



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Population-Based Prevention Research

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Table of Contents

Executive Summary	1
Introduction	2
Background on Prevention Research	2
Overview on Population-Based Prevention Research	3
Examples of NIH-Supported Projects and Programs	3
<i>Examination of Disease Risks</i>	4
<i>Studies to Develop or Test Preventive Interventions</i>	5
<i>Studies of Health Disparities Across Population Subgroups</i>	9
<i>Translation of Research Findings to Population-Wide Applications</i>	11
<i>Programs on Communication Technologies to Enhance Health</i>	13
NIH Dollars Spent on Population-Based Prevention Research	17

April 2002

Population-Based Prevention Research

Executive Summary

In Senate report No. 107-84, the Committee on Appropriations requested that the National Institutes of Health (NIH) prepare and submit a report on total dollars spent on population-based prevention research (p. 185).

Research on disease prevention is an integral part of the NIH mission. The Institutes and Centers have a broad portfolio of prevention research and training, as well as programs to disseminate the findings to scientists, health professionals, communities, and the public. Approximately one-quarter of the overall NIH budget is devoted to research on disease prevention. Ultimately, knowledge gained from NIH supported prevention research enables the application of sound science into clinical practice, health policy, and community health programs, thereby improving the health of the public.

The NIH provides substantial support for prevention research studies that are population-based. This research encompasses clinical studies of specific groups, of populations at increased risk for the condition being studied, and of groups of people that are representative of the general population or a segment of the population. The determination of disease risks and testing of interventions on these risks provides information that can be generalized to those populations and subsequently applied in a real world setting to improve health.

This report provides examples of NIH population-based prevention activities in areas of interest identified by the Senate Committee on Appropriations: Examination of disease risks; studies to develop or test preventive interventions; studies of health disparities across population subgroups; translation of research findings to population-wide applications; and programs on communication technologies to enhance health. The project summaries describe an array of population-based prevention programs supported by the NIH responsive to this request. However, they do not represent the entire scope and variety of such activities.

In FY2001, the NIH spent approximately \$2.049 billion on population-based prevention research programs supported by 22 of the Institutes and Centers. This represents over 4,000 research projects (extramural and intramural) and accounts for approximately 40 percent of the FY2001 NIH prevention research budget (\$5.124 billion).

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Introduction

In its report on the Fiscal Year 2002 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

“The Committee urges NIH to significantly expand its support for studies that examine the biological, behavioral, and environmental risks for disease. The Committee is especially interested in the assessment of prevention-focused interventions designed to enhance health status, the exploration of health disparities across population subgroups, the examination of strategies designed to move the findings of laboratory-based research from individuals to population-wide applications, and the exploration of the potential uses of communication technologies to enhance human health. The Committee urges NIH to submit a report to the Committee by April 1, 2002, that indicates total dollars spent on population-based prevention research by Institute and relevant disease areas where possible.” (Senate report No. 107-84, page 185)

The following report has been prepared by the NIH of the Department of Health and Human Services in response to this request.

Background on Prevention Research

Research on disease prevention is an integral part of the NIH mission. The Institutes and Centers have a broad portfolio of prevention research and training, as well as programs to disseminate the findings to scientists, health professionals, communities, and the public. Approximately one-quarter of the overall NIH budget is devoted to research on disease prevention. Narrowly defined, disease prevention research includes studies that develop and test interventions that prevent the occurrence or progression of disease, disability and injury, as well as studies designed to identify risks for these conditions. Ultimately, knowledge gained from NIH-supported prevention studies makes possible the application of sound science into clinical practice, health policy, and community health programs, thereby reducing disease burden and improving the health of the public. To target preventive interventions where they are most needed, NIH has increased its focus on research to examine the health needs of racial and ethnic minorities and to reduce health disparities among these groups. In addition, many research projects include study designs and methods that accommodate cultural differences of acceptability and effectiveness.

Overview on Population-Based Prevention Research

Studies of large and generally representative populations are required to permit valid public health inferences about effect. The NIH provides substantial support for prevention research studies that are population-based. These studies encompass a broad interdisciplinary portfolio of research, research training, information dissemination, and public education programs that address health issues across population subgroups and over the entire life span. Population-based research encompasses studies of specific groups (including families), of populations at increased risk for the condition being studied, and of groups of people that are representative of the general population or a segment of the population. The determination of disease risks and testing of interventions on these risks provides information that can be generalized to those populations and subsequently applied in a real world setting to improve health. Often, these studies include health education activities that form the foundation for many community-wide prevention strategies.

Population-based prevention research selects representative participants from defined populations or subpopulations. The orientation of these projects is toward identifying specific risk factors for disease and testing interventions on risk factors in order to prevent disease development or progression. Such research seeks to understand the genetic, biologic, environmental, behavioral, or social determinants of disease in human populations defined by geographic, cultural, or psychosocial characteristics. - e.g., geography, community attributes, race and ethnicity, gender, age, health status, or high-risk groups. Knowledge gained from these studies is used to develop and test interventions designed to improve the health status of these populations, such as through changes in lifestyle habits or through improvements in the social and physical environment. The outcomes of this research provide an evidence base for recognition of risks to health and for interventions to reduce these risks.

Examples of NIH-Supported Projects and Programs

Population-based prevention research programs supported by the NIH include research grants and contracts, training awards, education programs, and communications and outreach activities. The Senate Committee expressed an interest in several specific areas of population-based studies, examples of which are provided in this section of the report. These project summaries describe an array of population-based prevention programs supported by the NIH responsive to this request. However, they do not represent the entire scope and variety of such activities.

Examination of Disease Risks

National Longitudinal Study of Adolescent Health (Add Health): Since 1994, the National Institute of Child Health and Human Development (NICHD) has led this study with support from 17 other Federal institutes, offices and agencies. Add Health is a landmark research program that continues to provide researchers with data needed to better understand the biologic and environmental factors that promote healthy transitions to adulthood. The Add Health study has resulted in comprehensive data on the determinants of health and health-related behaviors in adolescence. The study provides nationally representative information on physical, mental, and emotional health; health risk behaviors; and use of health services. Moreover, the study yields information on how adolescent health is influenced by the adolescent's environment: parents, siblings, peers, school, neighborhood, and community.

Cooperative Psychiatric Epidemiology Studies: The National Institute of Mental Health (NIMH) is funding a comprehensive research program to study the mental health of Whites, African Americans, Latinos, and Asian Americans based on nationally representative samples of the U.S. population. The studies will provide nationally representative data on prevalence of mental disorders, use of services for mental health reasons, and data on persistence, severity of disorders, and limitations in activities caused by mental health problems. Data from these studies will allow for analyses of disability and burden to the U.S. population due to mental disorders. Analyses of risk patterns across groups will help to better target prevention efforts and maximize preventive effects of population based intervention strategies.

National Epidemiologic Survey on Alcohol and Related Conditions (NESARC): The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is conducting this survey to gather data needed to estimate the prevalence and incidence of alcohol use disorders and their associated disabilities in the U.S. general population. Information on prevalence and incidence will allow examination of the natural history of alcohol use disorders and their associated disabilities, identification of subgroups of the population at risk for these disabilities, and development of rational and scientifically-based intervention and prevention programs. NESARC is planned to be a longitudinal survey, with a second wave in 2004-2005. In 2001-2002, personal interviews are being conducted with approximately 48,000 respondents aged 18 years and older, including persons who reside in civilian noninstitutional group quarters (e.g., college dormitories, alcohol and drug halfway houses, or other group homes). The study will oversample for Blacks, Hispanics, and young adults (ages 18-24).

State Models for Oral Cancer Prevention and Early Detection: Each year approximately 30,000 new cases of oral and pharyngeal cancers are diagnosed and about 8,000 will die from these cancers. These statistics have changed little in

the past several decades. The five-year survival rate is 58 % for whites and 34% for blacks. The National Institute of Dental and Craniofacial (NIDCR) is currently funding innovative state-based studies of Oral Cancer Prevention and Early Detection in five states. These states (Illinois, New York, Michigan, North Carolina and Florida) are using different approaches such as social marketing, PRECEDE/PROCEED model, and Geographic Information Systems (GIS) to: 1) determine the incidence and mortality of oral cancers in their respective state; (2) assess the level of knowledge of oral cancer risk factors among health professions and the public; (3) document and assess health professionals' practices for early detection of oral cancers; and (4) determine whether or not the public is receiving an annual oral cancer examination. Findings from the needs assessments will be used to design, implement, and evaluate interventions to prevent and reduce health disparities related to oral and pharyngeal cancers.

Studies to Develop or Test Preventive Interventions

Prostate Cancer Prevention Trial (PCPT): The National Cancer Institute's (NCI) Community Clinical Oncology Program (CCOP) is conducting the PCPT trials through its clinical trials network. The trial is an intergroup study involving over 225 community and university hospitals across the country. The study tests the ability of finasteride (Proscar), a 5-alpha-reductase inhibitor of androgen synthesis, to reduce the incidence of prostate cancer, the most common non-skin cancer in men. Participation is open to all men between ages 55 and 70. Black men and men with a family history of prostate cancer are being aggressively recruited because they may have the greatest risk of developing prostate cancer. The entire trial lasts 10 years. The planned accrual goal of 18,500 men was reached and the follow-up phase is in progress.

Selenium and Vitamin E Cancer Prevention Trial (SELECT): The SELECT trial is sponsored by the National Cancer Institute (NCI) and is the largest prostate cancer prevention trial to date. The study will determine whether two dietary supplements, selenium and vitamin E, can protect against prostate cancer, the most common form of cancer in U.S. men. Coordinated by a network of researchers, the Southwest Oncology Cooperative Group (SWOG) began enrolling patients in July 2001. The study plans to recruit more than 32,000 men over age 55 at more than 400 study sites in the U.S., Puerto Rico, and Canada.

Lifestyle Interventions for Blood Pressure Control (PREMIER): The purpose of this National Heart, Lung, and Blood Institute (NHLBI) funded study is to determine the effectiveness of multi-component lifestyle intervention programs in lowering blood pressure. Eight-hundred-eleven participants have been randomly assigned to receive (1) an intensive behavioral intervention to facilitate their achieving the lifestyle changes that are currently recommended for blood pressure control – reduced salt intake, increased physical activity, and

weight control or weight loss, as needed, or (2) this same intervention coupled with a behavioral intervention to promote consumption of the DASH diet (an eating pattern rich in fruits, vegetables, and low-fat dairy products; low in total and saturated fat and cholesterol; and moderately high in protein), which has been shown to lower blood pressure, or (3) advice alone.

Longitudinal Study of Asthma from Birth to Adulthood: The NHLBI Longitudinal Study of Asthma from Birth to Adulthood is an epidemiologic, long term study of 974 children who were enrolled at birth and have been followed for 18 years. The study is identifying factors that lead to the development of chronic asthma, factors that determine how severe the disease becomes in patients who have it. The study has already led to scientific breakthroughs in our understanding of the impact environmental exposures early in life can have on the development of asthma. Findings from this research will be used to increase our knowledge about the causes of asthma and to identify promising targets for intervention to prevent development of the disease.

Smoking Cessation Programs: Smoking Cessation in Emergency Respiratory Patients is a study funded by NHLBI that compares standard and enhanced smoking cessation programs in 618 smokers, 18 years of age and older, who come to a hospital emergency department with an acute respiratory illness. Smoking Cessation in the Chest Pain Observation Unit is a study of 636 adults that tests a special program tailored to those admitted to a hospital because of chest pain. Both studies are also examining factors that may predict the success of quitting and are evaluating the cost effectiveness of the interventions. These programs are targeted to members of the population who are at high risk of developing smoking-related diseases. However the programs are expected to be more successful than conventional smoking cessation programs because of people's greater willingness to make behavior changes during acute medical events.

Look AHEAD: Action for Health in Diabetes (AHEAD) is a multicenter randomized clinical trial to examine the long term effects of a lifestyle intervention designed to achieve and maintain weight loss through decreased caloric intake and exercise. The study is enrolling 5,000 obese participants with type 2 diabetes over a 2.5 year period. The aim is to determine if lifestyle interventions can prevent heart attacks, stroke and cardiovascular death in this population. Participants are randomly assigned to one of two interventions, the Lifestyle Intervention or Diabetes Support and Education, and will be followed for a total period of up to 11.5 years. Sixteen Look AHEAD Clinical Centers around the U.S. are recruiting volunteers from a diverse range of populations and will allow the study to examine health disparities across a number of minority groups. The study will also investigate diabetes control and complications, fitness, general health, health-related quality of life and psychological outcomes, as well as the cost and cost effectiveness of the Lifestyle Intervention relative to

Diabetes Support and Education. The study is co-funded by several NIH institutes and the Centers for Disease Control and Prevention (CDC).

Environmental Approaches to the Prevention of Obesity: This trans-NIH grant program was designed to solicit and support primary and secondary prevention approaches, targeting environmental factors that contribute to inappropriate weight gain. The program goal is to support research projects that develop and test approaches to modify external surroundings in the environment to prevent weight gain, without exclusive reliance on an individual's knowledge or motivation. The main objectives are to prevent inappropriate weight gain and enhance metabolic and cardiovascular fitness by improving diets (e.g., decreasing energy intake, increasing intake of high-fiber, water dense foods such as fruits and vegetables), increasing physical activity, and decreasing sedentary behaviors. A unique feature is that applicants are required to collaborate with one or more groups or organizations that will participate in the development and/or the implementation of the environmental modifications (e.g., schools, worksites, religious or community organizations, restaurants, food markets, health care settings, parks and recreational facilities, and state public health departments.)

Vitamin Intervention for Stroke Prevention: More than 700,000 strokes occur in the U.S. each year. Seven to ten percent of individuals who survive an initial stroke go on to have a second one. Previous research has suggested that elevated levels of the amino acid homocysteine in the blood may be a risk factor for stroke. The vitamin supplements folic acid, vitamin B6 and vitamin B12 have been shown to reduce blood levels of homocysteine. The National Institute of Neurological Disorders and Stroke (NINDS) is funding a multi-site randomized clinical trial of 3600 patients to test whether a vitamin supplement containing high doses of these three vitamins, added to best medical management and risk factor modification programs, can reduce the recurrence of a second stroke in patients with elevated homocysteine levels. If successful, this intervention may serve as an inexpensive and safer alternative to current customary risk factor reduction therapies, such as antiplatelet or anticoagulant drugs.

Social Network-Based Intervention To Reduce Lead Exposure: The National Institute on Environmental Health Sciences (NIEHS) will study an existing social network-based lay health advisor intervention and will then add an inter-generational component to test the effectiveness in mobilizing a Native American community to respond to heavy metal contamination from lead and zinc mining. The 800 acre research area is on land which is home to eight Indian tribes. The study will see the extent to which the intervention contributes to belief, attitude, and behavior changes that will reduce heavy metal exposure and absorption in Native American children.

Immunity Conferred by Smallpox Vaccination: The Federal government has recently decreed the production of enough doses of smallpox vaccine to potentially vaccinate the entire U.S. population in the event of widespread exposure to smallpox. The National Institute on Aging (NIA) is reviewing the immunity conferred by smallpox vaccination in Baltimore Longitudinal Study of Aging (BLSA) participants, examining its duration and assessing the degree of protection in the segment of the population who were previously vaccinated with 1, 2, 3, or more vaccines. Routine vaccination ceased 30 years ago, but researchers hope to quantitate the type of immune activity present in individuals 30-60 years after receiving their last vaccination. The effect of having received multiple successive vaccinations is thought to strengthen the intensity and duration of protection, but there is no reliable supporting data. Study results will provide information that can be used to aid decisions relevant to the current American population in the unfortunate instance of an actual smallpox release.

Osteoporosis Prevention in Pre-Adolescent Girls (Be A Star! Bank on Your Bones!): The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is supporting a behavioral and educational intervention designed to decrease modifiable risk factors for osteoporosis in at-risk pre-adolescent girls. Girl Scout troops are receiving either a behavioral and educational intervention or education only. The intervention group receives interactive sessions using various media to provide instructional material on osteoporosis and its prevention; incentives (e.g., jump rope, booklet of jump rope games) are provided; and self-monitoring of calcium intake and weight-bearing activity is used to reinforce healthy behaviors. The targeted group of girls is ideal for this intervention, since they are at a stage of rapid accrual of bone mass. The hope is that the intervention will maximize their opportunity for attaining peak bone mass, thus serving the ultimate goal of preventing osteoporosis.

Long Term Efficacy of Youth Suicide Risk Prevention: Suicide constitutes a major health concern among today's youth. This longitudinal study funded by the National Institute of Nursing Research (NINR) is testing the long-term efficacy of three randomized suicide preventive interventions delivered to youth during their adolescent years. More specifically, this research will test the long term efficacy of the interventions for: 1) reducing suicide risk behaviors and related risk factors (emotional distress, drug involvement) and 2) enhancing mediating factors including personal resources (i.e., problem solving, coping, personal control), and social resources (social support) in a sample of 460 suicide vulnerable youth age 18-23 and a comparison group of 140 youth. This study is one of few follow-up studies of indicated suicide-risk prevention interventions in the United States.

Effectiveness of 4 Popular Diet Strategies for Weight Loss & Cardiac Risk Reduction: Controversy surrounds the growing number of unconventional diet plans targeting weight loss and cardiac risk reduction. Data on the relative effectiveness of these strategies are limited, especially under conditions of

realistic dietary adherence. Researchers funded by the National Center for Research Resources (NCR) aim to compare, by randomized controlled trial, the clinical effectiveness of 4 popular dietary treatment strategies for weight loss and cardiac risk reduction. One-hundred sixty subjects with excess body mass and one or more metabolic cardiac risk factors will be randomized to 1 of 4 dietary treatment strategies, group sessions with a dietitian and physician, and dietary instruction. Primary outcomes will be body mass index, and cardiac risk score measured by the Framingham equation. Secondary outcomes will be changes in blood pressure, fasting serum lipids, glucose, glycohemoglobin, insulin, urine C-peptide, and renal function, reported as change from baseline at 2, 6, and 12 months. Three-day diet diaries, urine nitrogen and ketones, and monthly telephone surveys will assess dietary adherence. The results of this randomized clinical effectiveness trial will substantially validate or challenge the conventional dietary approach to cardiac risk and body fat reduction.

Studies of Health Disparities Across Population Subgroups

Centers for Population Health & Health Disparities: Social determinants of cancer health disparities, (which include environmental, cultural, and social factors acting at the community or population level), influence exposure and vulnerability to disease, behaviors that increase risk of cancer, effectiveness of health promotion efforts, likelihood of diagnosis in later stages of disease, and access to and quality of health care to cancer patients. They also play a role in the disparities in cancer outcomes between groups defined by their racial, ethnic, and socioeconomic status. To achieve better understanding of these social factors in cancer disparities, and how they interact with behavioral and biologic pathways, the National Cancer Institute (NCI) is working with the National Institute for Environmental Health Sciences (NIEHS) and other NIH partners to support 8-10 centers of excellence to provide a stimulus for new interdisciplinary research (an integrated approach on the part of biomedical, behavioral, and social scientists working in concert) aimed at understanding the complex interaction of the multiple determinants of cancer.

Jackson Heart Study (JHS): The JHS is sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center on Minority Health and Health Disparities (NCMHD), in partnership with Jackson State University, Tougaloo College, and University of Mississippi Medical Center. The primary objective is to investigate the causes of cardiovascular disease (CVD) in African-Americans to learn how to best prevent this group of diseases in the future. Death rates for CVD in the U.S. are considerably higher among African-Americans, and CVD death rates in Mississippi are the highest in the nation and particularly high among African-Americans. The JHS will be the largest investigation of CVD that has been undertaken in an African-American population and plans to include up to 6,500 African-American men and women, ages 35 to 84, as well as their family

members. The initial phase of the study began in the fall of 2000 and will take about three years to complete. An extensive examination will include a series of questionnaires, physical assessments, and laboratory measurements. Newer areas of focus include early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations of CVD with common disorders such as high blood pressure, obesity, and diabetes.

Geographic and Racial Differences in Stroke: Stroke mortality is 50 percent higher in African Americans as compared to white Americans. In the Stroke Belt of the Southeastern U.S., deaths from stroke are approximately 25 percent higher than in the rest of the nation. Within the Belt, an area called the “Stroke Buckle,” mortality rates are even higher. The National Institute of Neurological Disorders and Stroke (NINDS) is currently funding a new study to determine if these disparities in stroke mortality may be due to geographic and racial differences in both prevalence of stroke risk factors and susceptibility to these risk factors. Thirty thousand individuals over the age of 55 who are initially stroke-free will be followed for three years. One third of the participants will be from the Stroke Belt, one third from the Stroke Buckle, and one third from the rest of the U.S. Within each of these groups, one half of participants will be African American and one half white; also, one half of participants will be male, and one half female. The risk factor status of participants will be collected by telephone interviews, home visits, and other survey methods, and then compared to stroke incidence and mortality during the three year period. It is hoped that the results of this study will allow for the design of more effective preventive interventions to reduce stroke mortality among these groups.

Initiative to Reduce Infant Mortality in Minority Populations in the District of Columbia: The DC Initiative to Reduce Infant Mortality in Minority Populations is funded by the National Institute on Child Health and Human Development (NICHD). The study currently has two controlled intervention trials aimed at improving the perinatal health of African Americans and Hispanics. The Healthy Outcomes of Pregnancy Education (Project DC HOPE) is designed to reduce preterm birth by addressing the following risk factors during prenatal care and postpartum: smoking, depression, and partner abuse. The Building Futures for Youth Project is a public school- based educational program for children and their parents designed to postpone sexual involvement in 5th and 6th graders by enhancing academic achievement, improving parental communications, setting life goals, and giving children the skills to maintain sexual abstinence.

Family and Community Health Study: The National Institute of Mental Health (NIMH) is funding a longitudinal study examining the role that families, communities, and individual characteristics play in the inhibition and promotion of African-American mental health and adolescent risk behavior. These studies follow 897 families across a range of settings (urban and rural), family structures

(single parent, intergenerational, nuclear), and income levels. The study includes an innovative examination of coping with stressors such as race-related negative events among care givers. It also focuses on the ways in which multiple levels of influence affect mental health over time and on factors that affect adolescent decisions to engage in or avoid risk behaviors.

Tri-Ethnic Center for Prevention Research: The National Institute on Drug Abuse (NIDA) is funding a multidisciplinary center for the prevention of drug abuse among ethnic minority and rural youth. The Center researchers are working to determine how characteristics of individuals, families, schools, and communities influence rates of adolescent drug use in rural, ethnic minority communities. Three types of prevention programs currently being tested include: (1) a state-wide initiative to prevent the use of methamphetamines and other drugs based on Center developed methods for producing change in rural communities; (2) media campaigns specifically tailored for rural ethnic minority communities to reduce adolescent tobacco use; and (3) cognitive behavioral treatments that reduce trait anger, leading to reductions in substance use and the violence and victimization resulting from the combination of anger and substance use. Concurrent work involves the collection of community level data to identify community level predictors of substance abuse in about 30 Mexican American, 30 African American, and 30 white non-Hispanic rural communities through interviews with law enforcement, school, and key medical informants.

Translation of Research Findings to Population-Wide Applications

Asthma Management at School: Interventions to Improve Asthma Management at School is a research project funded by National Heart, Lung, and Blood Institute (NHLBI) in 128 schools in three cities across the country. Over 2,500 children with asthma participate in these programs, along with their teachers and school administrators. The goal of the project is to develop and evaluate coordinated asthma programs to ensure that schools provide access to medication, an environment as free of allergens and irritants as possible, education for asthma self-management skills, and staff resources to link efforts at school with the family and family physician's asthma care. Findings from this study will provide schools with important tools for helping children with asthma participate fully in school activities.

Inner-City Asthma Study (ICAS) of Children: This multi-site clinical study was initiated by the National Institute of Allergy and Infectious Diseases (NIAID) to identify multiple factors associated with asthma severity, especially among African American and Hispanic inner-city children. The study implemented a comprehensive educational, behavioral, and environmental intervention program aimed at altering factors identified as major contributors to asthma severity. Researchers found that a combination of cockroach allergy and exposure to high

levels of cockroach allergen is a major risk factor for asthma severity in this population. The study demonstrated that the use of an asthma counselor in conjunction with indoor environmental controls substantially reduced asthma morbidity. A renewal of the ICAS was funded jointly by NIAID and the National Institute of Environmental Health Sciences (NIEHS) in 1996. This study is evaluating an intervention that emphasizes cost-effective measures for improving the indoor environment and physician education. In collaboration with the Center for Disease Control and Prevention (CDC), NIAID launched a 4-year program in FY2001 to disseminate and implement the successful counselor-based education intervention that reduced symptoms and hospitalizations in inner-city children with moderate to severe asthma.

Clinical Trials Network on Diabetes in Children: The increase of type 2 diabetes in children and adolescents is presumed to be a consequence of widespread obesity and decreased physical activity. The recently concluded Diabetes Prevention Program (DPP) demonstrated the effectiveness of increased physical activity and moderate weight loss in preventing the development of type 2 diabetes in high risk adults. The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) has, therefore, initiated a clinical trials network to develop population-based approaches for preventing the development of type 2 diabetes in children. Seven clinical sites, plus a coordinating center, have been funded through this network, which will conduct two separate trials, a school-based intervention to prevent the development of type 2 diabetes, and a multi-arm study to determine the most efficacious, safe, and cost-effective strategies to treat type 2 diabetes in children. Effective treatment of type 2 diabetes, with maintenance of normal blood sugar levels, is essential for the prevention of the long-term vascular complications of diabetes. These trials will be conducted at multiple sites, in order to insure geographic and racial/ethnic diversity.

Translational Research for the Prevention and Control of Diabetes: This new program announcement by (NIDDK) solicits research to translate recent advances in the prevention and treatment of type 1 and type 2 diabetes into clinical practice for individuals and communities at risk. This program announcement seeks applications for clinical and behavioral studies to develop and test: 1) improved methods of health care delivery to patients at risk for developing diabetes, 2) improved methods of diabetes self management, and 3) cost effective community-based strategies to promote health lifestyles to reduce the risk of diabetes and obesity. Applications addressing diabetes research translation to underserved communities and populations are particularly encouraged.

Topical Microbicide for HIV: Over the past several years, the National Institute of Allergy and Infectious Diseases (NIAID) has been involved in the development of a novel vaginal microbicide called PRO 2000 Gel. A phase 1, multi-center study testing the safety of this microbicide was recently completed. The study examined the safety of 2% and 4% PRO 2000 Gel administered once or twice

daily for 14 consecutive days in sexually active, HIV (-) women and sexually inactive, asymptomatic HIV (+) women. PRO 2000 was well tolerated in both groups of women, and there were no serious adverse events. Importantly, all of the participants indicated they would be willing to use the product again if it were shown to protect against HIV infection. A Phase II/III clinical trial of PRO 2000 is planned for the future.

Prevention of Child and Family Stress: The National Institute of Mental Health (NIMH) supports prevention centers that apply basic research findings to the development of new approaches to prevention. One center has focused on how families cope with high stress situations, such as poverty, divorce, and grieving, and has identified factors that affect the likelihood of mental health problems in these contexts. The investigators used this research to develop and test six preventive interventions to change the demonstrated risk and protective factors and improve mental health outcomes. The Center is currently expanding their work to include populations such as immigrant Mexican American families, and is examining ways to integrate effective interventions into existing mental health and legal (divorce) services. A second prevention center has conducted observational studies that identified specific ways in which parents and children interact to reduce or enhance risk for subsequent aggressive behavior in the children. Based on this work, interventions were developed to change specific care-giving behaviors such as coercive discipline, positive involvement, problem solving, child supervision, and skills encouragement to improve child outcomes. These effective interventions have been implemented in a wide variety of settings, including schools, foster care, and prisons (a pilot in underway for incarcerated parents.) Dissemination of this model is also taking place among Hispanic and American Indian communities.

Programs on Communication Technologies to Enhance Health

Closing the Digital Divide: The National Cancer Institute (NCI) is supporting four research and development projects to overcome the digital divide by testing the efficacy of new communication technologies in cancer prevention and education. These projects involve partnerships among NCI-supported Cancer Centers and Cancer Information Service (CIS) Centers at universities and a wide range of community-based organizations including Head Start, urban and rural community groups, senior centers, and computer suppliers. For example, a regional CIS office partnered with a Comprehensive Cancer Center, Head Start Center, a group concerned with urban policy, and a group that supplies computers to children to develop techniques for teaching Head Start parents how to use computers to access health information on the Web.

Evaluation of Home Asthma Telemonitoring (HAT) in Adults: Evaluation of Home Asthma Telemonitoring (HAT) in Adults is a National Heart, Lung, and Blood Institute (NHLBI) study of over 240 adult asthma patients who live in the inner-city. The study is evaluating whether an internet-based (HAT) system will help patients follow their treatment plan more carefully and improve patient communication with their health care providers. The HAT system allows a patient to send information about symptoms and lung function on a regular basis to their health care provider through a home computer. The health care provider can then alert the patient if the treatment plan should be changed or if they need to see the doctor. This monitoring method may be particularly helpful to inner city patients who have difficulty getting to a clinic that provides quality asthma care, and it may be cost effective by preventing severe asthma attacks that require emergency department visits and days lost from work.

Innovative Approaches to Prevention of Obesity: Several of the grants received under this trans-NIH program are specifically focused on studying use of the Internet as a tool to help improve maintenance of weight loss. For instance, many individuals succeed in losing weight through a weight loss program, but most of these individuals regain all of the weight over time. One obesity prevention pilot grant has developed an online Weight Connection program to provide a variety of ongoing counseling and feedback after an initial weight loss intervention. This program is being compared with a standard weight loss program for maintaining weight loss. Another example is a study that is using an Internet Website designed to help new mothers who have gained excessive weight during pregnancy. The Maternal Obesity Management Study (MOMS) has been specifically tailored to address the needs of new mothers and the cultural issues relevant to minority women. Researchers will compare a traditional lifestyle program providing group sessions on healthy diet, activity, and weight loss with a lifestyle program that also includes an Internet-based component intended to improve maintenance of weight loss.

The Eye Site: This traveling exhibit was developed by the National Eye Institute (NEI), and is designed to increase knowledge about low vision—the warning signs, the causes, and what can be done; increase referrals of people with low vision to eye care specialists in low vision; increase the use of adaptive devices; increase the use of vision rehabilitation services/devices; and, increase knowledge about NEI and its medical research. The exhibit consists of five kiosks and is designed to attract a cross section of the population from young to senior citizens. The exhibit contains an interactive multimedia touchscreen program; provides information on low vision services and resources; and displays aids and devices that help people with low vision. The Eye Site explains the causes of low vision, offer personal accounts of people with low vision, and provides a self-assessment to help people determine whether they have low vision. A highlight of the touchscreen program is an animated character that guides the viewer, as well as

several short videos giving “hands-on” advice. The exhibit will visit shopping centers and possibly other high traffic consumer locations throughout the U.S.

Multimedia Support Resource Programs on Early Hearing: The National Institute on Deafness and Other Communication Disorders (NIDCD) is supporting research that focuses on the development and dissemination of health communication information on hearing, balance, smell, taste, voice, speech, and language. NIDCD-supported scientists are developing multimedia support resource programs on early hearing detection and intervention that could be disseminated nationally by CD-ROM, DVD-ROM, or the Internet. Another NIDCD-supported scientist is using video-based computer technology and American Sign Language to develop a multimedia cancer education and prevention program for people who are deaf. In addition, NIDCD-supported scientists are creating an interactive Website that will provide self-help strategies on the identification, treatment and prevention of voice disorders and improve vocal health. The program is being designed for elementary, middle and high school teachers, a group with one of the highest incidences of voice disorders in comparison to other occupational groups.

Interactive Internet Intervention for Positive Parenting Programs: The National Institute of Mental Health (NIMH) is funding several studies that are using communication technologies to enhance health, with an emphasis on rural and semi-urban populations where travel to prevention intervention sites may be difficult. Researchers are studying the feasibility of a home-based behavioral parent-training program for Head Start parents of 4-year-old children at risk for aggressive and disruptive behavior problems. The intervention is CD-ROM and Internet-based, with a parent “coach” who makes periodic home visits to support and enhance the multimedia programming, and a monitored electronic bulletin board and monitored parent discussion groups. Another project is adapting an efficacious group cognitive behavioral intervention for preventing and treating adolescent depression into an Internet-based intervention for use in HMO settings. This study is also developing an Internet-based intervention for parents of children experiencing behavior problems, for use in a variety of community-based settings.

Effective Media Strategies for Drug Abuse Prevention: This National Institute on Drug Abuse (NIDA) study is designed to identify strategies to improve the effectiveness of mass media campaigns to prevent drug abuse. The investigators are working to reach high sensation seeking youth, i.e., youth who are more at-risk because of their propensity for risk-taking and seeking novel experiences. They are using a combination of high saturation (i.e., 4-6 week groups of ads devoted to a particular message type such as “marijuana-negative consequences”) and low saturation televised Public Service Announcement (PSA) campaign materials developed for the Office of National Drug Control Policy (ONDCP). The study provides data on the campaign’s ability to reach at risk adolescents and

to change patterns of risk-taking attitudes and behavior. This study will collect data regarding the ability of a low saturation campaign to sustain its impact and the role of youth protective and risk factors in modifying the campaign's impact. In addition, this project provides the prevention community with information on how the sensation value of PSAs relates to campaign effectiveness. This research informs the ongoing efforts of the National Youth Anti-Drug Media Campaign.

NIH Dollars Spent on Population-Based Prevention Research

The NIH has a substantial investment in this area. In FY2001, the NIH spent approximately \$2.049 billion on population-based prevention research programs supported by 22 of the Institutes and Centers. This represents over 4,000 research projects (extramural and intramural) and accounts for approximately 40 percent of the FY2001 NIH prevention research budget (\$5.124 billion).

NATIONAL INSTITUTES OF HEALTH				
Population-Based Prevention Research				
(dollars in thousands)				
Participating	FY 1999	FY 2000	FY 2001	
ICs	Actual	Actual	Actual	
NCI	\$151,089	\$177,079	\$209,322	
NHLBI	331,662	378,325	363,803	
NIDCR	21,659	23,983	26,496	
NIDDK	119,844	137,000	156,000	
NINDS	48,847	46,000	51,059	
NIAID	192,481	214,986	272,777	
NIGMS	0	0	0	
NICHHD	134,212	148,150	152,970	
NEI	42,266	44,800	50,221	
NIEHS	14,906	25,800	39,806	
NIA	164,573	189,800	217,400	
NIAMS	32,984	36,868	37,326	
NIDCD	1,089	2,334	2,634	
NIMH	161,966	199,985	225,618	
NIDA	82,500	89,700	101,400	
NIAAA	34,449	38,545	40,920	
NINR	8,569	10,230	10,796	
NHGRI	15	1,029	1,480	
NIBIB *	--	--	0	
NCRR	22,426	22,693	30,982	
NCCAM	4,803	5,700	6,799	
NCMHD *	--	--	21,287	
FIC	10,563	11,176	14,543	
NLM	8,599	8,257	8,364	
OD **	1,264	7,418	7,329	
NIH	1,590,766	1,819,858	2,049,332	

* NIBIB and NCMHD established in FY2001

** OD includes ORWH and OBSSR

7/26/02