objective One: Expand the Knowledge Base for Women of Special Populations About Health Disparities

Communicate to women the influence of sex, gender, race/ethnicity, and economic circumstance on health and health outcomes and successful methods to reduce disparities.

3.1.1.1 Action Plan

Continue to broaden contacts with community- and faith-based organizations with an interest in women's health and the health of special populations.

Continue to develop educational materials targeted at specific special populations of women that address health issues specific to their communities.

Collaborate with community-based advocacy groups and organizations and local and state women's and minority health offices to facilitate the distribution of educational materials developed by the ORWH, including brochures, handouts, posters, videos, and broadcast announcements, at community events such as health-related fairs, workshops, and conferences.

Continue to participate in community health events to expand public awareness of women's health research.

Continue to develop and present workshops, meetings, and symposia to educate advocates in issues related to and methods of reducing health disparities of special populations of women.

Encourage the participation of special populations of women in clinical research by increasing their knowledge and trust of the clinical research arena and building awareness of the importance of their inclusion in clinical trials.

3.1.1.2 Performance Measures

Increased size of the network of advocates for special populations of women with which the ORWH collaborates.

Increased volume and diversity of ORWH-published educational materials targeting special populations of women.

Increased volume and diversity of educational materials sent to community-based advocacy groups and organizations and state and local women's and minority health offices to promote understanding of the health concerns of special populations of women.

Greater participation in community events, such as health fairs, at which the ORWH distributes materials specifically targeted to special populations of women.

Increased number of women of special populations attending ORWH sponsored and co-sponsored events.

Increased number of workshops, meetings, and conferences, facilitated by the ORWH, that address differences in health among special populations.

Greater attendance at ORWH-facilitated workshops, meetings, and conferences by women of special populations.

Increased total number and percentage of women of special populations participating in clinical research, especially in clinical research that targets their specific populations.

3.1.1.3 Outcome Measures

Increased interest among the advocacy community in collaborating with the ORWH to develop and distribute new and innovative educational materials addressing health issues for special populations of women.

More requests to the ORWH to disseminate information on women's and minority health at community events and workshops, meetings, and symposia.

Greater awareness of health disparities within special populations of women

More clinical data specific to special populations of women that help address and eliminate health disparities.

3.2 Area of Emphasis Two: Outreach, Information Dissemination, and Public Health Education Targeted at the Health Professionals

3.2.1 Objective One: Expand the Knowledge of Health Disparities of Special Populations of Women Among Health Professionals

Facilitate the continuing education of health professionals about the magnitude of health disparities faced by special populations of women and successful interventions that can reduce health disparities among special populations of women.

3.2.1.1 Action Plan

Expand the pipeline of information on clinical studies of special populations of women.

Encourage the participation of professional societies in disseminating information on health disparities of special populations of women to health professionals.

Encourage health professionals to target their health interventions to special populations of women.

Encourage health professionals to use their experience with patients to assist with the development of new health professional-administered interventions targeted at special populations of women.

3.2.1.2 Performance Measures

Increased number of requests by health professionals for information on health concerns of diverse populations of women.

Increased number of professional societies with which the ORWH collaborates to disseminate to health professionals educational materials on health disparities faced by special populations of women.

3.2.1.3 Outcome Measures

Increased interest among individual health professionals in clinical research addressing the health disparities of special populations of women.

Increased interest within and among professional societies in addressing health disparities of special populations of women.

Increased requests for information by health professionals on research on special populations of women.

Implementation of effective health professional-based interventions to reduce health disparities faced by special populations of women.

More optimal treatment based on knowledge gained from clinical research on special populations of women.

3.3 Area of Emphasis Three: Outreach, Information Dissemination, and Public Health Education Targeted at the Research Community

3.3.1 Objective One: Increase Interest in Health Disparity Research Related to Special Populations of Women

Encourage research on ways to reduce health disparities faced by special populations of women.

3.3.1.1 Action Plan

Encourage increased research on the extent and magnitude of health disparities faced by special populations of women and approaches to reducing these disparities.

Continue to provide educational arenas, such as the Women's Health Special Interest Group and the Women's Health Seminar Series, to inform the research community and public of current research addressing health issues of special populations of women.

3.3.1.2 Performance Measures

Increased number of collaborations to research health disparities confronting special populations of women.

Increased amount of research on health disparities that affect special populations of women.

Increased number of applications for leveraged funds to develop health professional-administered interventions targeted at special populations of women.

Increased number of applications for leveraged funds to study health disparities of special populations of women.

Increased emphasis on special populations of women in presentations of the Women's Health Seminar Series and the Women's Health Special Interest Group and increased attendance and participation by women of special populations.

3.3.1.3 Outcome Measures

Larger pool of information on the effects and methods of reducing health disparities faced by special populations of women.

Increased interest in developing future studies to examine health disparities faced by special populations of women.

3.3.2 Objective Two: Encourage Publication of Clinical Research Results on Special Populations of Women

Encourage the publication and distribution of the research results involving special populations of women, related to the role of gender, race/ethnicity, culture, and economic circumstances in the health and health outcomes of women.

3.3.2.1 Action Plan

Continue to work with journal editors to encourage them to publish research results and analyses that report the difference or lack thereof in health and health outcomes among special populations of women.

OFFICE OF **R**ESEARCH ON **W**OMEN'S **H**EALTH

Encourage researchers to report experiences, successful and unsuccessful, in working with special populations of women.

Encourage researchers to report data by sex and race/ethnicity.

3.3.2.2 Performance Measures

Revised editorial policies of peer-reviewed journals that require publication of research results from analysis of sex and race/ethnicity.

Increased number of publications reporting on differences of health and health outcomes among special populations of women.

3.3.2.3 Outcome Measures

More accurate data on health and health outcomes specific to special populations of women.

Decrease in the dearth of information on health disparities among special populations of women.

[xlviii] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Agenda for Research on Women's Health for the 21st Century. A Report on the Task Force on the NIH Women's Health Research Agenda for the 21st Century, Volume 1. Executive Summary. DHHS Publication No. 99-4385. (1999)

[xlix] Wizemann, Theresa M. and Mary-Lou Pardue, ed. *Exploring the Biological Contributions to Human Health: Does Sex Matter?* Report of the Committee on Understanding the Biology of Sex and Gender Differences, Board on Health Sciences Policy, Institute of Medicine. Washington, D.C.: National Academy Press, 2001.

[l] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Agenda for Research on Women's Health for the 21st Century, Volume 6. Differences Among Populations of Women; Scientific Meeting and Public Hearing, Santa Fe, New Mexico, July 1997. DHHS Publication No. 99-4390. (1999)

[li] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Agenda for Research on Women's Health for the 21st Century. A Report of the Task Force on the NIH Women's Health Research Agenda for the 21st Century, Volume 7. New Frontiers in Women's Health. DHHS Publication No. 01-4391. (2001)

[lii] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Programa de Trabajo Para La Investigacion De La Salud De La Mujer En El Siglo XXI. A Report of the Task Force on the NIH Women's Health Research Agenda for the 21st Century, Volume 1. DHHS Publication No. 01-4392. (2001)

[liii] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Women of Color Health Data Book. NIH Publication No. 02-4247. (2002)

[liv] Pinn VW. Equity in biomedical research. *Science* 1995; 269:739.

[lv] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Outreach Notebook for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research. NIH Publication No. 03-7036. (2003)

[lvi] US Department of Health and Human Services, Public Health Service, National Institutes of Health. Science Meets Reality: Recruitment and Retention of Women in Clinical Studies and the Critical Role of Relevance. A Report of the Task Force sponsored by the NIH Office of Research on Women's Health. NIH Publication No. 03-5403. (2003)

The Office of Rare Diseases

NIH Health Disparities Strategic Plan
Fiscal Years 2004-2008

OFFICE OF **R**ARE **D**ISEASES

MISSION/VISION STATEMENT

The Office of Rare Diseases (ORD) was established in 1993 in the Office of the Director (OD) of the National Institutes of Health (NIH). On November 6, 2002, the President established the Office by law and expanded its responsibilities by signing Public Law 107-280, the Rare Diseases Act of 2002. A rare disease (also called an orphan disease) is a disease or condition affecting fewer than 200,000 persons in the United States. An estimated 25 million people in the United States suffer from one of the more than 6,000 rare diseases.

ORD stimulates and coordinates research on rare diseases. To leverage its resources, stimulate rare diseases research activities, and foster collaboration, ORD works with NIH Institutes and Centers (ICs) and Offices to support

- An $18 million per year NIH grants program for a Rare Diseases Clinical Research Network with 10 research consortia and one data and technology center;
- Other NIH collaborative research, training, and pilot and demonstration opportunities;
- An intramural program for patients with undiagnosed rare conditions, and programs to stimulate intramural clinical research on rare diseases including the training of researchers and biochemical geneticists;
- A scientific conferences program to stimulate research where little exists, where research progress may have stalled, or in response to scientific opportunities; and
- An information center to provide individualized reliable and valid information to the public, researchers, and health care providers.

STRATEGY FOR ADDRESSING HEALTH DISPARITIES

In its research and education activities, ORD strongly emphasizes the importance of consideration for populations with health disparities. In activities that it supports solely, such as work with federations of patient advocacy organizations, ORD similarly works on increasing involvement of organizations that represent minorities and other underrepresented or disadvantaged populations.

1.0 AREAS OF EMPHASIS IN RESEARCH

1.1 Area of Emphasis One: Providing Information on Rare Diseases Research to Latino Patients

In the 1980s, the National Commission on Orphan Diseases received extensive testimony establishing that patients with rare diseases have difficulty accessing the necessary information to make informed decisions about their health. It can be argued that having a rare disease is in effect a health disparity.

Despite advances, the 2001 Report of the Special Emphasis Panel of the NIH on the Coordination of Rare Diseases Research found the lack of health information still daunting for patients and their families. The Rare Diseases Act of 2002, P.L. 107-280, provided a legislative mandate to provide information on rare diseases to the public via an information center. ORD has partnered with the National Human Genome Research Institute (NHGRI) to create the Genetic and Rare Diseases (GARD) Information Center. The information center provides free and timely access to accurate, reliable information about genetic and rare diseases. In 2004, after the development of the initial infrastructure in English, services in Spanish were added.

1.1.1 Objective One: Reaching Out to Latino Communities

The NHGRI, ORD, and The National Council of La Raza's Institute for Hispanic Health (NCLR/IHH) will partner in a pilot project to demonstrate efficient ways to reach Latino communities with information about genetic and rare diseases.

1.1.1.1 Action Plan

In FY2004, the Information Center developed the necessary infrastructure to be able to answer requests in Spanish via e-mail, mail, and instantaneously over the telephone. In FY2005 and subsequent years, the Information Center, together with NHGRI and ORD, will promote the availability of services in Spanish by working with a variety of Latino community groups. The NCLR/IHH will execute a year-long pilot project to demonstrate efficient ways to reach Latino communities with information about genetic and rare diseases. Two community-based affiliate organizations, *La clínica del pueblo*, based in Washington, DC, and *La clínica de la raza*, in Oakland, California, will partner with the NHGRI and the ORD. These community-based organizations have extensive combined experience of working with the community in providing health information, in large part through *promotores de salud* (lay health promoters).

1.1.1.2 Performance Measures

ORD will examine utilization of the services in Spanish over the next 2 years and expect an increase in requests for information services from the Latino population.

1.1.1.3 Outcome Measures

The ORD and NHGRI are in the process of developing a user satisfaction survey. The survey will indicate areas of improvement for responses in Spanish as well as in English.

1.1.2 Objective Two: Scientific Conferences Focusing on Populations Experiencing Health Disparities

ORD collaborates with Institutes, Centers, and Offices at NIH to stimulate rare diseases research by cosponsoring scientific conferences where research is lagging or to take advantage of scientific opportunities. The outcomes of these workshops have included the establishment of research priorities, development of collaborative research protocols, criteria for diagnosing and monitoring rare diseases, specific discoveries, publications, and new research endeavors. These workshops have also contributed to the exchange of ideas and information among basic and clinical investigators, voluntary patient support groups, NIH staff, and the pharmaceutical industry.

The ORD is a major participant on the Trans-NIH Sickle Cell Disease Therapies Working Group, which was given the responsibility to develop an action plan to implement the recommendations resulting from a conference, including improved communication with the sickle cell research community

1.1.2.1 Action Plan

Throughout the years, ORD has regularly co-funded scientific conferences on rare diseases that affect underserved populations. In FY2004, ORD supported the following scientific conferences:

New Directions for Sickle Cell Therapy in the Genome Era

The conference was held at the Natcher Conference Center of the NIH in Bethesda, Maryland, on November 19-21, 2003. The conference was organized and supported by the NHGRI; the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; the ORD; the Fogarty International Center; and the Foundation for the National Institutes of Health. More than 120 individuals from the United States and abroad attended this invitation-only meeting.

The goal of this conference was to consider how the new tools and techniques of genomics might be applied both to understand more fully the biology of sickle cell disease and to develop more effective therapeutic and preventive strategies for the disease.

Collaborative Approaches to Discovering Genes in African Americans and Hispanics Utilizing Mapping by Admixture Linkage Disequilibrium (MALD)

Conference participants reviewed the development of the new set of markers for MALD mapping in African Americans and collaborated on plans to develop such a map for Latinos, and discussed dissemination of knowledge of novel analysis techniques, understanding applicable diseases, and designing databases to support MALD analysis.

International Workshop on Biliary Tract Cancers: Current Perspectives and Future Directions

Even though the difference in biliary tract cancer-related mortality between White Americans and African Americans has decreased, there still is a higher incidence in African Americans. Also, gallbladder and bile duct cancers are far more common in Asia than in the West.

OFFICE OF **R**ARE **D**ISEASES

The purpose of the conference was to bring together more than 100 leading scientists across various disciplines to identify collectively what is currently known about biliary tract cancers, what questions still need to be answered, and how these questions can be best addressed with currently available resources, in particular the resources from the National Cancer Institute-China collaborative study. This 2-day workshop provided a unique forum for cross-pollination from multiple disciplines, which will stimulate further interdisciplinary collaboration. The participants identified future directions for biliary tract cancer research and made recommendations as to whether data in the current literature are sufficient to explain the high rates of biliary tract cancers in Native Americans and Latinos and whether further studies in these special populations with high rates are warranted.

Working Group for the Development of a Sickle Cell Disease Physician Consultation Network

This conference considered ways in which the NIH can address current needs. Participants focused on the development of a virtual network of physicians with expertise in hemoglobin disorders available for consultation to physicians who need advice.

Engaging Latino Communities in the Future of Genomics Science

NHGRI and ORD gathered leaders from the Latino community to begin a dialogue about the opportunities and the complex challenges that genetic and genomic science may soon present. Latinos are the largest minority group in the United States and suffer from a greater incidence of many diseases, including many that are rare. Genetic and genomic research promises to help address a wide range of health concerns, but these fields also may present complex choices that often require additional education and explanation to help individuals make the most informed choices. By engaging Latino leadership in discussions about such choices, NHGRI and ORD work to ensure that this community benefits from the scientific advances.

Workshop on Bioiron, Thalassemia, Sickle Cell Disease, and Hemochromatosis

Conference participants debated how to best enhance translational research in iron overload, with hyper-transfusion and malabsorption as the iron source, and to provide opportunities for collaboration for junior scientists.

In FY2005, ORD will continue to support scientific conferences that focus on those who experience health disparities. If the Office receives more scientifically sound applications, it will increase its co-funding in this area.

1.1.2.2 Performance Measures

ORD will encourage submissions of applications for scientific conferences on subjects that benefit those affected by health disparities.

1.1.2.3 Outcome Measures

To look toward increased numbers of scientific conferences focused on minority and other underrepresented or disadvantaged populations, ORD will monitor the number of applications for scientific conferences that benefit underserved populations.

1.2 Area of Emphasis Two: Partnering with ICs and Offices in Funding Research

ORD collaborates with Institutes, Centers, and Offices at NIH to stimulate rare diseases research by cosponsoring scientific conferences where research is lagging or to take advantage of scientific opportunities. The ORD is a major participant on the Trans-NIH Sickle Cell Disease Therapies Working Group, which is instrumental in working with ICs and Offices to co-fund promising research opportunities.

1.2.1 Action Plan

In FY2004, ORD co-funded with NIH ICs nine Bench-to-Bedside grants for 2-year periods at the NIH Warren Grant Magnuson Clinical Center. Intramural clinical, translational, and basic scientists at the NIH enter into basic science-clinical collaboration with colleagues in laboratories, clinics, divisions, Institutes, or Centers with a focus on an area of science/research directly related to a rare disease. One application, Therapeutic Application of Intravascular Nitrite for Sickle Cell Disease, is a collaboration of the clinical center and the National Heart, Lung, and Blood Institute. The principal investigator is Dr. Mark Gladwin.

Sickle cell disease is an autosomal recessive disorder and the most common genetic disease affecting African Americans. Approximately 0.15 percent of African Americans are homozygous for sickle cell disease, and 8 percent have the sickle cell trait. Hemoglobin S polymerization leads to red cell rigidity, microvascular obstruction, inflammation, and end-organ ischemia-reperfusion injury and infarction. Previously published data indicate that up to 50 percent of sickle cell patients have endothelial dysfunction due to impaired bioavailability of endogenous nitric oxide (NO) due in large part to scavenging of nitric oxide by cell-free plasma hemoglobin. These data suggest that therapies directed at restoring NO bioavailability might prove beneficial. We have recently discovered that the nitrite anion, available currently for human use as a component of the cyanide antidote kit, is a vasodilator *in vivo* by generating NO in tissues with lower oxygen tension and pH. The mechanism involves a novel physiological function of human hemoglobin as an oxygen- and pH-dependent nitrite reductase. To date we have observed that nitrite infusions in animal models significantly reduce liver and cardiac ischemia-reperfusion injury and infarction in mouse models, prevent cerebral vasospasm after subarachnoid hemorrhage in primates, and decrease pulmonary hypertension in newborn hypoxic sheep. This protocol is designed as a Phase I/II trial to address the hypothesis that nitrite infusions will vasodilate the circulation in patients with sickle cell disease at rest and during vaso-occlusive pain crisis, inactivate circulating cell-free plasma hemoglobin, reduce pulmonary artery pressures, and reduce ischemia-reperfusion injury.

ORD also participates with the NHLBI in PA-03-171 Exploratory and Developmental Research Grants for Investigations in Rare Diseases (R21). This Program Announcement permits researchers with novel ideas to obtain research support without the need for large amounts of preliminary data that often serves as a barrier to entry into the NIH grants system. It is anticipated that these efforts will ultimately result in an increased pipeline of therapeutic approaches to treatment and prevention of rare diseases, including sickle cell disease.

1.2.2 Performance Measures—N/A

1.2.3 Outcome Measures—N/A

2.0 AREAS OF EMPHASIS IN RESEARCH CAPACITY—N/A

3.0 AREAS OF EMPHASIS IN COMMUNITY OUTREACH, INFORMATION DISSEMINATION, AND PUBLIC HEALTH EDUCATION—N/A