Strategic PLAN

for Addressing Health Disparities

Fiscal Years 2002-2006

National Institute of Allergy and Infectious Diseases
NATIONAL INSTITUTES OF HEALTH

CONTENTS

MISSION

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support research that strives to understand, treat, and ultimately prevent the multitude of infectious, immunologic, and allergic diseases that endanger the lives of millions of people nationally and globally.

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, increased risk of disease from occupational exposure, and increased risk of disease from underlying genetic, ethnic, or familial factors.

NIAID has long recognized the importance of differential risks among populations for infectious and immunologic diseases. It is commonplace in the field of infectious diseases to identify subgroups within a population who are at higher risk for infection and disease because of certain factors; for example, elderly people who are more susceptible to serious influenza virus infections because of their age.

NIAID also recognizes that racial and ethnic differences affect susceptibility to infection and disease. African-American individuals with chronic hepatitis C virus infection do not respond as well to antiviral therapy as do members of other 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. It is important to study differential disease susceptibilities because of the pragmatic benefit of research products, such as improved therapies, vaccines, or other interventions. This research also reveals critical information about the disease process, which, in turn, yields more opportunities for prevention or treatment.

This plan is based on more than 50 years of progress in the understanding, treatment, and prevention of infectious and immunologic diseases. Many NIAID advances have helped to eliminate or mitigate health disparities. Development of effective glycoconjugate vaccines to prevent Hib infections, for example, has almost eliminated Hib-related diseases in the Native-American population. Development of effective therapies for hepatitis B, education and interventions to improve asthma control in inner-city populations, and development of better therapies for human immunodeficiency virus infection and acquired immunodeficiency syndrome (HIV/AIDS) are all NIAID-supported research advances that have reduced health disparities.

Not all citizens, however, reap the full benefits of our increased knowledge. Although health disparities affect numerous segments of the U.S. population, medically underserved populations bear a disproportionate share of the burden. NIAID maintains its commitment to improve minority health and attract capable minority scientists to infectious and immunologic disease research. Recognizing that we can achieve our mission only through the interaction and participation of the minority scientific community throughout the United States, NIAID is committed to an extensive campaign that involves colleges and universities, medical centers, other professional organizations, minority communities, and groups that assist underserved populations.

NIAID's *Strategic Plan for Addressing Health Disparities Fiscal Years 2002-2006* focuses on those diseases within the institute's research portfolio that disproportionately affect underserved minority and socioeconomic populations. The plan constitutes specific tactical objectives for providing 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/AIDS, particularly those that are less expensive and/or involve less complex regimens, will contribute to health equality.

This plan, however, speaks only to those NIAID programs and initiatives that clearly target significant avenues for reducing health disparities; for example, an HIV/AIDS vaccine, which has the potential to dramatically reduce the incidence of HIV/AIDS in minority communities. (Note: Because NIAID conducts research related to health disparities that is not reflected in this plan, financial reports of all spending on health disparities research will embody a broader scope than this plan.)

The NIAID *Strategic Plan for Addressing Health Disparities Fiscal Years 2002-2006* has three parts to strengthen NIAID programs.

I. RESEARCH

II. RESEARCH INFRASTRUCTURE AND TRAINING

III. EDUCATION AND OUTREACH

I. RESEARCH

The research facet of the NIAID *Strategic Plan for Addressing Health Disparities Fiscal Years 2002-2006* focuses on HIV/AIDS, transplantation, autoimmune diseases, asthma, tuberculosis (TB), hepatitis C virus (HCV), and sexually transmitted diseases (STDs). NIAID did not receive public comments on these research areas when its first *Strategic Plan for Addressing Health Disparities* was issued in the spring of 2000. NIAID has received confirmation, however, from advisory groups, community organizations, professional societies, and advocacy groups that those are important foci for the health disparities research agenda.

Given the devastating public health impact of HIV/AIDS, preventing this disease and making its treatment affordable and practical is NIAID's highest priority. Nonetheless, the public health needs for each of the foci in the research section of the *Strategic Plan* also are critical, too critical to be put in priority based on those criteria alone. Thus, scientific opportunity and the feasibility and potential impact of those opportunities will drive institute priorities. Because the emergence of scientific opportunity is unpredictable, priorities inevitably will shift over the next 5 years.

The research section of the plan addresses both NIAID's extramural and intramural research programs. The extramural program supports individual investigators, groups, and centers outside NIAID to conduct research. Such investigator-initiated research sometimes responds to a specific initiative and always undergoes a competitive review process. The intramural program conducts research. Because of these different foci, the action plans articulated for the extramural program tend to be more programmatic, while the plans for the intramural program tend to be more explicitly research oriented.

Area of Emphasis: I.A. HIV/AIDS

HIV/AIDS has had a direct impact on the lives of 36.1 million people worldwide (2.7 million in North America). By June 2001, a total of 793,026 cases were reported in the United States. Of the total U.S. cases, 38 percent were among African Americans and 18 percent among Hispanics—rates very disparate from the representation of these groups in the U.S. population.

Transmission due to substance abuse continues to be a significant factor contributing to the spread of HIV/AIDS in minority communities. As a result, a large proportion of minority women has become infected during sex with an injection drug user. African-American and Hispanic women comprise 78 percent of all reported cases among HIV-infected women in this country, with most of them infected through heterosexual sex. As a consequence, the majority of HIV-infected children in this country are African American or Hispanic.

NIAID supports a comprehensive portfolio of biomedical and behavioral research aimed at preventing and treating HIV/AIDS in minority communities. The institute has taken strong steps to ensure minority participation in clinical trials, natural history studies, and prevention studies to assure that enrollment reflects the national epidemic.

NIAID has and continues to increase its enrollment of minority participants in all of its clinical studies. Through this effort, in FY 2000, a total of 6,886 participants were enrolled in the Pediatric AIDS Clinical Trials Group (PACTG), of which 46 percent of the enrollees were African American and 23 percent Hispanic. Of the 7,158 patients enrolled in the Adult AIDS Clinical Trials Group during

FY 2000, 27 percent were African American, 17 percent Hispanic, 2 percent Asian/Pacific Islander, and 1 percent American/Alaskan Native. These and numerous other trials are meeting the challenge of increased enrollment of underserved populations in HIV/AIDS research. NIAID will continue to support research in therapy, vaccine development, and prevention of HIV/AIDS.

Objective I.A.1. Support research on vaccines that would help to reduce disparities in the incidence and prevalence of HIV/AIDS

A vaccine that effectively prevents infection with multiple strains of HIV/AIDS will be key to reducing disparities in the incidence and prevalence of this still fatal disease. While such a vaccine remains the ultimate HIV/AIDS vaccine objective, vaccines that provide immunity to one or more strains and vaccines that slow disease progression so that the immunized person is healthier and less contagious also are important objectives.

Action Plan I.A.1

Steps

1. Support and conduct research to discover, design, and develop HIV/AIDS vaccine candidates.
2. Study the scope and relationship of viral and human genetic variation in the context of vaccine development.
3. Support and conduct clinical trials to determine the safety and efficacy of vaccine candidates.

Timeline

FY 2002

- Fund initiatives to
  - Renew the Innovation Grant Program (IGP). This program fosters exploratory investigator-initiated HIV vaccine research at the earliest stages of concept development.
  - Establish Vaccine Design and Development Teams, which support consortia of scientists who have identified particularly promising vaccine concepts for targeted accelerated product development.
  - Expand the HIV Vaccine Research and Design Program (HIVRAD). This program advances concepts identified in the IGP through support of basic HIV/AIDS vaccine research and design including concept testing in animal models, development of potential vaccine candidates, evaluation of their mechanism of action, development of animal models, and studies of immune correlates.
  - Renew the Integrated Preclinical/Clinical AIDS Vaccine Development Program (IPCAVD). IPCAVD pursues the development, evaluation, and refinement of vaccine concepts through early clinical trials.
  - Renew the HIV Vaccine Development Resources contracts. These contracts support vaccine development through the manufacture of pilot lots of vaccine for testing, preclinical testing of vaccine candidates, and preparation of Food and Drug Administration (FDA) submissions.
- Fund applications addressing ongoing initiatives (initiatives launched in earlier years, such as the Simian Vaccine Evaluation Units).
- Fund related investigator-initiated research.
- Conduct clinical trials on HIV vaccines. In 2001, NIAID's Vaccine Research Center (VRC) received regulatory approval to move forward with its first clinical trial, "Evaluation of an HIV-1 DNA Vaccine Encoding a Modified Gag-Pol Protein in Uninfected Adult Volunteers." This is a phase I study of a genetic vaccine, VRC 4302, in HIV-negative volunteers that will evaluate the safety, tolerance, and immune response of three dose levels. Genetic vaccines contain genes that direct production of

specific proteins of HIV. In FY 2002, participants will enroll in this and other VRC phase I clinical trials. The VRC will produce and initiate preclinical testing of multivalent vaccines. The multivalent vaccine products will eventually be evaluated in phase I trials with the goal of advancing into phase II and phase III trials, if the results are promising.

FY 2003

- Fund initiatives to
  - Renew the Basic HIV Vaccine Research Program (IGP and HIVRAD).
  - Expand the HIV Vaccine Design and Development Teams.
  - Expand the HIV Vaccine Trials Network (HVTN). The HVTN carries out a comprehensive clinical research program (human testing) to identify safe and effective HIV vaccines.
  - Expand HLA (human leukocyte antigen) Typing and Epitope Mapping Relative to HIV Vaccine Design. This program supports the characterization of viral (HIV) and human genetic variation in the context of vaccine development.
  - Expand the New Technologies for HIV and HIV Vaccine Related Research. These programs stimulate the application of new technologies to develop assays needed in clinical HIV vaccine studies.
  - Expand Vaccine Preclinical Resources. This program ensures that preclinical vaccine development (vaccine candidate production, testing, generation of reagents and technologies, database management) proceeds expeditiously.
- Fund applications addressing ongoing initiatives.
- Fund related investigator-initiated research.
- Study immune reconstitution to understand the mechanisms by which recovery from HIV disease can be enhanced.
- Develop manufacturing processes and release tests that provide material for phase I/II clinical trials, with particular emphasis on techniques suitable for eventual large-scale manufacture of vaccines.
- Study viral immunity and develop animal models of viral immunopathogenesis.
- 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.
- Investigate novel aspects of the cellular immune response to pathogens supporting the rational development of a vaccine against HIV.
- Develop, validate, and perform assays of the immune response to HIV and other pathogens on clinical samples derived from recipients of candidate vaccines.
- Apply the tools of atomic resolution structural analysis, primarily x ray crystallography, to the design of an effective HIV vaccine.
- Produce and characterize viral stocks of simian immunodeficiency virus (SIV) and HIV, including diverse viral strains representing multiple genetic subtypes.
- Use genetic mutations and immunologic assessment to develop immunogens that elicit broadly neutralizing antibodies to HIV with the goal of developing safe and effective HIV vaccines.
- Design cytotoxic T lymphocyte (CTL)-based HIV vaccine candidates by preparing gene-based immunogens. HIV cDNAs will be inserted into relevant plasmids to produce effective immunogens that induce CTLs.
- Define the functional roles of uniquely identifiable leukocyte subsets in the healthy immune system to understand how perturbations in the balance of these subsets lead to disease.
- Develop new flow cytometry-based assays and technologies.
- Develop understanding of the cellular and molecular mechanisms by which various cytokines and co-stimulatory molecules regulate cellular immunity in vivo.

- Use virological, immunological, structural, and biophysical information on HIV-1 envelope glycoproteins to rationally design subunit vaccine candidates.

FY 2004-FY 2006
- Release new, expansion, and renewal initiatives as appropriate.
- Fund meritorious applications addressing ongoing initiatives related to HIV vaccine development.
- Fund related investigator-initiated research.
- Continue ongoing and initiate new activities at the VRC.

Performance Measures

- Publication of initiatives in the National Institutes of Health (NIH) Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Availability of new and improved vaccine candidates for testing.
- Publication of scientific advances relevant to HIV vaccines in refereed scientific journals.
- Interest of industry and governments in producing HIV vaccines.

Objective I.A.2. Support research on topical microbicides in order to reduce health disparities related to AIDS and sexually transmitted diseases

Efficacy trials for topical microbicides are planned through the HIV Prevention Trials Network (HPTN). This research will directly benefit minority women because microbicides are expected to reduce the risk of sexually transmitted HIV. In addition, studies to design and develop new microbicides will continue.

Action Plan I.A.2

Steps

1. Develop a topical microbicide that
   A. Prevents infection and viral replication by both cell-free infectious HIV particles and cell-associated infectious particles.
   B. Is safe and non-inflammatory (causes no irritation to the vaginal/cervical/urethral/rectal epithelium).
   C. Reduces infectivity of other sexually transmitted infectious agents.
2. Support research and development of safe and effective formulations and delivery methods.
3. Support preclinical to clinical translational research for topical microbicides.
4. Conduct clinical trials to determine safety, acceptability, efficacy, and effectiveness of potential topical microbicides.
5. Continue to promote NIAID programs to domestic and international researchers to ensure that researchers worldwide pursue the best approaches.

Timeline

FY 2002
- Fund initiatives to
  – Renew the Microbicide Preclinical Development Program, cosponsored with the National Institute of Child Health and Human Development (NICHD), to expand the range of microbicide candidates, with and without contraceptive activity, through support of discovery and preclinical development of novel or underexplored microbicides.
  – Fund the Integrated Preclinical/Clinical Program for HIV Topical Microbicides to target research on novel topical microbicides at the preclinical/clinical interface of the research pipeline.

FY 2003

- Fund initiatives to
  - Renew the Integrated Preclinical/Clinical Program for HIV Topical Microbicides to target research on novel topical microbicides at the preclinical/clinical interface of the research pipeline.
  - Establish Microbicide Design and Development Teams to advance microbicide candidates into phase I safety trials.
  - Expand the HPTN clinical and laboratory capacity for topical microbicide trials.

FY 2004-FY 2006

- Release new, expansion, and renewal initiatives as appropriate.
- Fund meritorious applications addressing ongoing initiatives.
- Fund related investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Availability of new and improved topical microbicide candidates for testing.
- Publication of scientific advances relevant to HIV/AIDS topical microbicides in refereed scientific journals.
- Interest of industry and governments in producing topical microbicides to prevent HIV/AIDS.

Objective I.A.3. Support research to prevent perinatal transmission of HIV

Prevention of perinatal transmission of HIV from mothers to their children is of vital importance and a high priority on the NIAID research agenda. Almost 3 million children have died of AIDS with perinatally acquired HIV-1 infection. Ninety percent of pediatric HIV infection is acquired by mother-to-child transmission, and 90 percent of these infected children live in the developing world. Experts estimate 1,600 infants are infected daily, amounting to 600,000 annually.

Opportunities exist to intervene successfully in the antepartum, intrapartum, and postpartum periods to prevent transmission from an HIV-infected woman to her infant. Safe, simple, inexpensive interventions that could be widely applicable, particularly in the developing world, are highly important.

Action Plan I.A.3

Steps

- Further develop and test strategies to prevent mother-to-infant HIV infection through clinical trials in the United States and international settings.
- 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.
- Identify, develop, and test treatments of HIV disease to improve the survival and quality of life of HIV-infected infants, children, and adolescents in the United States and international settings.
- Develop optimal use of treatment management strategies for HIV-infected infants, children, and adolescents from acute/early infection through advanced disease that are appropriate domestically as well as in resource-constrained communities.

Timeline

FY 2002
- Fund initiatives to
  - Continue the Women's and Infants Transmission Study (WITS) to study the impact of HIV infection on HIV-infected women and their infants.
  - Continue the HPTN to study methods of preventing perinatal transmission of HIV.
  - Renew the PACTG to evaluate treatments for HIV-infected children and adolescents, and for developing new approaches for the interruption of mother-to-infant transmission.

FY 2003
- Fund initiatives to
  - Continue the PACTG.
  - Continue the WITS.
  - Continue the HPTN.

FY 2004-FY 2006
- Release new, expansion, and renewal initiatives as appropriate.
- Fund applications pursuant to ongoing initiatives.
- Fund related investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Publication of scientific advances relevant to perinatal transmission of HIV/AIDS.
- Availability of new and improved antiretroviral treatments for testing.
- Interest of industry and governments in producing HIV/AIDS therapeutics.

Area of Emphasis: I.B. Organ Transplantation

Illnesses such as kidney failure, diabetes, leukemia, coronary disease, and liver disease affect millions of Americans. For many of these patients, organ, tissue, or cell transplantation would prevent, and in some cases reverse, the severe outcomes of these diseases. Between 1990 and 1999, the number of transplant procedures increased by 59 percent, and today, transplants are performed using more than 25 different organs and tissues, with first-year graft survival rates often exceeding 80 percent. Despite these successes, two major impediments remain—the critical shortage of donor organs (more than 75,000 patients are on organ waiting lists) and immune-mediated graft rejection.

Organ transplantation represents a key health disparity for African Americans. Health experts have shown that African Americans are less likely to be identified as candidates for renal transplantation or to find a suitable donor, and tend to remain longer on transplant waiting lists. There is a lower organ donation rate among African Americans, compared with other racial groups, although African Americans comprise approximately 35 percent of patients on the renal transplant waiting list.

Successful transplantation depends on the availability of donated organs and accurate methods to match donor and recipient HLA types. Recognizing that knowledge of the relevant HLA types in minority populations is incomplete, NIAID supports efforts to improve the definition of ethnically restricted HLA genes. NIAID also supports a national program to identify HLA genes in African-American, Native-American, and Hispanic populations.

This program has led to the development of specific DNA reagents to further enhance HLA typing in minority populations and the definition of 13 new

HLA genes in African Americans and 3 new HLA genes in Native Alaskan Yupiks. These efforts have contributed to reducing incomplete tissue matching for transplant recipients.

Objective I.B.1. Support programs that would help reduce disparities by improving donor matching for organ transplantation through discovery of immune response gene variants in minority populations and development and application of advanced technologies for rapid donor-recipient matching

Action Plan I.B.1

Steps

1. Support research to identify and catalog new HLA genes in minority populations.
2. Encourage the development and application of DNA-based technologies to rapidly type HLA genes.

Timeline

FY 2002
- Support the 13th International Histocompatibility Working Group (IHWG) to standardize and improve histocompatibility testing worldwide through the discovery, development, and distribution of information and new tissue typing reagents. The IHWG is a network of more than 200 laboratories in more than 70 countries that collect and share data on genes of the HLA complex.
- Support the IHWG project to identify single nucleotide polymorphisms in immune response genes, which will increase our ability to accurately predict, diagnose, and ultimately treat immune-mediated diseases.
- Continue to support Small Business Innovation Research (SBIR) grants for the development and application of DNA-based technologies to rapidly type HLA genes.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2003
- Continue to support the IHWG.
- Continue to support SBIR grants for the development and application of DNA-based technologies to rapidly type HLA genes.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2004-FY 2006
- Continue to support the IHWG.
- Continue to support SBIR grants for developing DNA-based technologies to rapidly type HLA genes.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of meritorious awards.

Outcome Measures

- Presentation of significant findings at scientific meetings.
- Deposition of new allele sequence data in the World Health Organization (WHO) database and GenBank.

- 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.

Objective I.B.2. Support clinical studies on the immunological mechanisms of graft acceptance and rejection to address health disparities in minority populations

Developing new immunosuppressive medications has improved graft survival such that the one-year graft survival rates for some organs approach 90 percent. In addition, preliminary data indicate that dietary supplementation with omega-3 fatty acids may have a beneficial effect on kidney graft survival in African Americans. There are still significant differences, however, in acute rejection among ethnic and racial groups. African Americans mount more vigorous immune responses against transplanted organs than do other racial groups.

Action Plan I.B.2

Steps

1. Support research to identify differences in immune response genes in African Americans.
2. Support clinical research on the immunological mechanisms of acute and chronic graft rejection.
3. Conduct clinical trials of novel therapies to prevent acute and chronic graft rejection.

Timeline

FY 2002

- Initiate a clinical trial to evaluate the effect of dietary omega-3 fatty acids in kidney transplant recipients. In 1999, a 3-year clinical study by an NIAID-supported investigator indicated that canola oil (a source of omega-3 fatty acids) and arginine in addition to immunosuppressive therapy resulted in fewer graft rejection episodes and fewer rehospitalizations in kidney transplant recipients, especially among African-American patients.
- Initiate clinical trials through the Cooperative Clinical Trials in Adult Kidney Transplantation to
  - Determine the ability of intravenous immunoglobulin (IVIG) to lower allosensitization in patients with high titers of anti-HLA antibodies. A preliminary study has shown that treatment with IVIG can lower a patient's panel reactive antibody (PRA) titer, suggesting that IVIG may allow these patients to be more suitable candidates for organ transplantation. PRAs are antibodies against potential donor HLA molecules. African Americans have high titers of PRA.
  - Evaluate the safety and efficacy of kidney transplantation in HIV-positive patients with end-stage renal disease and the interactions between the antirejection and the antiviral therapies.

FY 2003

- Renew the Cooperative Clinical Trials in Pediatric Kidney Transplantation. This program examines the causes of decreased patient and graft survival rates in children versus adults and the effects of immunosuppressive therapy on growth retardation.
- Continue to solicit, review, and fund applications for novel tolerance induction regimens in kidney and islet transplantation through the Immune Tolerance Network (ITN). The ITN is an international consortium of more than 70 basic scientists and clinical investigators in 9 countries established to test promising tolerogenic treatment regimens in islet transplantation, kidney transplantation, autoimmune diseases, and asthma and allergic diseases. The ITN is cosponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Juvenile Diabetes Research Foundation International.

FY 2004-FY 2006

- Release new, expansion, and renewal initiatives as appropriate.
- Continue support for ongoing initiatives.
- Continue support for ongoing investigator-initiated research related to organ transplantation.
- Fund meritorious new investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Publication advances regarding developing non-invasive methods to detect organ graft rejection.
- Publication of results from assessment of outcomes in kidney transplant recipients receiving IVIG.
- Publication of results from analysis of therapeutic interventions for organ graft rejection in African Americans.
- Publication of findings on the effect of dietary modifications on organ graft survival in African Americans.
- Publication of analysis of patient and graft survival rates in children.

Area of Emphasis: I.C. 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 more than 5 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 an increased prevalence of SLE and rheumatoid arthritis among many Native-American tribes.

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 1 out of 2,000 Americans and is more common and more severe in African-American women, occurring in as many as 1 in 250 young African-American women. SLE is twice as 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. Experts estimate the number of Americans affected by scleroderma to range from 40,000 to 165,000. Systemic scleroderma affects more African-American women than women of European descent.

NIAID supports a broad portfolio of basic, pre-clinical, 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.

Objective I.C.1. Support research on the causes, treatment, and prevention of autoimmune diseases to help reduce disparities in the incidence and prevalence of these diseases that disproportionately affect minorities

Basic and clinical research—which advances our understanding of the underlying immune mechanisms of autoimmune diseases—is important to reduce disparities in the incidence and prevalence of these diseases. This research will provide insight into the mechanisms of tolerance induction and lead to developing and evaluating new immune modulation interventions to treat and prevent autoimmune diseases. Close, cross-disciplinary interactions between basic and clinical researchers are central to the success of translating basic research findings to clinical applications.

Action Plan I.C.1

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 studying and treating autoimmune diseases.
2. Support the design, conduct, and analysis of clinical trials to determine the safety and efficacy of hematopoietic stem cell transplantation as a treatment for multiple autoimmune diseases, including SLE and systemic scleroderma.
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 disease.

Timeline

FY 2002

- 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, knowledge that can be applied to developing therapeutic and preventive approaches.
- Continue support for the Autoimmunity Centers of Excellence (ACEs) clinical trials to evaluate immunotherapies for SLE and scleroderma. The ACEs support integrated basic, preclinical, and clinical research focused on tolerance induction and immune modulation to treat and prevent autoimmune diseases. The ACEs are cosponsored by NIDDK, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the Office of Research on Women's Health (ORWH).
- Initiate clinical trials of tolerogenic approaches through the ITN for autoimmune diseases, including those that disproportionately affect minority populations. The ITN is an international consortium of more than 70 basic scientists and clinical investigators in 9 countries, established to test promising tolerogenic treatment regimens in islet transplantation, kidney transplantation, autoimmune diseases, and asthma and allergic diseases. The ITN is cosponsored by NIDDK and the Juvenile Diabetes Research Foundation International.
- Continue support for multisite clinical trials for evaluating hematopoietic stem cell transplantation as a treatment for systemic autoimmune diseases, including those affecting minority populations. The Clinical Trials in Stem Cell Transplantation for the Treatment of Autoimmune Diseases support the development of effective approaches for treating and preventing autoimmune diseases. This program is cosponsored by the National Heart, Lung, and

Blood Institute (NHLBI), NIDDK, the National Institute of Dental and Cranofacial Research, NICHD, and ORWH.
- Fund the clinical coordinating center to support the ACEs and the Clinical Trials in Stem Cell Transplantation for the Treatment of Autoimmune Diseases.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2003
- Issue an initiative to renew the ACEs, including the clinical trials component testing immunotherapies for SLE and scleroderma.
- Continue support for Clinical Trials in Stem Cell Transplantation for Treatment of Autoimmune Diseases.
- Continue support for the clinical coordinating center to support the ACEs and the Clinical Trials in Stem Cell Transplantation for Treatment of Autoimmune Diseases.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2004-FY 2006
- Support new and renewal initiatives, as appropriate.
- Continue support for ongoing clinical trials.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

Performance Measures

- Presentation of significant findings and reports on progress at biennial meetings of the ACEs and at national scientific meetings.
- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Initiation of clinical studies and trials.

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 treating and preventing autoimmune diseases.
- Availability of applications of clinical trial results to the diagnosis, treatment, and prevention of autoimmune diseases.

Area of Emphasis: I.D. Asthma

Over the past few years, health experts have focused attention on the disproportionate burden of asthma on minorities, particularly African-American and Hispanic children residing in inner cities. Data on overall asthma prevalence and severity, and on the impact of asthma on minority populations, highlight the extreme burden of this disease in medical, economic, and social costs.

Asthma affects more than 14 million Americans, or approximately 6 percent of the population, resulting in more than 130 million days of restricted activity and nearly 500,000 hospitalizations annually. Poorly controlled asthma is the leading cause of school absenteeism and hospital admissions among children. Recent studies estimate that in certain urban areas between 20 and 25 percent of school children suffer from asthma. African Americans are hospitalized for asthma three times more often than other Americans, and African Americans and Hispanics living in inner cities are two to six times more likely to die from asthma.

It is particularly disturbing that, from 1980 to 1993, the death rate from asthma doubled for children 5 to 14 years of age. Over this same period, the disparity between the burden of asthma on African-American and white populations remained unchanged, or actually worsened, as was the case for emergency room visits. Furthermore, the costs associated with asthma are substantial. A rigorous economic study estimated 1990 costs at $6.2 billion in asthma-associated costs; more recent analyses estimate more than $11 billion.

Disadvantaged populations have not benefited fully from the scientific advances that have improved asthma treatment and management for middle- and upper-income populations. To address this disparity, in 1991 NIAID established the National Cooperative Inner-City Asthma Study (NCICAS), which demonstrated the efficacy of a multifaceted asthma educational intervention in reducing asthma severity among inner-city children. The Centers for Disease Control and Prevention (CDC) is implementing this educational and behavioral intervention at 23 community-based health organizations nationwide in a 4-year, $12 million program launched in FY 2001.

Building on the success of NCICAS, in 1996 NIAID and the National Institute of Environmental Health Sciences (NIEHS) established the Inner-City Asthma Study (ICAS) to evaluate the effectiveness of physician education and an extensive environmental intervention on asthma severity. In September 2001, researchers finished collecting the data and are now analyzing them.

Objective I.D.1. 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 two decades, understanding of the pathophysiology and management of asthma has improved significantly, yet the prevalence of this disease has increased by more than 80 percent in all age and ethnic groups. The increasing prevalence and high morbidity from asthma among inner-city children demonstrates the need for developing new therapies to both reduce asthma severity and prevent disease onset. Recent studies suggest that the stage is set for developing 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 developing asthma.

Action Plan I.D.1

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 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

FY 2002

- Fund the Inner-City Asthma Consortium: Immunologic Approaches to Reduce Asthma and the Statistical and Clinical Coordinating Center for the Inner-City Asthma Consortium.
  - The Consortium will support a network of basic scientists and clinical investigators to evaluate the safety and efficacy of promising immune-based therapies to reduce asthma severity and prevent disease onset in minority children residing in inner cities.
  - The Consortium will conduct research to delineate the mechanisms underlying immune-based therapies and develop and validate surrogate biomarkers to measure disease stage, progression, and therapeutic effect. Other studies will involve immunologic pathogenesis and population-specific aberrations in response to drug dosing or drug selection for optimal disease control.
- Continue support for the Asthma and Allergic Diseases Research Centers (AADRCs). The AADRCs are one cornerstone of the pathobiology component of the NIAID asthma and allergy research program. They support basic and clinical research on the mechanisms, diagnosis, treatment, and prevention of these diseases. Renewal of the AADRCs will emphasize clinical studies of the immunobiology of asthma, a focus that has great potential to benefit minority populations.
- Fund proposals for phase I and II trials of tolerance induction for allergic diseases. These trials will be conducted through the ITN, an international consortium of more than 70 basic scientists and clinical investigators in 9 countries established to test promising tolerogenic treatment regimens in islet transplantation, kidney transplantation, autoimmune diseases, and asthma and allergic diseases. It is cosponsored by NIDDK and the Juvenile Diabetes Research Foundation International.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2003

- Continue support for the Inner-City Asthma Consortium and the Statistical and Clinical Coordinating Center.
- Issue initiative to renew the AADRC program, with increased emphasis on clinical research and developmental immunobiology as it pertains to the early life origins of asthma in humans.
- Continue support for the AADRCs.
- Fund proposals for phase I and II trials of tolerance induction to allergens relevant to asthma.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

FY 2004-FY 2006

- Continue support for the Inner-City Asthma Consortium and the Statistical and Clinical Coordinating Center.
- Continue support for the AADRCs.
- Issue initiative to renew nine AADRCs.
- Fund proposals for phase I and II trials of tolerance induction to allergens relevant to asthma.
- Continue support for ongoing investigator-initiated research.
- Fund meritorious new investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.

- Funding of awards.
- Initiation of clinical studies and trials.

Outcome Measures

- Presentation of significant findings at scientific meetings.
- Presentation and publication of clinical trials results.
- Presentation and publication of scientific advances in basic and clinical research studies.
- Identification and evaluation of new approaches for treating and preventing asthma.
- Applications of clinical trial results to diagnosing, treating, and preventing asthma in underserved populations.

Area of Emphasis: I.E. Tuberculosis

A number of factors have combined to cause a disproportionate impact of *Mycobacterium tuberculosis* among minorities and low socioeconomic populations in the United States. Foreign-born minorities who have emigrated from tuberculosis (TB) endemic countries may harbor TB infection or active disease. In addition, the problems of urban poverty, high HIV infection rates, and the effects of household crowding may converge to increase the incidence of TB disease in this population. During 1999, approximately 76 percent of active TB cases were reported among racial and ethnic minorities. Worldwide, TB is the leading cause of death for people infected with HIV and 15 percent of HIV-positive individuals die of TB, according to WHO.

NIAID supports an extensive portfolio of TB research aimed at improving diagnosis, prevention, and treatment of TB in minority populations. NIAID's Tuberculosis Research Unit (TBRU) encompasses an international, multidisciplinary team of collaborators who translate basic TB research findings into improved clinical tools and strategies. TBRU-initiated studies develop or evaluate a variety of new assays, markers, prevention strategies, and treatments. A new drug, now under study, that needs to be taken less often would help solve compliance problems that currently exist within minority populations. A shortened therapeutic regimen is also being tested for efficacy in a clinical trial. In addition, NIAID supports epidemiologic studies to better understand the genetic and environmental factors that contribute to TB disease susceptibility and transmission.

Objective I.E.1. Support research on vaccines that would help reduce disparities in the incidence and prevalence of TB

A widely delivered vaccine that effectively prevents adult pulmonary TB would dramatically reduce the burden of this disease in minority populations and the health disparities associated with TB. Effective immunotherapeutic agents that prevent those with latent TB infection from developing active disease or that would be given to TB patients in addition to standard TB therapy to speed and improve cure rates would also be important advances to help reduce health disparities.

Action Plan I.E.1

Steps

1. Support preclinical and clinical research to develop TB vaccine candidates.
2. Support studies of host and pathogen genetic contributions to TB susceptibility and resistance and epidemiologic studies of transmission, incidence, and prevalence within high burden populations.
3. Conduct clinical trials of safety, immunogenicity, and efficacy of TB vaccine and immuno-therapeutic candidates.

Timeline

FY 2002
- Continue to support the TBRU and expand the TB Research Materials and Vaccine Testing contracts to increase vaccine research and development and related genetic and epidemiologic studies.
- Fund new initiatives to
  – Support development of novel TB vaccine candidates (Millennium Vaccine Initiative).
  – Elucidate the mechanisms underlying TB latency and reactivation disease so that novel vaccine candidates can target the large number of minorities already infected with *M. tuberculosis* and at risk for developing active disease (Response to the Presidential Vaccine Initiative—Overcoming the TB Latency Challenge).
- Fund applications pursuant to ongoing related initiatives, such as the Challenge Grant, "Development of a Recombinant Tuberculosis Vaccine" and "A Non-human Primate Model of TB and AIDS."
- Fund related investigator-initiated research.

FY 2003
- Fund an initiative to support development of new animal models for TB vaccine development.
- Continue to support the TBRU and expanded TB Research Materials and Vaccine Testing contracts.
- Fund applications pursuant to ongoing initiatives.
- Fund related investigator-initiated research.

FY 2004-FY 2006
- Release new, expansion, and renewal initiatives as appropriate.
- Fund applications pursuant to ongoing initiatives.
- Fund related investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Availability of new and improved vaccine candidates for testing.
- Publication of scientific advances related to TB vaccines.
- Interest of private and public sector partners in development of TB vaccines.

Objective I.E.2. Support research on improved therapeutic and diagnostic strategies that would reduce disparities in the incidence and prevalence of TB

Current recommended therapy for TB requires patients to adhere to long and complicated regimens (four drugs over 6 to 9 months). Developing new drugs that would simplify and shorten these regimens, providing effective treatments for drug-resistant TB, and shortening effective prophylactic courses for treating latent TB infection (which has relatively high prevalence in minority populations) would make major contributions to reducing health disparities in the treatment and cure of TB.

Action Plan I.E.2

Steps

1. Support research to discover, design, and develop novel TB therapies.
2. Support research to develop inexpensive, robust, sensitive, and specific diagnostics of TB infection and disease, especially for immunocompromised (for example, HIV-positive) individuals, in whom current diagnostics are inadequate.
3. Conduct clinical trials to determine safety and efficacy of novel therapeutic strategies.

Timeline

FY 2002

- Continue to support the TBRU and the TB Research Materials and Vaccine Testing contracts to increase the conduct of drug and diagnostics research and development.
- Support clinical trials of shortened regimens and novel therapeutic candidates under the TBRU.
- Fund an initiative to encourage Partnerships for Novel Therapeutics and Vector Control Strategies in Infectious Diseases.
- Fund applications pursuant to ongoing related initiatives, such as the Challenge Grants for TB drug development.
- Continue to support the TB Structural Genomics initiative to determine the 3-dimensional structure of 400 TB proteins, leading to discovery of novel drug targets.
- Fund drug- and diagnostics-related investigator-initiated research.
- Continue to conduct a TB telemedicine program through the NIAID Division of Intramural Research. The TB telemedicine program is a collaboration with physicians at South Texas Hospital. The majority of patients in this program are impoverished Mexican Americans from rural South Texas who receive state-of-the-art TB treatment from an NIAID TB expert and collaborators in Texas. Telemedicine technology allows the South Texas Hospital physicians and NIAID investigators to simultaneously interview and examine patients and study patient x rays, pathology, and laboratory tests. This program allows patients who normally would not have access to experimental therapies and clinical trials to benefit from the expertise and innovative approaches available at NIH.

FY 2003

- Fund a new initiative to support development of new animal models for TB drug development.
- Continue to support the TB Structural Genomics initiative to determine the 3-dimensional structure of 400 TB proteins, leading to discovery of novel drug targets.
- Continue to support drug-screening contracts. Southern Research Institute in Birmingham, Alabama, has established a Tuberculosis Antimicrobial Acquisition and Coordinating Facility (TAACF) to acquire compounds for screening against *M. tuberculosis*, maintain a computerized chemical database of compound structures, coordinate and distribute compounds for evaluation in vitro and in an animal model, and report data to suppliers.
- Continue to monitor progress under the Challenge Grants for TB drug development.
- Fund drug- and diagnostics-related investigator-initiated research.

FY 2004-FY 2006

- Release new, expansion, and renewal initiatives as appropriate.
- Fund applications pursuant to ongoing initiatives.
- Fund drug- and diagnostics-related investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Publication of scientific advances related to TB therapeutics and diagnostics.
- Availability of new and improved therapeutic candidates for testing.
- Interest of private and public sector partners in developing TB drugs and diagnostics.
- Identification of active anti-TB compounds in vitro.

- Evaluation of active compounds in preclinical and then clinical studies.

Objective I.E.3. Conduct tuberculosis epidemiology studies in an area with a high concentration of racial and ethnic minorities

The objective of this program is 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 better characterize TB transmission in this defined geographic area. Molecular subtyping of the TB organism can uncover previously unrecognized outbreaks and will lead to greater understanding of transmission dynamics among this population.

Action Plan I.E.3

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 *M. tuberculosis* 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 FY 2000.

FY 2002
- Maintain appropriate community liaisons to facilitate patient ability to participate in NIAID Division of Intramural Research programs related to *M. tuberculosis*. Facilitate patient participation by providing transportation for 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 tuberculosis patients and 250 control subjects. Interview patients using a standardized questionnaire designed to gather basic demographic and socioeconomic data and to identify TB risk factors.

FY 2003-FY 2006
- Collect clinical material and epidemiologic data from a minimum of 500 tuberculosis patients and 250 control subjects each year of the project.
- Conduct molecular characterization of *M. tuberculosis* strains from a minimum of 750 patients per year.
- Compile results and delineate molecular epidemiology and risk factors associated with TB transmission in this geographic area.

Performance Measures

- Number of subjects enrolled in the trial.
- Percentage of subjects that remain enrolled through trial completion.
- Completion of the trial.

Outcome Measures

- Publication of scientific advances regarding risk factors and transmission dynamics associated with TB in the population.

Area of Emphasis: I.F. Hepatitis C

Hepatitis C virus (HCV) is a blood-borne pathogen that infects the hepatocyte cells in the liver and causes liver damage. Populations at highest risk for this infectious disease are injection and cocaine drug users and individuals who received blood or blood products before 1992. Transmission more rarely occurs via sexual, body piercing/tattooing, and unknown routes. Approximately 3.9 million Americans show evidence of infection, with 74 percent being active carriers of the virus. U. S. population-based surveys indicate that HCV more heavily affects minority populations and people living in poverty. NIAID has calculated that 44.3 percent of HCV-infected individuals are minorities. In addition to a higher prevalence, the racial disparity is compounded for African Americans because they have a uniquely poor response to HCV therapies.

Viral genotyping and inherent genetic differences between whites and African Americans are coming to light to begin to explain these differences, but investigators need to look further, as part of the health disparities research plan.

Five years ago, NIAID took the lead and developed a Hepatitis C Framework for Progress that outlined the important research questions from the standpoint of its mission. In addition, experts developed a timeline to provide key resources and initiate research in specific areas. Two years ago, multiple NIH institutes and centers broadened this framework, incorporating their individual mission and mission-specific objectives.

Objective I.F.1. 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—extramural and intramural. They are presented separately in this document.

Objective I.F.1a. Extramural program in hepatitis C vaccine development

Vaccine development for HCV is primarily in a research and development phase. Extramural investigators are working to identify what composes the protective immune response. Focus areas include: defining early natural history; investigating mechanisms and correlates of recovery, persistence, and resistance; and identifying mechanisms of immune evasion. Investigators are employing several novel approaches to developing vaccine candidates.

Extramural investigators were the first to develop infectious clones—an advance that has significantly expanded the field. Investigators are working to develop key missing resources such as cell culture and small animal models. NIAID is supporting research studies in chimpanzees. In terms of clinical research, the study of newly infected individuals and natural history is an emphasis area. More than a decade ago, the National Institute on Drug Abuse (NIDA) initiated an HIV infection study in a group of injection drug users, which is 85 percent African American. Now, NIAID is funding research on acquisition of HCV in this group.

These investigators have successfully taken a multidisciplinary approach to understanding infection, natural history, and disease. Last year they published the finding that African Americans are more likely to

acquire HCV infection but that the disease progresses more slowly in this population. A similar approach is being taken to study acquisition of HCV in health care workers via needlestick exposures. Such studies are critical for understanding the immune response in its natural host.

Action Plan I.F.1a

The extramural action plan is guided by the Hepatitis C Framework for Progress.

Steps

1. Support development of animal models and other systems.
2. Support preclinical and clinical research to develop HCV vaccine candidates.
3. Support host and pathogen genetic contributions to HCV infection and disease progression outcomes.
4. Support both prophylactic and therapeutic clinical trials of safety, immunogenicity, and efficacy of HCV vaccine candidates.

Timeline

FY 2002
- Continue ongoing support to develop infection and disease preclinical models including cell culture, mouse, tamarin, and chimpanzee systems.
- Continue to fund research designed to understand host and viral components of recovery and persistence outcomes, resistance to infection, and mechanisms of protective immunity to HCV infections in animal models and humans.
- Continue to support preclinical vaccine efforts, including new construct development.
- Continue to collaborate with NIDA on international efforts focused on HCV acquisition in sex workers.
- Continue application of advanced technologies such as genomics, proteomics, and the use of overlapping peptides for vaccine development and host immune response studies.
- Begin to support the acquisition, production, and provision of research and reference reagents for the research community.
- Begin phase I evaluation, via the Collaborative Antiviral Studies Group (CASG), of a hepatitis C immunoglobulin to prevent reinfection of transplanted livers.
- Begin phase I evaluation of hepatitis C vaccine candidates in normal volunteers via the Vaccine and Treatment Evaluation Units (VTEUs).
- Plan phase I evaluation of vaccine candidates in HCV chronic carriers.
- Fund new initiative for cell and animal model development for hepatitis C.
- Fund recompetition of VTEUs.

FY 2003
- Continue above initiatives.
- Fund related investigator-initiated research.
- Expand the acquisition, production, and provision of research and reference reagents.
- Partner with industry involved in HIV vaccine research and development to apply the same novel technologies such as human cytotoxic T lymphocytes epitope strategies and vector development to HCV.
- Expand activities to understand mechanisms of recovery, persistence, and resistance to HCV infection as well as disease progression.
- Begin phase I evaluation of HCV vaccine candidates for treating chronic carriers.

FY 2004-FY 2006
- Continue above.
- Fund related investigator-initiated research.
- Release and fund new, expansion, and renewal initiatives.

Objective I.F.1b. 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 developing a safe and effective hepatitis C vaccine. The action plan for hepatitis vaccine development is based on NIAID's Hepatitis C Framework for Progress, developed by a panel of expert scientists, including representatives who are implementing this plan in NIAID intramural laboratories.

Action Plan I.F.1b

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.

Timeline

FY 2002

- Develop capabilities for studies and evaluation in human acute infection cohorts and include specimen collection and repository capabilities. Continue examining the genetic heterogeneity of HCV isolates and the implications of that heterogeneity on disease outcomes by launching studies to delineate the immunological mechanisms behind genetically based differences in disease outcome.
- Take advantage of infectious cDNA clones and viral pools. The availability of chimpanzees and titered challenge pools of polyclonal and monoclonal HCV has permitted researchers to dissect the immune response to HCV infection. These ongoing studies are yielding important information about the role of humoral and cellular immunity, cytokines, and other biologically active substances in controlling HCV infections.
- Develop and make available a standardized set of viral reagents for use in evaluating human immune responses, to include HCV antibodies and cDNA clones and confirming sequences in databases. Prototype strains of the various genotypes of HCV, including some of those discovered in the NIAID Laboratory of Infectious Diseases, have been biologically amplified in chimpanzees and packaged and distributed for use as challenge inocula in various studies, including studies of passive and active immunoprophylaxis. This work is ongoing.

FY 2003-FY 2006

- Continue to use infectious cDNA clones and viral pools and to develop and make available a standardized set of viral reagents for use in evaluating human immune responses to include HCV antibodies and cDNA clones and confirming sequences in databases.
- Characterize immune response in the chimpanzee—the only existing model. Full-length cDNA clones of HCV (genotypes 1a, 1b, and 2a) have been constructed and transcribed RNA used to transmit hepatitis C to chimpanzees by in vivo hepatic transfection. Researchers are following chimpanzees, transfected with infectious cDNA clones of HCV, to determine the natural history of infection.
- Develop, characterize, and comparatively evaluate model systems of infection, both tissue culture and small animal models. Exploit appropriate models

for immune response research and vaccine evaluation. NIAID investigators have constructed an infectious cDNA clone of GB virus-B (GBV-B), a monkey virus that is the closest relative to HCV. In addition, they have prepared challenge pools of GBV-B and have determined the infectivity titer of these in tamarins. They will continue to use the GBV-B tamarin system to study characteristics of the virus that it shares with HCV.

- Provide for detailed, multiple, and iterative vaccine approaches and detailed immune response studies. NIAID intramural investigators will employ challenge pools of polyclonal virus, representing each of the major genotypes, in vaccine evaluation studies and will supply these pools to extramural laboratories as a service to the scientific community.
- Use basic and clinical research results to devise ever more rational vaccination strategies.
- Promote development of better methods to study the immune response.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Addition of research and reference reagents.
- Funding of awards.
- 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 vaccine.

Outcome Measures

- Publication of scientific advances.
- Application of new technologies.
- Availability of new candidate vaccines for testing.
- FDA licensure of effective hepatitis vaccine.

Objective I.F.2. Support research on improved therapeutic strategies for hepatitis C and related areas that would reduce disparities in treatment outcomes

NIAID's "bench-to-bedside" focus supports a wide range of research, development, and evaluation activities. Based on NIAID's Hepatitis C Framework for Progress, there is special emphasis on understanding viral replication and discovery of new therapeutic targets, availability of both preclinical and clinical resources to accurately evaluate the safety and effectiveness of candidate drugs, and understanding the mechanisms of viral clearance.

Two of the nine Hepatitis C Cooperative Research Centers have disease progression and therapy clinical projects specifically focused on minority populations. One center is looking at long-term natural history and disease progression in a well-defined Alaskan-Native cohort. A second center, new from the latest recompetition, is performing a clinical trial in HCV chronic carriers using pegylated interferon and ribavirin. They are over-sampling African Americans, seeking to enroll 75 African Americans and 50 whites. The trial is powered to provide more definitive evidence related to response rate differences. In addition to clinical outcome, a multidisciplinary group of investigators will investigate virological and host differences (for example, immunological and genetic) between the two groups.

Finally, a third center plans an early phase clinical trial to evaluate a novel immunomodulatory adjunct to improve standard therapy. In addition, NIAID is providing funding for NIDDK's HALT-C trial. These efforts are focused on understanding the virological and immunological responses and their association with recovery and disease progression. If more successful therapeutic modalities can be identified, the prevalence of hepatitis C will decrease.

Action Plan I.F.2

Steps

1. Support model system development.
2. Support understanding of viral replication.
3. Support development of new therapeutic modalities.
4. Perform preclinical evaluation of candidate antivirals.
5. Support research focused on host and pathogen genetic contributions to and mechanisms involved in sustained elimination of HCV in response to therapy.
6. Support research on early predictors of both disease progression and sustained response to therapy.
7. Support clinical trials of new antivirals, immunomodulators, and therapeutic vaccines.

Timeline

FY 2002
- Continue to support ongoing development of infection and disease preclinical models including cell culture, mouse, tamarin, and chimpanzee systems.
- Fund new initiative for cell and animal model development for hepatitis C.
- Promote and fund evaluation of candidate therapies in preclinical models.
- Continue to fund research on viral replication.
- Continue to fund research on mechanisms involved in determining response versus nonresponse to therapy.
- Continue to support preclinical development of new therapeutic strategies.
- Continue to apply advanced technologies such as genomics, proteomics, and the use of overlapping peptides for therapeutics development and host immune response studies.
- Initiate novel combination treatment trial.
- Begin to support the acquisition, production, and provision of research and reference reagents for the research community.
- Continue evaluating therapies in HIV/HCV co-infections.
- Plan phase I evaluation of a vaccine as a therapeutic strategy.
- Recompete and expand the Collaborative Antiviral Testing Groups to include HCV.
- Recompete the Collaborative Antiviral Studies Group.

FY 2003
- Continue initiatives above.
- Fund related investigator-initiated research.
- Expand the acquisition, production, and provision of research and reference reagents.
- Begin phase I evaluation of HCV vaccine candidates for treating chronic carriers.
- Fund the Collaborative Antiviral Testing Group and the Collaborative Antiviral Studies Group.

FY 2004-FY 2006
- Release and fund new, expansion, and renewal initiatives.
- Fund related investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Addition of research and reference reagents.
- Funding of awards.
- Initiation of clinical trials.

Outcome Measures

- Publication of scientific advances related to HCV replication and therapeutics including development and use of model systems for preclinical antiviral development and increased understanding of the

host and viral parameters involved in sustained response to therapy.
- Availability of new technologies for application.
- Availability of new candidate therapies for testing.

Area of Emphasis: I.G. Sexually Transmitted Diseases

The current sexually transmitted disease (STD) epidemic in the United States disproportionately affects minority populations. Recent studies indicate that the more prevalent non-ulcerative STDs (such as chlamydial infection, gonorrhea, and trichomoniasis) as well as ulcerative diseases (genital herpes, syphilis, and chancroid) increase the risk of HIV transmission by at least three- to five-fold. Although chlamydial infection, human papillomavirus (HPV) infection, and genital herpes are widespread across racial and ethnic groups, STD rates tend to be higher among African Americans than whites. For genital herpes, one study determined that African Americans accounted for 60 percent of cases in STD clinics. Reported rates for gonorrhea and syphilis have been shown to be as much as 30 times higher for African Americans than for whites. Based on data for 1999, when all reportable STDs are combined, African Americans and Hispanics account for 45 percent of all STDs.

The long-term consequences, as well as the incidence of STDs, are higher among nonwhites 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 the reported clinic visits for pelvic inflammatory disease (PID). A disease of the upper reproductive tract, PID is primarily caused by sexually transmitted bacterial infections. Moreover, women in these populations suffer more often from cervical cancer, a sequela of HPV infection.

Among all populations, adolescents bear an enormous burden of STDs. In 1998, 64 percent of the 14 million new STD cases occurred in young people under age 24, with more than 3 million cases occurring in teenagers.

Objective I.G.1. Support research on therapeutics that would help reduce disparities in the incidence and prevalence of syphilis

In 1999, syphilis rates among African Americans were more than 30 times greater than the rate of infection among non-Hispanics whites, which was 0.5 per 100,000. Based on 1999 data, minorities account for approximately 75 percent of all reported cases of syphilis. This makes syphilis a serious health concern in this population. [NOTE: CDC's STD Surveillance 1999 Report notes that its surveillance data are based on cases of STDs reported to state and local health departments. In many areas, reporting from public sources, for example, STD clinics, is more complete than reporting from private sources. Since minority populations may use public clinics more than whites, the differences in rates between minorities and whites are potentially misleading.]

Action Plan I.G.1

Steps

1. Intensify efforts to assess new, easy-to-administer treatments for syphilis and gonorrhea such as a single-dose oral therapy that will increase compliance among affected populations for that disease.
2. Collaborate with CDC on research activities related to the Syphilis Elimination Plan.

Timeline

FY 2002
- Support a large efficacy study examining azithromycin for treating syphilis.
- Support research on cutaneous immune response in early syphilis.
- Support relevant investigator-initiated research.

FY 2003
- Continue efficacy study for treatment of syphilis.
- Support additional relevant investigator-initiated research.

FY 2004-FY 2006
- Complete azithromycin efficacy trial for syphilis and analyze data.
- Recompete STD Clinical Trials Unit.
- Continue to support relevant investigator-initiated research.

Performance Measures

- Identification and testing of new treatment modalities for syphilis and gonorrhea.
- Additional awards for research and clinical programs in syphilis and gonorrhea.

Outcome Measures

- Availability of new treatment modalities for syphilis and gonorrhea.
- Publication of scientific advances relevant to syphilis and gonorrhea.

Objective I.G.2. Support research on vaccines that would help reduce disparities in the incidence and prevalence of STDs

A widely delivered vaccine that effectively prevents STDs would dramatically reduce the burden of these diseases and the health disparities associated with them in minority populations.

Action Plan I.G.2

Steps

1. Stimulate syphilis vaccine development by analyzing the newly sequenced genome of *Treponema pallidum*.
2. Stimulate development of vaccines against genital herpes, gonorrhea, and chlamydial infection.

Timeline

FY 2002
- Continue to support grants for developing vaccines to prevent chlamydial infections and gonorrhea.
- Support an efficacy trial of a herpes vaccine.
- Support relevant additional investigator-initiated research.

FY 2003
- Continue to support grants for developing vaccines for STDs.
- Continue efficacy trial of herpes vaccine.
- Continue to support relevant investigator-initiated research.

FY 2004-FY 2006
- Recompete the STD Cooperative Research Centers grant program.
- Continue to support relevant investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards for vaccine research in STDs.
- Initiation of clinical trials.

Outcome Measures

- Availability of new STD vaccine candidates for testing.
- Publication of scientific advances relevant to STDs.

Objective I.G.3. Support intervention/ prevention/behavior studies to help reduce disparities in the incidence and prevalence of STDs

Intervention/prevention/behavior research is a high priority for NIAID. The spiraling acute and chronic morbidity of STDs, particularly among minority populations, provide a clear rationale for developing better, more effective strategies to prevent these diseases.

Action Plan I.G.3

Steps

1. Develop studies to examine strategies for intervening and preventing STDS. These include exploring the impact that restoring normal vaginal flora has on the frequency of STDs and evaluating douching as a risk factor for pelvic inflammatory disease in African-American women.
2. Expand the understanding of factors that contribute to high-risk sexual behavior in African-American and Hispanic women.
3. Evaluate behavioral approaches to STD prevention and control in inner-city high schools.
4. Conduct clinical studies of African-American adolescents that will identify behavioral and cultural risk factors for acquiring STDs.

Timeline

FY 2002
- Continue to support the STD Cooperative Research Center focused on preventing STDs. Through this center, two studies examining strategies for preventing bacterial vaginosis, genital herpes, and chlamydial infections will be conducted.
- Continue to support the STD Cooperative Research Center focused on multidisciplinary research on sexual behavior, clinical epidemiology, immuno-biology, and pathogenesis of gonococcal and chlamydial infections.
- Continue to support the STD Cooperative Research Center program with emphasis on research into more effective interventions for preventing STD morbidity in adolescents.
- Continue to support a longitudinal study to examine social and sexual networks of Hispanic adolescents in San Francisco.
- Continue to support research on STD risks associated with adolescent sexual networks.
- Continue to support additional relevant investigator-initiated research.

FY 2003
- Complete a longitudinal study to examine social and sexual networks of Hispanic adolescents in San Francisco.
- Continue to support additional relevant investigator-initiated research.

FY 2004-FY 2006
- Recompete the STD Cooperative Research Centers grants program.
- Continue to support relevant investigator-initiated research.

Performance Measures

- Publication of initiatives in the NIH Guide and the Commerce Business Daily.
- Funding of awards.
- Initiation of clinical trials and evaluations of behavioral interventions.

Outcome Measures

- Publication of scientific advances related to STD therapeutics, vaccines, diagnostics, and behavioral interventions.
- Availability of new and improved therapeutic candidates for testing.
- Interest of private and public sector partners in developing STD drugs, diagnostics, and behavioral interventions.

II. RESEARCH INFRASTRUCTURE AND TRAINING

Intellectual talent propels the research enterprise. As long as some minorities are underrepresented among immunology and infectious disease researchers, training and developing the careers of members of those populations will be an NIAID priority. NIAID supports a comprehensive portfolio of biomedical and behavioral research aimed at addressing health disparities through capacity building. These activities include

1. Fostering infrastructure development.
2. Promoting the training and career development of minority investigators.
3. Stimulating interest in the biomedical sciences among young minority students.

Area of Emphasis: II.A. Research Infrastructure of Minority Institutions and Research Careers of Minority Investigators

NIAID is strongly committed to increasing the number of minority researchers in all areas of science within its mission. This commitment arises from realizing that scientists from all segments of U.S. society can and should contribute to eliminating health disparities which exist in this country. As a result, NIAID supports a wide spectrum of activities to develop infrastructure at minority institutions, as well as fostering the careers of minority investigators to increase their competitiveness within the research community. These programs are designed to insure that an increasing number of qualified minority researchers become productive and remain in the areas of NIAID-funded biomedical research.

Objective II.A.1. Support research infrastructure development of minority colleges and universities through the Research Centers in Minority Institutions program and the Minority Biomedical Research Support program

The ability of the United States to address health disparities is directly related to the capacity of minority institutions to conduct biomedical and behavioral research. The Research Centers in Minority Institutions (RCMI) program has been administered by NIH's National Center for Research Resources since 1990. The program supports predominantly minority health professional schools and graduate institutions in the health professions and health-related sciences. Under the RCMI program, NIAID funds the AIDS infrastructure initiative, which seeks to expand physical facilities and faculty competence in virology, immunology, molecular biology, and neurobiology. The purpose of NIAID support is to enable minority institutions to join mainstream AIDS research at the national and international levels. NIAID funding of RCMIs is particularly timely because the institutions are located in communities in which the AIDS epidemic has hit particularly hard.

The Minority Biomedical Research Support (MBRS) program awards grants to colleges, universities, and health professional schools with at least 50 percent minority student population. This program supports developing biomedical research faculty by funding faculty-initiated research projects, faculty salaries, and salaries of support staff. The program also supports infrastructure development by providing funds to purchase equipment and renovate facilities. Finally, the program awards grants to biomedical research institutions to be used for tuition remission

of minority graduate students. This program is administered by the National Institute of General Medical Sciences (NIGMS) and NIAID. Other NIH institutes participate by providing funds.

Action Plan II.A.1

Steps

Fund efforts to build infrastructure capacity and faculty competence in minority institutions that conduct biomedical and behavioral research.

Timeline

FY 2002
- Continue to support AIDS studies in at least six minority institutions, three of which are historically black colleges, through the RCMI program.
- Continue to provide funds for the MBRS program.

FY 2003-FY 2006
- Increase the number of minority institutions participating in the RCMI program.
- Continue to provide funds for the MBRS program.

Performance Measures

- Number of RCMIs supported.
- Number of researchers supported under this mechanism.
- Performance measures for the MBRS program are addressed in the NIGMS strategic plan.

Outcome Measures

- Number of AIDS research grants awarded to minority researchers at RCMIs.
- Collaborative partnerships between junior minority researchers at RCMIs and NIAID-supported researchers to foster mentoring relationships and sharing of scientific expertise.
- Outcome measures for the MBRS program are addressed in the NIGMS strategic plan.

Objective II.A.2. Support career development of minority scientists through the Research Supplements for Underrepresented Minorities program

The Research Supplements for Underrepresented Minorities (RSUM) program supports minority students and scientists who work with independent researchers supported by NIAID-funded research project grants. NIAID will closely monitor this cadre of young investigators to insure they continue to progress in their chosen areas of research.

Action Plan II.A.2

Steps

1. Continue advertising the RSUM mechanism at scientific conferences attended by minority students and professionals as well as on the NIAID Web site.
2. Establish a database to record and track the RSUM awardees funded by NIAID for success in receiving an NIH Independent Researchers Award (R01).

Timeline

FY 2002
- Continue to fund and support 80 percent of applications received for this mechanism, with the expectation that a larger number will be funded because of a larger applicant pool.

FY 2003-FY 2006
- Continue to fund and support 80 percent of applications received for this mechanism, with the expectation that a larger number will be funded because of a larger applicant pool.

Performance Measures

- Number of RSUMs supported in FY 2003.
- Number of researchers supported under this mechanism.
- RSUM tracking database operational by end of FY 2003.

Outcome Measures

- Progress of grantees as documented by established methods such as quarterly performance reports.
- Success of award recipients in securing NIH research grant support at the conclusion of their supplemental award.

Objective II.A.3. Support early career development of minority scientists through the Enhancement Awards for Underrepresented Minorities

NIAID supports a number of programs to foster the career development of minority scientists and increase their competitiveness within the research community. These programs are designed to insure that qualified minority researchers become productive and remain in areas of NIAID-funded biomedical research. NIAID aims to increase its commitment in this area by initiating a new award.

Action Plan II.A.3

Steps

1. Initiate and fund a new enhancement award for underrepresented minority scientists.
2. Broadly advertise new initiatives to generate enough applications to insure the success of the initiative.
3. Target advertising to minority investigators to encourage their participation in the scientific agenda.

Timeline

FY 2002
- Issue Program Announcement for Underrepresented Minority Scientists Enhancement Award.

FY 2003-FY 2006
- Make awards from applicant pool. Anticipate funding four 4-year awards.

Performance Measures

- Funding of four awards in FY 2003.

Outcome Measures

- Monitor progress of grantees by established methods such as quarterly performance reports.
- Success of award recipients in securing an NIH research grant support in FY 2007.

Objective II.A.4. Foster the career development of minority graduate students and postdoctoral trainees through the Bridging the Career Gap program

In 1993, NIAID launched the Bridging the Career Gap program, with the goal of giving young minority investigators the tools and information needed to carve out successful careers in biomedical research. This biennial program brings young NIAID-supported minority scientists to NIH. The 2-day seminar addresses career choices, networking, the importance of selecting the right mentor, and the NIH grant system and components. NIAID staff work very closely with many of these students throughout the various phases of their careers. Celebrating its fifth anniversary in FY 2002, this program will be repeated in FY 2004 and FY 2006.

Action Plan II.A.4

Steps

1. Encourage young minority scientists receiving NIAID support to attend the NIAID Bridging the Career Gap Seminar.
2. Fund travel expenses of participants.

Timeline

FY 2002
- Bridging the Career Gap Seminar held on October 4-5, 2001. Feedback from participants validates continuing this initiative in FY 2004.

FY 2003-FY 2006
- Encourage young minority scientists receiving NIAID support to attend the Bridging the Career Gap Seminar in FY 2004 and FY 2006 in an effort to increase attendance.

Performance Measures

- Attendance numbers.

Outcome Measures

- Views and opinions of attendees gathered at the conclusion of each Bridging the Career Gap Seminar.
- Success rate of attendees in later securing NIH research grants.

Objective II.A.5. Ensure that the career development of young, independent minority investigators is fostered through the use of regular research award mechanisms

NIAID will increase funding of minority scientists applying for research grants by using current grant mechanisms. The amount of funding dedicated specifically to this purpose varies according to the meritorious applicants in the pool. NIAID has taken strong measures to insure that funding for minority scientists is increasing. This has been incorporated into the spending plans of NIAID FY 2002-FY 2006 appropriations.

Action Plan II.A.5

Steps

1. Advertise Program Announcements, Requests for Applications, and Requests for Proposals through various media and conferences to insure wider audience of minority scientists.
2. Adapt award mechanisms to foster support of minority researchers—Research Scholar Development Award (K22). The K22 program supports postdoctoral trainees as they make the transition to assistant professor positions in academic institutions. This mechanism's eligibility criteria have been modified to include minority postdoctoral trainees supported on RSUMs.

Timeline

FY 2002-FY 2006
- Increase advertising of the program via NIH and NIAID Web sites, professional journals, and promotions at scientific meetings.
- Continue to use existing mechanisms to fund minority investigators.

Performance Measures

- Number of new placements of advertisements of research initiatives that target minority investigators.

Outcome Measures

- Number of awards to underrepresented minorities.

Area of Emphasis: II.B. Research Training for Minorities

NIH and NIAID training programs are designed to guarantee the pool of qualified researchers this country needs to remain at the forefront of scientific discovery. A well-trained cadre of minority researchers who bring a special blend of cultural knowledge and intellectual interest is required to address and resolve health disparities issues. NIAID hopes that an increase in the number of minority investigators participating in its scientific agenda will provide the level of minority presence needed to ensure that the agenda appropriately targets minority concerns and that clinical research is designed to respond to the needs and concerns of minority populations. This, in turn, would increase the benefits of research efforts to those communities. Training efforts focus on NIAID intramural and extramural programs.

Objective II.B.1. Provide intramural research training opportunities for minorities

NIAID will continue and expand its highly successful mechanism of recruiting minority pre- and post-doctoral scientists into its intramural research laboratories. Special seminars and events are planned for minority program trainees to enrich their research experience and their professional development.

Action Plan II.B.1

Steps

1. Develop office infrastructure to support outreach, recruitment, and program management.
2. Develop national recruitment contacts.
3. Enrich NIAID training experiences for minority scientists.
4. Increase the number of sponsored minority postbaccalaureate and postdoctoral Intramural Research Training Awards (ITRAs).
5. Track graduates of minority training programs for program evaluation, networking, and recruitment contacts.
6. Inform scientists about NIAID diversity issues and progress.

Timeline

FY 2002

- Expand office staff to include program assistant and program analyst.
- Develop and test data management systems; enter information for minority trainees and summer interns (approximately 200 records).
- Develop a national database of recruitment contacts.
- Develop relationships with universities serving minorities to inform them about programs and identify students interested in NIAID programs.
- Create an Office of Special Emphasis Web page with key links.
- Initiate annual reports to NIAID laboratory chiefs regarding Division of Intramural Research (DIR) diversity issues and progress.
- Increase the number of sponsored minority postbaccalaureate IRTAs from five to seven.
- Plan four to six seminars for minority trainees. Videoconference to include NIAID Rocky Mountain Laboratories (RML) in Hamilton, Montana.
- Plan and conduct a one-day retreat for minority trainees focusing on NIAID's scientific challenges. RML minority trainees to attend.
- Write report based on the initial tracking information, including results and recommendations for DIR minority programs.

FY 2003

- Expand office staff to include a program assistant for the Graduate Partnership Program. Role will include recruiting minorities to NIAID–university doctoral programs.
- Revise data management system and enter information for all DIR trainees, including pre- and post-docs (approximately 600 records).
- Expand national recruitment contact database.
- Visit selected universities to meet with science professors and minority students to inform them about NIAID programs. Include current minority trainees in visits.
- Focus recruitment activities on increasing diversity at RML.
- Revise recruitment video and brochures.
- Increase the number of sponsored minority postbaccalaureate IRTAs from seven to nine.
- Plan four to six seminars for minority trainees. Videoconference to include RML.
- Develop newsletter for current and past NIAID minority trainees.
- Update tracking information.
- Hold diversity trainee program for DIR scientists.

FY 2004-FY 2006

- Increase the number of sponsored minority postbaccalaureate IRTAs from 9 to 10.
- Increase the number of sponsored minority postdoctoral IRTAs from five to seven.
- Plan four to six seminars for minority trainees. Videoconference to include RML.
- Update tracking information.
- Organize NIH workshop, Strategies for Increasing Diversity at NIH, using NIAID as the model.
- Hold retreat for past and current NIAID minority trainees (1996 to present).

Performance Measures

- Computerized data management system
  – Stores data on all DIR trainees.
  – Provides search-sort-report abilities.
  – Interfaces with other NIH databases.
  – Maintains contact with all DIR minority trainees (past and present) for newsletters and announcements.
  – Tracks career paths of minority program participants.
  – Maintains national recruitment database and tracks recruitment contacts.
- National recruitment database used by DIR for minority trainee and tenure track recruitment efforts.
- Minority trainee participation in seminars, workshops, and retreats.
- Tracking report assists office in program planning for minority trainees.
- Office of Special Emphasis visibility increased among DIR scientists and NIH community.

Outcome Measures

- Postbaccalaureate and postdoctoral minority programs expand significantly.
- Network of NIAID minority trainees established.
- Tenure track job postings yield qualified minority candidates.
- Article published about programs that successfully increase diversity in the scientific community.

Objective II.B.2. Support research training opportunities for minorities by providing extramural fellowships

NIAID will continue to support predoctoral research training for minorities through the National Research Service Award (NRSA) program. The NRSA Predoctoral Fellowships for Minority Students (F31) provide up to 5 years of support for education and research training leading to the Ph.D., M.D., or equivalent research degree. The fellowship covers student tuition and living expenses and provides

institutional allowance to help defray other student expenses such as supplies and travel.

NIAID also will continue to provide training opportunities through the Minority AIDS Training Program within the Adult AIDS Clinical Trials Group. This program recruits and trains minority health professionals (M.D.s) by providing postdoctoral fellowships for four minority clinical researchers each year.

Action Plan II.B.2

Steps

1. Use the F31 fellowship mechanism to fund minority predoctoral training.
2. Provide up to four fellowships per year to minority clinical researchers in HIV/AIDS research.

Timeline

FY 2002-FY 2006
- Continue to support F31 fellowships.
- Continue to offer up to four fellowships per year to minority clinical researchers.

Performance Measures

- The number of F31 fellowship awards.
- The progress of F31 fellows as documented in annual progress reports during the award period.
- The progress of Minority AIDS Training Program fellows as documented by established methods such as quarterly performance reports.

Outcome Measures

- Degrees attained by NIAID-funded F31 recipients.
- Participation of former fellows in research on microbiology, immunology, and infectious and immunologic diseases (participation indicated by grants awarded to, publications by), and specifically HIV/AIDS research, in the case of former Minority AIDS Training Program fellows.

Objective II.B.3. Support the beginning research careers of minority medical students by the use of Short-term Research Training Grants

NIAID will continue funding the Short-term Research Training Grant in STD Research at Howard University School of Medicine. This program works in partnership with the Sexually Transmitted Disease Cooperative Research Centers (STD-CRCs) and funds minority medical students' summer research activities at STD-CRC sites. By 2003, NIAID will use this model to establish similar programs in its other disease areas with institutions that focus on serving minority students.

Action Plan II.B.3

Steps

1. Initiate new Short-term Research Training Grants in the Division of AIDS and the Division of Allergy, Immunology and Transplantation for minority medical and graduate students.
2. Link training grants at majority NIAID Centers for Excellence to minority institutions.

Timeline

FY 2002
- Plan and develop new Short-term Research Training Grants in the Division of AIDS and the Division of Allergy, Immunology and Transplantation.

FY 2003-FY 2006
- Implement and award new Short-term Research Training Grants in the Division of AIDS and the Division of Allergy, Immunology and Transplantation.

Performance Measures

- Number of Short-term Research Training Grants awarded to minority institutions.
- Number of minority medical students exposed to areas within NIAID's scientific programs, through Short-term Research Training Grants.

Outcome Measures

- Number of Short-term Research Training Grant participants who eventually participate in biomedical research.

Area of Emphasis: II.C. Stimulating Interest in the Biomedical Sciences and Biomedical Research Careers Among Minority Students

NIAID has long recognized that increasing the participation of minorities in science requires attention to the pipeline of students who have not yet made career decisions. NIAID has supported programs that address several segments of the pipeline from undergraduates on the cusp of career decisions to students in precollege programs. These efforts aim to interest minority students in training for research careers.

Objective II.C.1. Support the Introduction to Biomedical Research Program (IBRP) in order to stimulate minority student interest in research careers

The Nation's biomedical research agenda requires using every segment of its diverse population. Yet, the pipeline of minority scientists in the United States is so meager that minorities are underrepresented. This is quite notable within the ranks of NIH biomedical researchers where the representation of minority scientists is extremely low.

In FY 2002, NIAID's IBRP will have been in existence for 24 years. The program brings outstanding minority undergraduate and first-year graduate/medical students to the NIH campus for a week-long program of mentoring, advice, and scientific talks. NIAID staff work very closely with many of these students throughout the various phases of their careers.

Action Plan II.C.1

Steps

Continue to support the long-standing and highly successful IBRP program. Current plans provide for continuing it at least through FY 2006.

Timeline

FY 2002
- NIAID had intended to bring 60 academically outstanding underrepresented minority students to NIH/NIAID for a week of scientific seminars and exposure to biomedical research laboratories. Due to concern about the safety of air travel in the wake of tragic national events in September 2001, however, IBRP will have only 20 or 25 participants.

FY 2003-FY 2006
- Continue to support the IBRP program by bringing 60 underrepresented minority students to NIAID for a week of scientific seminars and exposure to biomedical research training.

Performance Measures

- Number of applicants.
- Number of attendees.

Outcome Measures

- Number of IBRP participants accepted into the NIAID Division of Intramural Research (or other NIH intramural programs) via the NIH Pre-intramural Research Training Initiative Program.
- Number of IBRP students accepted into the NIH/NIAID Intramural Summer Internship Program.
- Number of IBRP students accepted to graduate school in the biomedical sciences.

Objective II.C.2. Support the Temple University Longitudinal Initiative to increase the number of underrepresented minorities receiving advanced degrees in biomedical sciences

The Temple University Longitudinal Initiative (TULI) is a multiyear program, which selects its participants when they are in the 7th grade. (A few 8th, 9th, and 10th graders are occasionally admitted.) The students attend summer classes and apprenticeships at Temple University in Pennsylvania until they are in the 10th grade. From 11th grade until senior year in college, the students participate in summer internships at participating Canadian universities, a pharmaceutical company, and NIH. NIAID funds this program in collaboration with other NIH institutes and sponsors four internships in NIAID intramural laboratories.

Action Plan II.C.2

Steps

Continue to support the TULI program.

Timeline

FY 2002-FY 2004
- Continue to support the TULI program and provide internship positions in NIAID intramural laboratories.

FY 2005-FY 2006
- Consider renewal of support after examining the program's progress.

Performance Measures

- Number of participants.

Outcome Measures

- Bachelor of Science degrees earned by TULI participants.
- Matriculation of TULI participants in Ph.D. and M.D. programs.
- Number of TULI participants who successfully receive Ph.D. or M.D. degrees (very long-term outcome).

Objective II.C.3. Support the development of novel educational materials to stimulate high school student interest in science and research careers

NIAID will expand its efforts with the NIH Office of Science Education (OSE) to reach high school students through its scientific curriculum supplement, "Emerging Diseases." NIAID staff are members of the OSE Resource Group and will continue to participate fully in their ongoing activities.

In addition, NIAID will develop additional educational/outreach materials in Spanish, both in print and on the Web site.

Action Plan II.C.3

Steps

1. Work with OSE in broadcasting the existing NIAID curriculum on the Internet via an open classroom concept with the Public Broadcasting System (PBS).
2. Disseminate instructional materials to science teachers through the OSE Web site which was established for this purpose.

Timeline

FY 2002

- Begin discussions with OSE and PBS on establishing an open classroom concept with NIH/NIAID as the focus.
- Continue to support OSE's effort to disseminate NIAID's Curriculum Supplement as well as those of the other five participating institutes.

FY 2003-FY 2006

- Launch Open Classroom initiative with OSE in FY 2004, when all nine of the curricula are completed.

Performance Measures

- Establishment of an Open Classroom on PBS by 2004.
- Number of NIAID curricula (printed and/or electronic) distributed to national high schools.

Outcome Measures

- Number of viewers/participants of the NIAID segment of Open Classroom.
- Number of classes/teachers/students using the NIAID high school curricula.

III. EDUCATION AND OUTREACH

Area of Emphasis: III.A. Outreach and Transfer of Health Information to Minority Communities

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 finds out what features 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 that will 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 developing and disseminating 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 used as a reliable source of health information. The institute needs to strengthen and expand efforts to produce health information that is culturally appropriate and to ensure that the information is disseminated to appropriate communities. It is also critical to develop methods to assess the effectiveness of these outreach and communication efforts.

Objective III.A.1. Support the National HIV Vaccine Communications Outreach as part of interactions with minority populations

NIAID will continue to implement a national HIV vaccine trial communication effort to increase public understanding of HIV vaccine research and to facilitate recruitment and retention of volunteers in vaccine trials. This effort is critically important to ensure that the participants in NIAID clinical trials programs represent the affected racial/ethnic populations.

Action Plan III.A.1

Steps

1. Develop a broad-based, national, research-driven communications campaign with Ogilvy Public Relations Worldwide.
2. Develop messages through research, focus groups, and national surveys.
3. Build national community partnerships.
4. Launch a national education campaign.
5. Collaborate closely with the HVTN and the NIAID National HIV Vaccine Communications Steering Group.
6. Provide issues management support.

Timeline

FY 2002-FY 2003
- Continue the contract with Ogilvy Public Relations Worldwide.

FY 2004-FY 2006
- Release new or expansion HIV vaccine outreach initiatives, as appropriate.

Performance Measures

- Completion of research component of communications campaign.
- Launch of public awareness campaign.

Outcome Measures

- Increased support for HIV vaccine research in "at risk" communities.
- Successful recruitment and retention of vaccine study volunteers.

Objective III.A.2. Support programs that will help reduce disparities by improving donor matching for organ transplantation through donor outreach programs

Outreach is an essential complement to biomedical research in the effort to improve matching of donated organs with patients who need them. NIAID continues to support demonstration and education research projects to increase minority involvement in organ donor registries.

In Louisiana, the Legacy Donor Registry continues its efforts to increase organ donation by
- Expanding the range of the current registry with new and nontraditional approaches to increasing organ donor recruitment.
- Improving the consent process to enhance organ donations.
- Facilitating medical community access to donor registry information.

The Legacy Donor Registry began its Corporate Donor Program in 2000 and has conducted organ donation awareness events that reach major corporations and employers in Louisiana.

NIAID also continues to support the demonstration and education research project at the Hope Heart Institute to evaluate the effectiveness of a unique community-based outreach network to increase organ donation among minority populations in Seattle and Tacoma, Washington. This project involves

1. Developing and distributing educational materials in local neighborhoods and churches, using the services of VISTA (Volunteers In Service To America) volunteers recruited from targeted African-American and Asian communities.
2. Producing an educational video for local communities and schools.
3. Producing public service announcements for Department of Motor Vehicles offices.
4. Developing a computerized database of community residents to record donation preferences, educational levels, and medical histories.

A second research project of the Hope Heart Institute aims to increase organ donation among rural Alaskan Natives. Culturally sensitive educational materials and community health education programs are being developed on transplant options, and living and cadaveric organ donation for this population, including
- An educational video featuring Alaskan-Native transplant recipients and donor families.
- An attitudinal survey.
- Regional training for Native Corporation local health educators, community health aides, local school teachers, and regional hospital staff.

Action Plan III.A.2

Steps

Support donor registries to increase awareness of organ donation among minority groups.

Timeline

FY 2002
- Support demonstration and education research projects to increase minority involvement in organ donor registries.
- Legacy Donor Registry project increases minority involvement in organ donor registries by using new and non-traditional approaches for organ donor recruitment.
- Hope Heart Institute projects
  – Evaluate a unique community-based outreach network to increase organ donation among minority populations in Seattle and Tacoma, Washington.
  – Evaluate the effectiveness of culturally sensitive educational materials and community health education programs to increase organ donation among rural Alaskan Natives.

FY 2003
- Continue to support the Legacy Donor Registry project.
- Disseminate evaluation findings from the Hope Heart Institute projects.

FY 2004-FY 2006
- Continue to support the Legacy Donor Registry project.

Performance Measures

- Increases in minority organ donation (Legacy Donor Registry).
- Development of educational materials to increase organ donation awareness among minority populations (Hope Heart Institute projects).

Outcome Measures

- Publication of findings on effective means to increase organ donation in minority populations.
- Dissemination of educational materials that build on lessons learned by the Legacy Donor Registry and the Hope Heart Institute projects.

Objective III.A.3. Improve the access of racial and ethnic minorities to tuberculosis clinical trials

The objective of this program is to establish relationships with community-based, public health, and hospital-based clinics in the Washington, D.C., metropolitan area that are treating patients with TB to facilitate participation of these clinics in future NIAID basic studies and clinical trials.

Action Plan III.A.3

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 TB epidemic in these facilities located in 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 recruiting.
5. Recruit patients into TB clinical trials.

Timeline

This program began in 1999 and is slated to run through 2005.

FY 2002

- Maintain liaisons in one to six hospitals or public health department-based clinics that are diagnosing and treating at least three new cases of TB per month and one to three 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 DIR investigation of TB.
- Collect prospective data from these facilities on a yearly basis from available records to better characterize the ongoing TB epidemic where these facilities are located and in 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 multi-drug-resistant TB in these facilities.
- Develop informational brochures appropriate for patients and physicians at the participating facilities.

FY 2003-FY 2005

- Maintain liaisons in hospitals and public health department-based and community-based clinics.
- Continue collecting prospective data from these facilities yearly.
- Facilitate patient recruitment for DIR clinical studies and provide clinical material, clinical data, and epidemiologic data for both basic and clinical research studies.
- Arrange periodic meetings (approximately one every three months) with key staff of participating facilities to discuss program progress and any specific areas needing direction or attention.
- Maintain social work and community outreach programs to facilitate patients' ability to participate in NIAID DIR programs. Services must include collecting clinical and research specimens in the field and the ability to monitor and report on directly observed therapy. Programs may include providing transportation for patients to NIH and identifying incentives for study participants, such as providing daycare and meals.
- Provide laboratory and diagnostic tools for identifying *M. tuberculosis* from clinical specimens.
- Convene an annual one-day meeting of program contractor, participating clinics and hospitals, participating NIH intramural scientists, and other key personnel to discuss and share the progress and intended direction of the program.

Performance Measures

- Number of sites participating in program.
- Establishment of patient services to promote patient participation.
- Number of brochures distributed.

Outcome Measures

- Increased enrollment of ethnic and racial minorities in DIR TB clinical trials using 1999 as the base year.

Objective III.A.4. 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, Department of Health and Human Service (DHHS) sister agencies, non-governmental organizations (NGOs), 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, asthma and tuberculosis, illustrate NIAID partnerships.

The NIAID Inner-City Asthma Study was cofunded by NIEHS, and the U.S. Environmental Protection Agency jointly funded a substudy under that initiative. Also in the area of asthma, NIAID collaborated with NHLBI, Synermed Communications, the American Lung Association, and the American Academy of Family Practice (AAFP), to develop continuing medical education (CME) materials for primary care physicians on topics including asthma, sinusitis, otitis media, and allergic rhinitis.

NIAID support of the Tuberculosis Research Unit (TBRU) at Case Western Reserve University in Ohio is coordinated with other major organizations involved in TB research, including CDC, U.S. Agency for International Development, FDA, WHO, The Global Alliance for TB Drug Development, the International Union Against Tuberculosis and Lung Disease, and interested industrial partners.

Also, the NIAID Program Announcement "Collaborations for Advanced Strategies in Complications of HIV Infection" is cosponsored with four other NIH institutes—NIDDK, NIDA, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute of Mental Health.

Action Plan III.A.4

Steps

1. Invite other NIH institutes and centers or scientific organizations with similar research agendas to participate in the NIAID Introduction to Biomedical Research Program (IBRP) as guest lecturers and extend student one-on-one sessions with members of their scientific staff.
2. Seek input from program staff to identify appropriate organizations and societies.
3. Maintain existing partnerships.

Timeline

FY 2002

- Enter discussions with at least one institute or scientific organization, for example, the American Chemistry Association, to establish a scientific guest lecturer as part of IBRP seminar sessions and one-on-one sessions with scientific staff.
- Maintain existing partnerships.

FY 2003-FY 2006

- Expand IBRP one-on-one sessions to include one or two other NIH institutes/centers.
- Continue with an institute/center or scientific organization guest lecturer in the seminar sessions.
- Maintain existing partnerships.

Performance Measures

- Scientific guest lecturer incorporated into IBRP seminar segment.
- One-on-one interface sessions with other institutes and scientific organizations.
- Cosponsorship of initiatives, meetings, and workshops.

Outcome Measures

- Views and opinions of IBRP participants regarding the quality of the IBRP experience.
- Complementary activities across NIH, DHHS, and the Federal government.
- Complementary activities among government, NGOs, and industry.

Objective III.A.5. NIAID will continue to seek input and participation from diverse groups on its National Advisory Allergy and Infectious Diseases Council, as well as ad hoc community advisory boards, blue ribbon panels, and scientific workshops, in order to maximize and improve its health disparity agenda

Action Plan III.A.5

Steps

1. Seek input from the National Advisory Allergy and Infectious Diseases Council (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

FY 2002
- Present NAAIDC with NIAID's *Comprehensive Strategic Plan on Health Disparities* and seek comments.
- Present NIAID standing review committees and other ad hoc groups with NIAID's *Comprehensive Strategic Plan on Health Disparities* and seek comments.

FY 2003-FY 2006
- Use input and comments from NAAIDC, NIAID standing review committees, and ad hoc groups to improve NIAID's *Comprehensive Strategic Plan on Health Disparities*.
- Continue to seek input from NAAIDC, NIAID standing review committees, and ad hoc groups on matters pertaining to health disparities.

Performance Measures

- Substantive input, comments, and recommendations from NAAIDC, NIAID standing review committees, and ad hoc groups on NIAID's *Comprehensive Strategic Plan on Health Disparities*.

Outcome Measures

- Revisions to the NIAID *Comprehensive Strategic Plan on Health Disparities* and implementation of initiatives based on revisions to the plan.

Objective III.A.6. Support participation of NIAID scientists in the presentation of information to audiences in minority communities and expand the translation and dissemination of health information materials to high-risk populations, as part of the institute's efforts to reach minority populations

In 1998, NIAID intramural staff at RML began an outreach program for local public schools. In 2000, RML expanded the program to schools located in Native-American 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 about a decade, NIAID has written and published biennial booklets on minority health research (*A Partnership for Health: Minorities in Biomedical Research*) and women's health research (*Women's Health in the U.S. Research on Health Issues Affecting Women*). This pair of booklets gives the latest statistics

on health disparities related to immunology and infectious diseases, highlights recent scientific findings of particular concern to minorities and women, and articulates research plans and priorities. These documents are key tools in NIAID's effort to reach out to minority communities with information on biomedical research of special interest to those populations. Both are distributed to outside organizations, at scientific meetings, and to the general public.

The NIAID NCICAS (1991-96) 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 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 used 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.

Action Plan III.A.6

Steps

1. Expand outreach by NIAID Intramural Staff located at RML to public schools located in Native-American communities.
2. Continue to publish and disseminate NIAID's minority research and women's health booklets.
3. Collaborate with CDC to disseminate the asthma intervention guidelines developed and tested by the ICAS.

Timeline

FY 2002

- Conduct "introduction to science sessions" in Montana public schools.
- Update and publish the *Partnership for Health* and *Women's Health in the U.S.* booklets. Incorporate requirements of Section 508 of the Rehabilitation Act into the Web-based version of these documents.
- Support dissemination of the asthma intervention guidelines.

FY 2003-FY 2006

- Continue the outreach to Montana public schools by RML scientists.
- Continue to update booklets on a biennial basis, FY 2004 and FY 2006.
- Continue outreach efforts to Native-American students in the Montana public school system.

Performance Measures

- Publication of updated versions of the booklets *Partnership for Health* and *Women's Health in the U.S.*, as well as provide Section 508 compliant versions for the NIAID Web site.
  - Number of copies of each booklet distributed.
  - Range of venues in which the booklets are distributed.
- Number of outreach sessions targeted to Native Americans in Montana public schools by RML staff.
- Number of copies of the ICAS intervention guidelines disseminated.

Objective III.A.7. NIAID will continue to support Internet-based methods of communication and audiovisual materials to disseminate health information to people subject to health disparities

NIAID's Web site provides a wealth of health information useful to those subject to health disparities. Equally important, the site includes research plans and links for people seeking to participate in clinical trials.

Action Plan III.A.7

Steps

1. Establish a standards committee to formulate the redesign of the NIAID Web site and establish standards for both print and electronic materials.
2. Regularly review the content of the NIAID Web site for opportunities to enrich and supplement content.
3. Incorporate requirements of Section 508 of the Rehabilitation Act into Web-based publications.

Timeline

FY 2002
- Develop a more subject-oriented and user-friendly Web site.
- Develop a publication standards guide to be used in developing institute printed and film media.
- Explore software to make the NIAID Web site Section 508 compliant.

FY 2003-FY 2006
- Begin the redesign of the NIAID Web site based on new standards.
- Develop a publication standards guide to be used in developing institute printed and film media.
- Make the NIAID Web site Section 508 compliant.

Performance Measures

- Completion of NIAID Web site redesign.
- Compliance with Section 508.
- Prominence of minority and women's health issues on the NIAID Web site.
- Completion of publications and media standards guide.
- Dissemination of publications and media standards guide.

Outcome Measures

- Number of hits on NIAID Web site locations pertinent to health disparities.
- Compliance of Web site and printed materials with standards guide.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

June 2002
www.niaid.nih.gov

FOR ADMINISTRATIVE USE