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THE PUBLIC HEALTH SERVICE

STRATEGIC PLAN TO
COMBAT HIV & AIDS
IN THE UNITED STATES

U.S. Department of Health and Human Services



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FOREWORD

by Louis W. Sullivan, MD
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The Federal government is spending more money on, and devoting more resources and more attention to, the AIDS epidemic than to any other infectious disease ever. Not since the "War on Cancer" was launched twenty years ago has such a focus of time, energy and public and private money and resources been brought to bear on any one disease.

This Public Health Service (PHS) plan represents the latest product of the PHS' and the Department's continuing review of the dynamic nature of the epidemic. Previous planning activities resulted in similar PHS strategic documents in 1985, 1986, and 1988. In late 1990, Healthy People 2000 set forth specific goals and objectives for HIV and AIDS which will be pursued through this decade.

By the end of 1993, the Federal government will have devoted nearly \$17 billion in the fight against HIV infection and AIDS. For FY 1992, the Federal budget allotted almost \$4.4 billion for AIDS research, prevention, treatment, income support and education programs. That represented a 170 percent increase in funding from the FY 1988 level.

Eleven years ago the AIDS virus was unknown to scientists. Three years later, thanks to government scientists, we had isolated the HIV virus, learned how the disease is transmitted, discovered how it attacks the immune system, and made many other important discoveries. We have already made substantial progress in combatting the disease. We are now devising improved techniques to detect the infection and treat the illnesses.

*The Bush Administration has initiated new drug review procedures, implemented by the Food and Drug Administration (FDA), that have brought promising new AIDS therapies, such as ddI, to the market in record time. In addition to AZT and ddI, seven other drugs have received FDA approval for the treatment of AIDS-related illnesses, and more than 50 other drugs and at least five potential vaccines are now in early stage clinical trials. We **are** preparing the nation's health care infrastructure for the wide-scale trial of these agents which should begin very soon.*

We have also launched tremendous public awareness and education campaigns about AIDS. One such campaign is CDC's "America Responds to AIDS," the multifaceted ad campaign specifically addressing the AIDS issue. To date, an estimated \$90 million of air time showing 65,000 television public service ads has been donated to the campaign.

Our Healthy People 2000: National Health Promotion and Disease Prevention Objectives, includes 14 HIV-specific prevention objectives for the nation. In addition, CDC has established a "Blueprint for the '90's" -- which, in collaboration with community, state, national and international partners, stresses prevention of HIV infection through the promotion of safe behavior.

The CDC has implemented the largest health hotline in the world, part of which provides one-to-one advice and information regarding AIDS. This hotline receives more than 3,000 calls per day. And the National AIDS Clearinghouse provides more than one million pieces of educational materials nationwide every month.

Early in my administration, I directed Dr. James O. Mason, Assistant Secretary for Health, to develop a plan to halt the spread of AIDS. As head of the PHS, Dr. Mason's immediate staff developed the PHS' Strategic Plan to Combat HIV & AIDS in the United States which has been used within PHS to guide their efforts. PHS is the 45,000-strong force "deployed" to protect Americans from threats to the Nation's health. The work of the PHS affects every American practically every day.

The strategic plan is a comprehensive endeavor to direct the efforts of the PHS in the battle against AIDS. Laid out in this plan are the strategic activities of the PHS. Taken together, these are a map providing direction toward controlling and defeating this disease. They give us an appreciation for how far we have come in understanding AIDS and HIV infection, and a grasp of how the PHS must proceed to achieve our ultimate goals. Future work of the PHS will be built upon this strategic plan and its predecessors.

*It is abundantly clear that the battle to stop the spread of HIV infection, and to **find** a cure for those infected, is historical. The tremendous resources, both human and financial, being brought together against this one particular disease is unparalleled. These resources make it possible **for** PHS to carry out traditional public health efforts to shield and protect the public, and to undertake complex research in order to develop an effective therapeutic agent and vaccine. It is through the continuing collaboration of the local, State, and Federal government with the cooperation of the public and private sector that we will defeat HIV and AIDS.*

The spread of the human immunodeficiency virus (HIV) and of the acquired immunodeficiency syndrome (AIDS) is a major challenge facing the Nation. The Public Health Service (PHS) has the responsibility, the personnel, and the expertise to lead the effort to halt the AIDS epidemic.

As the lead Federal agency for health related issues, the PHS provides national leadership in combatting the HIV epidemic. PHS has effectively marshalled and organized its resources to pursue well conceived and well targeted strategies encompassing education and prevention, biomedical research, epidemiology, and health services. In its larger leadership role, the PHS chairs, and regularly convenes, the Federal Coordinating Committee on AIDS, a cross-Departmental forum designed to improve interdepartmental communications on HIV and AIDS efforts.

*This plan builds upon the ground work laid by PHS' earlier planning activities^{1,2,3} and the PHS' national prevention objectives." It discusses the role of the PHS in combatting the AIDS epidemic and the **principles** that will guide the direction of PHS' AIDS-related activities. It describes PHS' strategies, activities, and objectives, and the resources that it has committed to the AIDS challenge.*

*The Public Health Service shares responsibility with State and local governments for stopping the spread of the HIV infection and for providing services to the underserved segments of society. Within the scope of its mission, PHS will continue to provide leadership in national planning, in surveillance, and in AIDS prevention, research, and services. In addition, PHS will continue to collaborate with and to support other governmental agencies, voluntary health organizations, **advocacy** groups, community-based organizations, and professional societies, among others, to address shared HIV and AIDS problems.*

*Great efforts were taken to make this document concise and succinct. It is a product of diligent efforts by officials of the PHS agencies⁵ and of staff offices of the Office of the Assistant Secretary for Health. This strategic **plan** reflects the PHS' resolve to achieve the goal of halting the Nation's AIDS epidemic.*

James O. Mason, MD, DrPH
Assistant Secretary for Health

¹ Public Health Service plan for the prevention and control of acquired immune deficiency syndrome (AIDS). Public Health Rep 100:453-455, September-October 1985.

² Coolfont report: A PHS plan for the prevention and control of AIDS and the AIDS Virus. Public Health Rep 101:341-348, July-August 1986.

³ Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Rep Vol. 103 Supplement NO.1 (Revised), 1988.

⁴ Healthy People 2000, National Health Promotion and Disease Prevention Objective, U.S. Department of Health and Human Services. DHHS Publication No. (PHS) 91-50212.

⁵ The Agency for Health Care Policy Research (AHCPR), Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and the National Institutes of Health (NIH).

THE PUBLIC HEALTH SERVICE'S STRATEGIC PLAN TO COMBAT HIV AND AIDS IN THE UNITED STATES

INTRODUCTION

Acquired immunodeficiency syndrome (AIDS) is a fatal infectious disease caused by the human immunodeficiency virus (HIV). People with HIV infection may develop multiple opportunistic infections, suffer diminished mental capacity, and require frequent hospitalization. Many are unable to support and care for themselves or for those who depend on them. At the present time, no vaccine can protect people from HIV infection, and there is no cure for AIDS.

The AIDS epidemic was recognized in the United States more than a decade ago. Of all AIDS cases that have been reported worldwide, almost half have been in the United States. Between June 1981 and June 1992, more than 230,000 AIDS cases and more than 152,000 AIDS-related deaths in the United States were reported to the Centers for Disease Control (CDC). More than 90 percent of these cases represented young adults in the prime of life.

HIV infection continues to spread nationwide. The CDC estimates that approximately one million persons in the United States are infected with HIV. Approximately 40,000 new infections occur in the United States annually. Poor innercity blacks, Hispanics, women, children, and intravenous (IV) drug users are affected disproportionately.

Since HIV infection mainly affects individuals in early adult life, AIDS has become a leading cause of death among young adults. AIDS now ranks sixth among diseases in terms of potential life lost by individuals age 65 years of age or younger; and it is estimated to be one of the five leading causes of death among women aged 15 to 44 years.

The most common mode of HIV transmission is unprotected sexual intercourse with an infected individual. HIV transmission by IV drug users who share drug paraphernalia is increasing. On the other hand, transmission via contaminated blood transfusion in the United States virtually has been eliminated, and transmission in hemophiliacs receiving blood clotting factor concentrates has been eliminated due to heat treatment.

Table 1 provides CDC's most recent AIDS projections for the United States from 1990-1994. By the end of 1994, the cumulative number of reported AIDS cases in the United States may reach 390,000. In that year alone, as many as 42,000-93,000 new cases could be diagnosed, and there could be 45,000-76,000 AIDS-related deaths.

Although the largest proportionate increases in AIDS cases are expected to occur among those infected heterosexually, homosexual and bisexual males and IV drug users still will account for the majority of the cases.

Despite the challenges of the AIDS epidemic, there has been significant progress in biomedical research and patient care. More resources have been devoted to research on HIV infection and AIDS than to any other disease except cancer. Since AIDS was first identified in 1981, more scientific and public health advances have been made in a shorter time than in the control of any other complex disease in the history of medicine.

Significant advances have been made in the care of people with HIV infection and AIDS. Now there are FDA approved drugs that protect against Pneumocystis carinii, which causes a form of pneumonia that is often a fatal complication of AIDS. In addition, zidovudine (AZT) and

dideoxyinosine (ddI) have been shown to delay the onset or progression of AIDS significantly. As a result of these advances, fully 60 percent of the patients diagnosed with AIDS in 1987 survived 18 months following diagnosis, whereas fewer than 40 percent survived as long two years earlier.

While these advances are encouraging, the burden of HIV-related disease is expected to grow tremendously, requiring increased medical and social services well into the next century. During the course of their illness, people currently infected with HIV will become progressively ill, develop AIDS, and die from causes attributable to the infection.

TABLE 1.
Projected numbers of acquired immunodeficiency syndrome (AIDS) cases, deaths, and living persons with AIDS, United States, 1990 -1994.

Year	New cases*	AIDS cases Alive ^B	Deaths
1990	53,000	117,000	39,000
1991	44,000 - 69,000	128,000 - 145,000	43,000 - 47,000
1992	47,000 - 77,000	134,000 - 173,000	45,000 - 57,000
1993	47,000 - 86,000	135,000 - 200,000	46,000 - 66,000
1994	42,000 - 93,000	130,000 - 226,000	45,000 - 75,000
cumulative total through 1994	405,000 - 550,000		325,000 - 390,000

- Estimates are based on the existing AIDS case definition, not the proposed CD4 definition.
- Projections are adjusted for unreported diagnoses of AIDS by adding 18% to projections obtained from reported cases (corresponding to 85% of all diagnosed cases being reported: $1/0.85 = 1.18$) and rounded to the nearest 1,000.
- A Number of cases diagnosed in that year.
- B Number of persons diagnosed with AIDS alive at any time during that year.

Source: **CDC**

The cumulative national cost of treating all persons with HIV annually increased significantly between 1991 and 1992. It is forecast to escalate 48 percent from \$10.3 billion in 1992 to \$15.2 billion in 1995.

Early and aggressive treatment of HIV infected persons without AIDS and persons with AIDS has led to significantly higher cost of treating persons in the initial stage of the HIV disease. It is estimated that the lifetime cost of treating a person with AIDS is \$102,000 while the lifetime cost of treating a person through the course of the HIV disease is approximately \$150,000.

The estimated one million persons currently infected with HIV and the 40,000 - 80,000 new infections occurring annually will require an ever-increasing level of medical care and place significant strains on health care budgets. Each HIV infection will result in a minimum of \$455,000 in foregone wages and productivity. Currently, the cost of medical care and lost wages generates an economic benefit value of \$605,000 per infection; therefore, each infection which can be prevented will result in direct and indirect savings of \$605,000.

Federal spending on AIDS has increased steadily since AIDS was recognized as a new disease, from \$8 million in fiscal year (FY) 1982 to \$4.9 billion in FY 1993 (Figure 1). The current PHS AIDS budget (FY 1992) is \$2.0 billion, a 5 percent increase over

FY 1991 (Figure 2). Appendix 1 summarizes Federal spending by agency for HIV and AIDS from FY 1982-1993; Appendix 2 provides Federal spending by Agency for research, prevention, treatment, and income support for 1991- 1993.

Figure 1

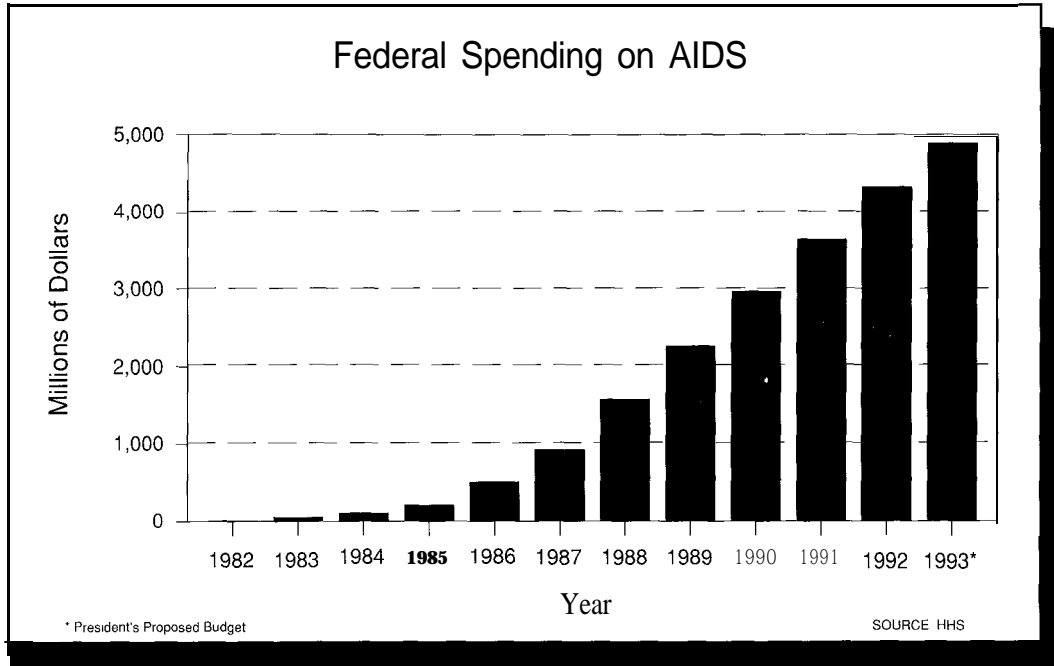
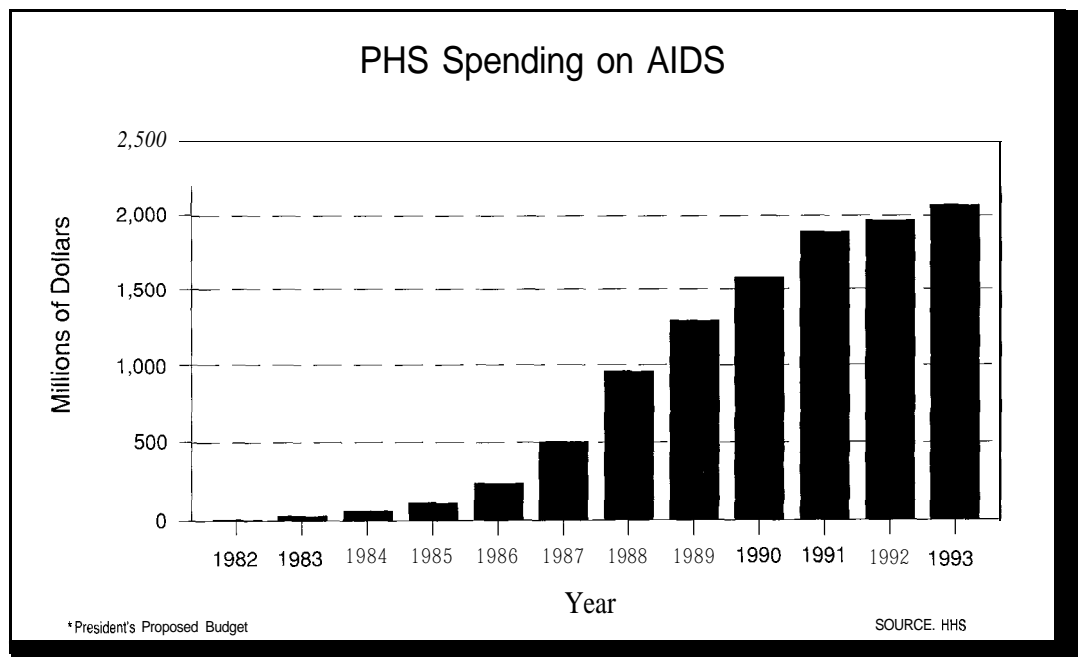


Figure 2



ROLE OF THE PUBLIC HEALTH SERVICE IN COMBATTING AIDS

Several Federal departments and agencies, including the Public Health Service, are responding to the AIDS epidemic. The Federal Government acts in concert with and in support of State and local governments, which have substantial prevention and primary care responsibilities. Federal, State and local governments and many other organizations in both the public and private sectors must work in concert to address the AIDS problem. Appendix 3 summarizes the major Federal AIDS programs and AIDS-related activities.

PHS policy, resources, and cross-cutting issues are managed by the PHS HIV Leadership Committee, which consists of the Assistant Secretary for Health and PHS agency heads. The PHS Leadership has general management responsibility for setting policies, for developing strategies, and for controlling PHS AIDS activities. Implementation and management of PHS policies and strategies, the responsibility of the individual PHS agencies, is coordinated through the PHS Executive Task Force on AIDS and the National AIDS Program Office (NAPO).

As reflected by the following mission statement, the Public Health Service plays a major role in combatting the AIDS epidemic:

*The Public Health Service mission for addressing AIDS and the HIV epidemic, through programs of research, risk assessment, education, and prevention, is to prevent further spread of infection: to develop effective therapies for those already infected; and to enhance the capacity of the Nation's public **and** private organizations at the national, State, and local levels to deliver effective prevention, treatment, and related health care programs to all citizens.*

The goal of the Public Health Service's biomedical, epidemiologic, and behavioral research, prevention and education efforts is to halt the epidemic.

GUIDING PRINCIPLES

Ten principles guide PHS agencies as they formulate policy, set priorities, design programs, and carry out PHS' AIDS mission:

- Recognize prevention of HIV infection and AIDS as one of the Nation's highest health priorities.
- Address the AIDS epidemic as a shared responsibility of the public and private sectors at national, State and local levels.
- Continue to devote substantial resources to HIV and AIDS-related research while maintaining the balance between that and other health research.
- Focus PHS resources to realize the goal of halting the spread of HIV infection.
- Educate the public about behaviors which promote HIV infection.
- Encourage individuals to cease risky behaviors and to assume greater personal responsibility for their health.
- Strengthen public health initiatives that address drug abuse and sexually transmitted diseases.
- Strengthen public health systems through improved linkages among Federal, State, and local health departments.
- Support and expand the use of cost effective health care, disease prevention, and health promotion practices.
- Include AIDS constituencies in the PHS decision-making process.

PHS AIDS STRATEGIES AND STRATEGIC ELEMENTS

The PHS strategic plan for combatting HIV and AIDS describes the major strategies that PHS is pursuing and highlights important programmatic activities related to each strategy.

Although the plan contains elements which are not necessarily unique to any one agency, each PHS agency is responsible for implementing appropriate strategic elements.

The PHS AIDS budget (Appendix 4) reflects agencies' specific AIDS-related activities. The numbering of the planning elements and the budgeted activities correspond at the Roman numeral level.

Planned activities and related elements are listed for each strategy:

- I. Basic Science Research
- II. Risk Assessment and Prevention
- III. Product Evaluation, Research, and Monitoring
- IV. Clinical Health Services Research and Delivery

Each strategic element is then described in the following detail:

Need:

Statement of the problem

Long-Term Objectives

What is to be accomplished

PHS Role and Action

What PHS will do by the end of 1994 to achieve the objectives

I. BASIC SCIENCE RESEARCH

As the Federal agency with primary responsibility for biomedical and behavioral research, PHS conducts basic studies and clinical research aimed at understanding, treating, and preventing HIV infection and its sequelae. The rapid advances associated with PHS research activities are related directly to the priority status they merit, the dedication and brilliance of the scientific community, and the funding allocated to AIDS research. PHS' future research is expected to produce results that prevent HIV infection and make AIDS a treatable disease.

BASIC RESEARCH STRATEGY: Conduct and support development of safe and effective preventive, diagnostic, and therapeutic methods and agents.

STRATEGIC ACTIVITY I.A:

Conduct and support biomedical, neuroscientific, and neuropsychiatric research associated with HIV infection.

- I.A.1 Studying the cellular and molecular processes underlying the immune dysfunction of HIV infection.
- I.A.2 Developing an HIV nonhuman primate model.
- I.A.3 Studying the natural history, pathogenesis, and treatment of AIDS-related malignancies utilizing international studies as appropriate.
- I.A.4 Increasing the understanding of the natural history of HIV infection in women and in children and the effect of treatment through their participation in studies and clinical trials utilizing international studies as appropriate.
- I.A.5 Elucidating the natural history of HIV infection and AIDS in pregnant women and in children and developing surveillance systems to monitor HIV-infected pregnant women and their infants and children.

- I.A.6 Expanding the pool of U.S. and international scientists trained in research devoted to HIV infection and AIDS.

STRATEGIC ACTIVITY I.B:

Conduct and support the development of therapeutic agents and vaccines.

- I.B.1 Pursuing screening, discovery and development of targeted antiviral drugs bringing the most promising of the new drugs into clinical testing.
- I.B.2 Expediting the discovery and development of a safe and effective HIV vaccine through a comprehensive research, development, and clinical trials program.
- I.B.3 Increasing the number of clinical trials studying agents for the prevention and treatment of opportunistic infections associated with HIV.

STRATEGIC ACTIVITY I.C:

Develop therapeutic regimens.

- I.C.1 Developing therapies for treating and preventing central nervous system impairment and AIDS Dementia Complex.
- I.C.2 Elucidating the factors involved in endocrine dysfunction, nutritional deficiencies, and the wasting syndrome related to AIDS, and developing appropriate interventions utilizing international studies as appropriate.
- I.C.3 Improving methods for symptom management for patients with HIV infection and AIDS.

STRATEGIC ELEMENT I.A.1

Studying the cellular and molecular processes underlying the immune dysfunction of HIV infection.

THE NEED

The major pathway by which HIV causes morbidity and mortality is through the progressive destruction of a person's immune function. Understanding the mechanisms underlying this dysfunction and destruction of immunity, whether

the already extant immunity of adults or the developing immunity of children, or the potentially taxed and distorted immune systems of intravenous drug users (IVDUs) or pregnant females is critical to the ability to interrupt the process through targeted interventions. Additionally, the disorders complicating HIV infection, such as pulmonary Kaposi's sarcoma and interstitial pneumonitis, have not been well characterized, nor have their etiologies been established.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) elucidate HIV viral gene functions in order to understand the viral mechanisms responsible for the pathogenesis of HIV infection; 2) delineate the effects of HIV infection on various hematopoietic precursors and on any specific target cells and organ systems involved in this mechanism; 3) generate information for designing drugs and vaccines to block viral transfer by understanding HIV infection mechanisms; 4) understand the relationships among human leukocyte antigens phenotype, susceptibility to HIV infection and the rate of progression to AIDS in infected persons; 5) develop a sensitive *in vitro* assay that can accurately and reliably demonstrate HIV infection before antibody production; 6) develop animal models to lower the cost and increase the potential for testing of therapies, vaccines, and theories of pathogenesis; 7) understand how age-related reduced immune function relates to the possible difference in susceptibility of older individuals to infection with HIV and progression to AIDS; and 8) delineate risk factors associated with the development of cytomegalovirus (CMV) retinitis and other opportunistic infections.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Delineate the functions of important HIV regulatory proteins, such as *tat* and *rev*, and the theories to relate these proteins to mechanisms of HIV pathogenesis;
- Identify the immunologic risk factors for susceptibility to HIV infection and the subsequent progression to AIDS;

- Further characterize the nature and mechanism of action of a “negative regulatory factor” associated with the early loss of immune function in some asymptomatic infected persons;
- Implement studies to determine the etiology and appropriate treatment for HIV-associated cardiopulmonary complications of HIV infection;
- Define cofactors involved in the expression of HIV-related disorders;
- Delineate the differences in the immune dysfunction typical of different HIV-infected populations such as children, older persons, and intravenous drug users; and
- Examine how aging affects the development of HIV infection and AIDS.

STRATEGIC ELEMENT I.A.2

Developing an HIV nonhuman primate model.

THE NEED

Basic and clinical research on AIDS would be greatly accelerated by the development of a nonhuman primate model that is susceptible to HIV infection and that manifests (serologically and clinically) the symptoms and lesions observed in human AIDS. It would be possible to conduct basic research on HIV in such a model with increased confidence that the studies would be highly applicable to human AIDS.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) develop a nonhuman primate model susceptible to HIV infection that manifests symptoms of human AIDS; 2) develop methods to improve the reproductive efficiency of chimpanzees and rhesus macaques; 3) develop nonhuman primate models as well as smaller laboratory animal models for HIV encephalopathy; and 4) have available macaque models of HIV-2 for research on the same HIV-2 virus that causes disease in humans.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Increase by 10 percent the capability of the Regional Primate Research Centers to provide the technological expertise and resources to support nonhuman primate studies on vaccines and drugs to treat AIDS;
- Make available sufficient numbers of chimpanzees from breeding colonies for PHS-sponsored safety/efficacy testing of candidate AIDS vaccines;
- Make available new facilities and housing for chimpanzees used for AIDS investigation;
- Develop animal models for heterosexual and fetal transmission of AIDS in the nonhuman primate; and
- Initiate basic and clinical studies to elucidate the fundamental processes underlying infection and progression of HIV-2 in a susceptible nonhuman primate model.

STRATEGIC ELEMENT I.A.3

Studying the natural history, pathogenesis, and treatment of AIDS-related malignancies utilizing international studies as appropriate.

THE NEED

Persons infected with HIV are at high risk for development of multiple types of malignancies, including Kaposi’s sarcoma, Hodgkin’s and non-Hodgkin’s lymphomas, basal cell carcinomas, anorectal squamous cell carcinomas, hepatitis B-related hepatocellular carcinoma, and women-specific malignancies. Non-Hodgkin’s lymphoma (NHL), in particular, has been increasingly recognized as treatments for people with HIV infection and AIDS have improved and resulted in longer survival and prolongation of the duration of chronic immunosuppression. It is projected that HIV will be associated with 2.5 percent of all NHL by the end of 1992. It is anticipated that the number of HIV-associated

malignancies will increase as the life expectancy of AIDS patients is prolonged.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) define the full spectrum of malignancies associated with HIV infection and the specific risk factors associated with development of specific malignancies (immune status, mode of HIV transmission, type and extent of antiretroviral treatment); 2) determine the role of chronic immunosuppression in the development of specific malignancies; 3) define humoral mechanisms that stimulate or perpetuate tumor formation and growth, particularly for Kaposi's sarcoma and NHL; 4) identify the potential role of additional viruses as cofactors for development of specific malignancies; and 5) develop antitumor therapies and, ultimately, means of preventing the emergence of malignant clones.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Identify the risk factors for establishment and progression of specific AIDS-related malignancies;
- Define and characterize specific growth factors that stimulate and perpetuate tumor formation and expansion;
- Identify cofactors involved in the full expression of HIV-associated malignancies;
- Develop inhibitors that block the activity of growth factors and that might thereby be useful to interdict the formation or growth of tumors, especially Kaposi's sarcoma and NHL;
- Identify cytotoxic drugs active against specific AIDS-related tumors; and
- Develop interventions targeted toward HIV and others viruses (CMV, Epstein-Barr, Hepatitis B) to prevent malignant transformation in patients at high risk for specific types of tumors.

STRATEGIC ELEMENT I.A.4

Increasing the understanding of the natural history of HIV infection in women and in children and the effect of treatment through their participation in studies and clinical trials utilizing international studies as appropriate.

THE NEED

The rate of HIV in women is quickly rising and is not in proportion to their participation in clinical trials. This is due to the fact that women were not among the first groups to be infected in the United States.

THE LONG-TERM OBJECTIVE

The long-term objectives are: 1) include women, and children in all AIDS clinical studies in order to develop effective interventions designed to maintain optimal physiological and psychosocial functioning of infected women and their families across the spectrum of illness; 2) document effective treatment and validate specific interventions to ameliorate symptoms in female and pediatric patients; 3) assess and/or adapt existing histochemical, biotechnological, or psychosocial instruments for use with HIV-infected women and children in characterizing progression of symptoms in order to devise optimal interventions; and 4) correlate HIV- and AIDS-related symptom changes affecting the physiological and psychological status of women and children in terms of anatomic, biochemical and immunological measures.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private sector organizations, will:

- Develop and improve reliable and valid instruments to assess the clinical manifestations of HIV infection in women and children; and
- Characterize symptoms and treatment for symptoms of HIV disease progression in women and children.
- Improve the treatment of acute and chronic symptoms of women and children diagnosed with HIV based upon research findings.

- Study the impact of pregnancy on the natural history of HIV infection, as well as the impact of HIV infection in pregnancy.
- Conduct research to elucidate timing, mechanisms and factors of maternal-fetal transmission of HIV infection.

STRATEGIC ELEMENT I.A.5

Elucidating the natural history of HIV infection and AIDS in pregnant women and in children and developing surveillance systems to monitor HIV-infected pregnant women and their infants and children.

THE NEED

Insufficient information is known about the epidemiology and natural history of HIV infection in women and children. It is not well understood why some pregnant women transmit their infections to their children and others do not.

Many children have had severe HIV-related disease or have died before manifesting one of the opportunistic infections, cancers, or other conditions that would qualify them as AIDS cases. Efforts to maintain specificity in the pediatric surveillance definition have resulted in reduced sensitivity and a complicated case definition and pediatric reporting system. Expanded surveillance of HIV-infected women and children would more fully measure the problem of HIV infection in these families and support improved health-care planning as well as evaluation of targeted prevention strategies.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) understand the normal and HIV and AIDS-associated ranges for serological markers used to determine immune status for pregnant women, infants, and children; 2) determine how pregnancy affects the course of HIV infection and disease progression; 3) determine the effects of HIV infection on the course of pregnancy and potential associated complications; 4) establish a national surveillance system for diagnosed HIV infection in infants and children that includes data on pregnant women with HIV infection and their referral for prenatal

care; 5) determine the natural history of HIV infection in children; 6) determine frequency of and risk factors for transmission of HIV from mother to child; and 7) develop better test for early diagnosis of HIV infection in infants.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with the States, will:

- Improve methods for accurately determining the existence of HIV infection early in infancy;
- Report on current research efforts to identify and understand the different mechanisms by which the HIV can be transmitted from mother to fetus or newborn;
- Establish a method to determine whether an HIV-infected woman is likely to transmit HIV to her fetus or newborn;
- Establish normal and HIV-associated parameters for CD4+ T-Lymphocytes and CD4/CD8+ ratios in newborns and in children through age 15 months;
- Develop appropriate measures and norms for assessing central nervous system development which will improve understanding of the progression of HIV-related disease in infants, children, and adolescents;
- Initiate studies to determine the natural history of pulmonary and cardiac complications of HIV infection;
- Describe the interrelationship of biological and psychological growth and developmental patterns of children and infants with HIV infection and AIDS;
- Establish in all States an active surveillance system for diagnosed HIV infection in infants and children, and collect, in selected States, data on pregnant women with HIV infection;
- Conduct studies examining perinatal transmission and natural history of HIV infection in mothers and infants;
- Conduct studies of the spectrum of disease in HIV infected women and children; and

- Conduct analyses to determine the effect of the recent guidelines for prevention of *Pneumocystis carinii* pneumonia in children.

STRATEGIC ELEMENT I.A.6

Expanding the pool of U.S. and international scientists trained in research devoted to HIV infection and AIDS.

THE NEED

To understand and combat the complex disease caused by HIV, increased numbers of biomedical and behavioral researchers from all racial, ethnic, and socio-economic groups will be required in basic, clinical, and applied research areas. In order to accomplish this, incentives to enter the field of biomedical and behavioral research must be offered and the infrastructure necessary to support training and research must be expanded domestically and worldwide.

THE LONG-TERM OBJECTIVES

The long-term objectives are to expand from all racial and ethnic groups in the U.S. and internationally the pool of qualified biomedical and behavioral researchers trained in research devoted to HIV infection and AIDS, and to increase the research infrastructure for both research training and the conduct of biomedical and behavioral research.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Enlarge, through career awards, the targeted training programs for professionals interested in research/regulation as a career;
- Increase the involvement of minority professionals in biomedical, clinical and behavioral research through training in PHS research centers and community clinical programs;
- Expand training support through the NIH AIDS Loan Repayment Program in order to attract young scientists to the field of biomedical and behavioral research on HIV;

- Increase the number of full-time training positions for clinician scientists and basic research scientists entering biomedical and behavioral research:

- Expand facilities that support the training of HIV researchers and develop more laboratories meeting Biosafety Level-3 standards; and
- Establish active research training programs for scientists in foreign countries considered to be likely locations for international testing of AIDS drugs and vaccines and behavioral interventions.

STRATEGIC ELEMENT I.B.1

Pursuing screening, discovery and development of targeted antiviral drugs bringing the most promising of the new drugs into clinical testing.

THE NEED

The application of expertise in virology, enzymology, molecular biology, immunology, and other areas of fundamental research can enhance efforts to develop antiviral agents to fight HIV. The PHS has developed a comprehensive program for the discovery and development of drugs with anti-HIV activity. The AIDS Drug Screen is a rapid and high-capacity screen for the evaluation of compounds submitted from any source, including the private sector and academic institutions. Once an active new agent is identified through the drug screening process, the next stages in drug development include drug synthesis, drug formulation, and animal toxicology studies. These stages are necessary before a new agent can be taken into clinical testing in HIV-infected persons.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) have available a battery of targeted therapies, that can be tolerated together or sequentially in all patient populations, to prevent the spread of HIV and prevent immunosuppression or restore immune function in infected individuals; 2) complete preclinical development of promising new drugs from the AIDS Drug Screen; 3) develop assays to test the specific mechanism of action of compounds with promising activity in the AIDS Drug Screen; and 4) identify new compounds with unique mechanisms

of HIV inhibition, including novel natural products.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Determine the high-resolution molecular structures for at least five of the HIV proteins;
- Test in large-scale *in vitro* screening assays candidate drugs that manifest anti-HIV activity and are capable of interfering with the HIV life cycle;
- Complete preclinical development of new promising compounds and novel natural product(s) from the AIDS Drug Screen;
- Identify viral molecular targets for pharmaceutical intervention against HIV and develop new compounds with emphasis on non-reverse transcription-based mechanism of HIV inhibition;
- Develop and implement two specific mechanistic assays in the AIDS Drug Screen, an assay for HIV tat inhibitors and an assay for HIV protease inhibitors; and
- Increase the number of immunorestorative agents available for study in clinical trials alone or in combination with an antiviral.

STRATEGIC ELEMENT I.B.2

Expediting the discovery and development of a safe and effective HIV vaccine through a comprehensive research, development, and clinical trials program.

THE NEED

Developing a vaccine effective in preventing HIV infection is a major public health priority in our national effort to combat this epidemic. Research using various strategies to stimulate a protective immune response against HIV are underway, as are efforts to determine which of these offer the most promise for further development.

Recently, researchers successfully used whole but inactivated simian immunodeficiency virus (SIV) in a vaccine that prevented infection in monkeys challenged intravenously with the homologous strain. This is the most encouraging evidence to date that a vaccine to protect against HIV is indeed possible, and it gives impetus to researchers' efforts to correlate such findings from animal studies with the human immune system and HIV infection.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) develop a T-cell-mediated vaccine for AIDS; 2) develop constructs of innocuous replicating vectors into which critical HIV target epitopes can be incorporated; 3) develop optimal methods to present HIV antigens to the human immune system so as to evoke maximal protective humoral and cellular immunity; 4) develop HIV vaccines that are effective in blocking transmission from infected mothers to their newborns and slow the progression of HIV infection from an asymptomatic state to AIDS; and 5) have new adjuvants progress into clinical trials, enabling HIV vaccines to demonstrate, qualitatively and quantitatively, comprehensive anti-HIV immunologic responses.

PHS ROLE AND ACTIONS

Beginning with whole inactivated vaccines, studies will make progress toward identifying the viral components necessary to induce protection and the mechanism of protection against SIV challenge. By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Identify the viral components necessary to induce protection and the mechanism of protection against SIV challenge;
- Determine the responses of T-lymphocytes, including cytolytic T-cell response, in chimpanzees undergoing active immunization;
- Improve the understanding of the role of secretory immunity in a protective response against transmission of HIV across mucous membranes;
- Conduct clinical trials of candidate HIV vaccines to elucidate those which are promising

based on comparative immunologic analyses in Phase 1-2 studies;

- Meet with domestic and international sponsors during all phases of product development with emphasis on earlier preclinical communications; and
- Using nonhuman primate models, optimize the immune response to HIV elements through design and use of adjuvants, including iscoms, liposomes, and novel vehicles.

STRATEGIC ELEMENT I.B.3

Increasing the number of clinical trials studying agents for the prevention and treatment of opportunistic infections associated with HIV.

THE NEED

Opportunistic infections (OIs) are the major causes of illness and death in people with AIDS. The treatment of these serious diseases poses a significant challenge to primary care physicians. Although several agents are now available for clinical use, many of the drugs have serious toxic side effects. Thus, the development of optimal therapies to treat these HIV-associated diseases is critically needed.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) identify well-tolerated oral therapeutic and prophylactic options for the most common opportunistic infections, to replace toxic drugs or those requiring frequent parenteral administration; 2) replace the need for frequent therapy of acute and chronic OIs with effective prophylaxis; 3) identify active agents (or combinations of agents) against presently untreatable OIs (e.g., cryptosporidiosis, *Mycobacterium avium intracellulare*) for which no standard therapies exist (i.e., establish standard therapies); and 4) significantly reduce or eliminate morbidity and mortality resulting from opportunistic HIV disorders of the oral cavity.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public- and private-sector organizations, will:

- Increase the number of cooperative groups of industry, academic, and government scientists pursuing the discovery and preclinical development of new agents to treat OIs;
- Have underway expedited testing of promising new agents and regimens (especially those that are orally bioavailable) for the treatment and prophylaxis of OIs in conjunction with the testing of new antiretrovirals or in the setting of established antiretroviral approaches;
- Increase the number of centers involved in OI studies, which are typically more complex and more resource-intensive than antiretroviral trials; and
- Modify existing clinical trials by adding a component to test agents designed to minimize oral opportunistic HIV disease, testing interventions to control toxic side effects, and including measures of quality of life.

STRATEGIC ELEMENT I.C.1

Developing therapies for treating and preventing central nervous system impairment and AIDS Dementia Complex.

THE NEED

According to a recent study, the most common neurological disorder in people with HIV and AIDS is dementia. The author of the study predicts that by 1991, 30 percent of the 135,000 people with AIDS in the United States will become demented.

Little information exists on the molecular and biological mechanisms underlying the appearance of central nervous system (CNS) degeneration, including sight-threatening retinitis, in HIV-infected individuals, and on the factors that influence the development and clinical course of HIV-related dementia. Even less is known about CNS impairment among drug-abusing populations. In addition, effective therapies are needed to treat dementing conditions associated with HIV infection and AIDS.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) determine the onset, incidence, course, prevalence, risk factors,

cofactors, and markers of the various problems of AIDS-related neuropsychiatric disease; 2) define clinically, physiologically, and immunologically the underlying mechanisms and pathogenesis of HIV encephalopathy and determine the roles of HIV mutability, strain variations, and infectious cofactors; 3) document the relationship of the immune-deficient state to the onset of opportunistic infections of the nervous system from the common viruses associated with AIDS patients; 4) develop animal models with utility for the study of the neuropathological effects of HIV; 5) develop effective assessment techniques for diagnosing HIV and AIDS-related dementing conditions; and 6) develop effective therapies to prevent and treat CNS impairment and AIDS Dementia Complex.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Evaluate the SIV model, which has been shown to bear a similarity to human HIV infection, for behavioral and neurological abnormalities present in the AIDS Dementia Complex in humans;
- Facilitate the use of standardized adult and pediatric neuropsychological and neurological assessment batteries in federally funded research studies;
- Define criteria for neurological activity of HIV strains;
- Develop culture-specific assessments of HIV dementing illnesses;
- Use measures of CNS function to tailor AIDS prevention and intervention efforts, drug abuse treatment programs, and HIV treatment regimens to specific populations; and
- Contribute essential research and neuropsychologic data relative to the employment of HIV-infected individuals in positions affecting public safety.

STRATEGIC ELEMENT I.C.2

Elucidating the factors involved in endocrine dysfunction, nutritional deficiencies, and the wasting syndrome related to AIDS, and developing appropriate interventions utilizing international studies as appropriate.

THE NEED

Subnormal stimulated cortisol levels and subtle defects in steroidogenesis are common in AIDS patients, while frank adrenal insufficiency is rarer. Wasting is also a major component of AIDS. It has an adverse effect on the immune system and thus increases susceptibility to opportunistic infections. The etiology of wasting is diverse, including metabolic disturbances (possibly mediated by cytokines) and gastrointestinal dysfunction and infection.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) establish optimal methods of diagnosis of adrenal insufficiency and other endocrine disorders in HIV infection and AIDS; 2) identify the various etiologies of wasting in AIDS and identify the pathogenesis of each component contributing to wasting, including specific mediators such as cytokines; 3) identify parameters to measure nutritional status of patients with HIV infection, developed sufficiently to enable assessment of nutritional deficiencies and implementation of nutrient therapies; and 4) understand the specific mechanism responsible for nonbacterial AIDS enteropathy and availability of treatment options to break the cycle of diarrheal illnesses.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Develop guidelines for physicians that include indications for testing for adrenal insufficiency, recommendations concerning the method of testing, and indications for glucocorticoid therapy in acutely ill AIDS patients at risk of adrenal insufficiency;
- . Make available improved diagnostic tests for assessing the nutritional status, metabolic

abnormalities, gastrointestinal dysfunction, and other causes of wasting in AIDS;

- Expand clinical trials of therapies for wasting, including nutritional interventions and interventions directed at specific infections and gastrointestinal or metabolic disturbances found to contribute to wasting in AIDS:
- Develop guidelines for the assessment of nutritional status of HIV-infected individuals and for the amelioration of nutritional deficiencies;
- Make available new treatment options for nonbacterial AIDS enteropathy; and
- Design and distribute consumer-directed educational material about food safety for persons who are HIV-infected.

STRATEGIC ELEMENT I.C.3

Improving methods for symptom management for patients with HIV infection and AIDS.

THE NEED

Physical problems frequently associated with HIV infection include: dyspnea, chest pain, and coughing associated with pulmonary infections; muscle wasting, frailty, weakness linked with anorexia; weight loss, diarrhea, and malaise due to gastrointestinal malabsorption; neurological impairment, mental deterioration, and brain atrophy as a result of HIV brain deterioration and HIV brain infiltration; and mouth ulcerations, skin decubiti, blood diastasis, and febrile episodes caused by the patient's immunocompromised defense system. Psychosocial problems associated with HIV infection and AIDS include quality of life issues and responsibilities and needs of significant others and caretakers.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) document effective treatment and validation of specific interventions to ameliorate symptoms; 2) correlate HIV and AIDS-related symptom changes affecting patients' physiological and psychological status with anatomic, biochemical, and immunologic measures; 3) perfect a bioadhesive delivery system

for delivering antimicrobial (particularly antifungal) compounds to noncompliant elderly, mentally compromised, and Third World populations at risk for HIV; and 4) complete studies of the psychological and psychiatric risk factors related to the progression of HIV-related symptoms in high-risk populations.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Delineate the quality of life parameters to be included in patient assessment during clinical trials;
- Characterize the symptoms of HIV progression;
- Develop reliable and valid instruments to assess the symptoms of AIDS;
- Support clinical studies in order to develop effective interventions designed to maintain optimal physiological and psychosocial functioning of infected individuals and their families across the spectrum of illness; and
- Appropriately disseminate results of clinical studies in this area to health professionals.

II. RISK ASSESSMENT AND PREVENTION

PHS' risk assessment and prevention strategy is intended to improve our knowledge of behaviors that spread HIV infection and of how to motivate people to avoid or change unsafe behaviors. Its efforts to prevent the spread of HIV infection in the United States consist of assessing risks, developing prevention technologies, implementing prevention programs, and building prevention capabilities. Epidemiology, surveillance, and the social and behavioral sciences are key to understanding and controlling HIV infection and to developing and testing appropriate interventions.

RISK ASSESSMENT AND PREVENTION

STRATEGY: Determine the incidence and prevalence of HIV infection and AIDS and develop and implement appropriate interventions.

STRATEGIC ACTIVITY II.A

Conduct surveillance of HIV infection and related diseases and estimate the burden of HIV illness.

- II.A.1 Developing statistical methods to make more precise and reliable HIV prevalence estimates.
- II.A.2 Determining the prevalence of HIV infection in the U.S. population by age, sex, race, ethnicity, geographic location, and behavioral characteristics.

STRATEGIC ACTIVITY II.B

Conduct epidemiologic research of behavioral and biological factors related to HIV transmission.

- II.B.1 Improving knowledge of risky sexual practices.

STRATEGIC ACTIVITY II.C

Support and conduct the development, implementation, and evaluation of HIV and AIDS prevention programs.

- II.C. 1 Developing, implementing and evaluating comprehensive AIDS health education programs designed to prevent or modify

behaviors that result in HIV infection in adolescents.

- B.C.2 Developing effective behavioral strategies to prevent the spread of HIV infection.
- II.C.3 Expanding and evaluating HIV counseling and testing and integrating aspects of early intervention programs.
- II.C.4 Preventing maternal transmission of AIDS.
- II.C.5 Preventing HIV infection in poly-drug and non-IV drug users.
- II.C.6 Assisting other countries in their AIDS prevention activities.
- II.C.7 Developing an HIV vaccine distribution plan.

STRATEGIC ACTIVITY II.D

Establish guidelines to prevent or reduce HIV infection (including guidance for health care workers).

- II.D.1 Preventing transmission of HIV in health care settings.

STRATEGIC ACTIVITY II.E

Improve public understanding of HIV infection,

- II.E.1 Expediting the dissemination of the latest information on proven prevention techniques, new therapies, and state-of-the-art health care.
- II.E.2 Encouraging abstinence or proper and consistent use of condoms.
- II.E.3 Encouraging HIV-infected persons to be aware of their infection and to seek early medical care and social services.

STRATEGIC ACTIVITY II.F

Support the development and evaluation of HIV information programs.

- II.F.1 Evaluating the effectiveness of public information programs in preventing HIV infection.

STRATEGIC ELEMENT II.A.1

Developing statistical methods to make more precise and reliable HIV prevalence estimates.

THE NEED

The PHS has estimated that about one million persons in the U.S. are now infected with HIV. This estimate is based on data from AIDS case surveillance and on information on HIV prevalence collected from CDC national seroprevalence surveys. However, these data are unable to provide precise estimates of the number of infected persons in the United States. A variety of statisticians and mathematicians have estimated numbers ranging from 600,000 to 1.2 million, depending on various models and assumptions.

As of October 1990, 33 States required reporting of HIV infection to their health departments. HIV infection reports are useful in directing HIV and AIDS-related prevention activities, including partner notification and referral for appropriate medical management. HIV infection reports also supplement AIDS surveillance data in providing a minimum estimate of the number of HIV-infected persons. Currently, there is no standardized system of HIV infection reporting for the United States; however, 20 States are working with CDC to standardize reporting.

Although State and local estimates of HIV prevalence are essential for local planning, few States and cities have the expertise to use statistical methods to estimate HIV prevalence.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) Refine statistical and mathematical models used to estimate HIV prevalence in the United States; 2) continue to collect data on patients meeting the CDC surveillance case definition for AIDS; and, 3) when possible, supplement this information with HIV seroprevalence data.

PHS ROLE AND ACTIONS

The PHS will regularly publish summary data, in a standardized format from all the States with required HIV infection reporting, which will provide improved estimates and understanding of

the extent and impact of the HIV epidemic in the United States.

By 1994, the PHS, in concert with other public organizations, will:

- Develop statistical methods to make more precise HIV prevalence estimates for defined groups, incorporating seroprevalence data available for these groups;
- Evaluate these statistical methods and have their limitations and possible biases understood;
- Write computer programs to implement these methods and distribute the programs to local public health officials;
- Publish these methods in peer-reviewed scientific journals, indicating acceptance by the scientific community, and train local public health personnel in workshops on the proper use of these methods;
- Make available estimates of the relative impact that education and drug therapy each has in reducing the magnitude of the epidemic;
- Develop risk estimates for HIV transmission in seropositive persons asymptomatic for AIDS undergoing AZT or other drug therapy; and
- Maintain the established national system of AIDS case surveillance and assist in the establishment of a national surveillance system for HIV infection.

STRATEGIC ELEMENT II.A.2

Determining the prevalence of HIV infection in the U.S. population by age, sex, race, ethnicity, geographic location, and behavioral characteristics.

THE NEED

The prevalence of HIV infection varies widely by geographic area and by demographic and behavioral subgroup. It is essential that HIV prevention activities be targeted to those geographic areas and population groups currently affected by HIV and to those into which the virus may be spreading. Knowledge of the current patterns of HIV infection and estimates of the

total number of infected persons are important for anticipating future health needs and establishing and targeting HIV programs. In addition, knowledge of HIV prevalence and trends over time are important for evaluating the effectiveness and impact of HIV prevention activities.

THE LONG-TERM OBJECTIVE

The long-term objective is to have surveillance information available at the national and local levels to monitor the full impact of HIV infection on morbidity and mortality. Separate surveillance methods should be in place to monitor infants, children, adolescents, and adults, given the varying manifestations of HIV in different age groups, in members of different racial and ethnic groups, in persons with different modes of exposure, and in persons receiving different sources of care. HIV seroprevalence data should be analyzed and used to target ongoing HIV prevention programs, to assess whether prevention programs are needed in specific locales and populations, and to evaluate such programs. In addition, results from surveys and studies of HIV infection should be used in planning for future health care needs and will be instrumental in promoting the institution or revision of health policies.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Publish data from special surveillance projects that provide a better understanding of the spectrum of HIV illness in different groups of persons; have Federal, State, and local agencies and organizations use prevalence data to plan, implement, target, evaluate, and redirect HIV programs;
- Implement studies of HIV infection among at-risk groups and women delivering live infants in 95 percent of targeted State and local health departments, and among at-risk adolescents in facilities for runaway youth, juvenile detention centers, and school clinics;
- Determine which diagnostic markers are the most reliable indicators of HIV infection and AIDS; identify and characterize oral diagnostic markers of HIV disease such as oral candidiasis, hairy leukoplakia, and oral Kaposi's sarcoma;

and make progress in identifying several significant natural correlates of immunity and specific surrogate markers that can be used to assess the impact of therapy on an individual patient, particularly as those markers may vary according to sex, age, race, or exposure category:

- Develop improved methods for estimating the impact of migration of HIV infected persons.

STRATEGIC ELEMENT II.B.1

Improving understanding of risky sexual practices.

THE NEED

Because HIV infection can be prevented largely through behavioral interventions, behavioral research is an important component of the effort to combat the AIDS epidemic. Improved knowledge of sexual behaviors and choices that place people at risk will assist in modeling the likely spread and level of HIV infection, developing and evaluating AIDS risk reduction programs, and increasing our understanding of differences in infection patterns across different age and cultural groups.

THE LONG-TERM OBJECTIVE

The long term objectives are: 1) To have available current data on prevalence of behaviors that place people at high risk of HIV infection, including as appropriate, regional and demographic subdivisions within the data set, optimizing the use of existing data; and 2) to have an accurate understanding of high risk sexual behaviors as a means of HIV transmission.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Evaluate current data collection efforts and revise these as appropriate to assure that the necessary information is available to determine the prevalence and impact of high risk sexual behaviors on the continuing transmission of HIV and to monitor the effects of education and behavior change programs;

- Establish a data analysis framework to incorporate the collected data quickly into a useful data set that can be analyzed and used for resource allocation;
- Make available information about current HIV and AIDS-related behavioral risks in adult populations; and
- Apply these findings to public health interventions.

STRATEGIC ELEMENT I.I.C.1

Developing, implementing and evaluating comprehensive AIDS health education programs designed to prevent or modify behaviors that result in HIV infection in adolescents.

THE NEED

Youth throughout the Nation are engaging in high risk behaviors that can lead to HIV infection. A school-based survey conducted in 1989 of a national probability sample of high school students showed that 3 percent had used IV drugs, that 59 percent had engaged in sexual intercourse, and that 21 percent had four or more sexual partners. Studies of Job Corps applicants, military recruits, and college students show that young persons are becoming infected with HIV.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) understand the factors associated with high-risk behavior; 2) identify the best and most effective approaches for communicating disease prevention and health promotion messages to high-risk adolescents; 3) have national education and health organizations work with State and local education agencies to train educational personnel and to implement comprehensive health education programs designed to prevent initiation of and to reduce the risk of behaviors associated with HIV infection and other important health problems; 4) collect information related to the prevalence of behaviors associated with the transmission of HIV infection to determine the effectiveness of school and community-based interventions. (See pages 11 and 12 for Year 2000 HIV Infection Objectives #3, #4, #10, and #11 which relate to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS. in concert with other public and private-sector organizations, will:

- Assess the prevalence of behaviors that result in HIV infection among high school and college age youth;
- Develop hypotheses and theoretical models explaining the association between drug use, including alcohol, sexual behavior, and the role of perceptions of risk and decisions regarding involvement in HIV transmission behaviors;
- Evaluate model intervention protocols in demonstration research programs in multiple sites with multiple populations of adolescents, including youth who are not in school;
- Develop a means to coordinate efforts among youth serving organizations in up to six cities to ensure that resources are used as effectively as possible to address the full range of health needs of high risk youth, including HIV prevention;
- Provide technical assistance to build coalitions in up to six major demonstration cities among local agencies and community-based organizations to prevent HIV infection among high risk youth;
- Disseminate information about effective educational materials and strategies designed to prevent HIV infection and recommend communication strategies for adolescents to prevention programs nationwide, resulting in measurable improvements in the design of educationally and culturally relevant alcohol and other drug abuse messages;
- Integrate HIV education within more comprehensive school health education programs;
- Disseminate effective HIV educational material to college students;
- Have at least 33 percent of the Pregnant and Postpartum Women Program grantees develop prevention messages as part of their overall service delivery plans; have at least 50 percent of the High Risk Youth Projects funded by the

PHS incorporate educationally and culturally relevant communication strategies as an integral part of their program; and

- Conduct evaluations to assess and improve the effectiveness of school- and community-based interventions designed to reduce behaviors that result in HIV infection.

STRATEGIC ELEMENT II.C.2

Developing effective behavioral strategies to prevent the spread of HIV infection.

THE NEED

To prevent the further spread of HIV infection, advances must be made to: 1) Develop behavioral intervention strategies for groups that have not been effectively reached by existing prevention efforts; 2) establish causal links between behavioral interventions and behavior change across and within populations; 3) assess existing intervention efforts and improve the existing strategies that have shown some effectiveness; and 4) develop an overall effective intervention program to promote behavior change that will prevent the further spread of the HIV epidemic.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) improve understanding of the effectiveness of different behavioral strategies to prevent the spread of HIV infection; 2) improve understanding of culture-specific approaches to HIV prevention; 3) improve translation of research findings to applied clinical and community settings; 4) evaluate existing prevention efforts; 5) develop effective intervention strategies for specific populations (including IDUs, women and youth); and 6) improve the understanding of psychosocial, interpersonal, and socioeconomic factors and barriers to effective behavior modification.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Conduct behavioral intervention evaluations to test HIV prevention strategies across multiple

sites and populations through cooperative studies

- Hold a conference to address key methodologic issues impeding AIDS prevention research;
- Develop a plan to specifically address existing knowledge gaps related to preventing the spread of HIV infection;
- Disseminate findings on prevention efforts that have demonstrated behavior change to State AIDS coordinators, federally supported AIDS prevention programs, and regional and community-based programs conducting HIV and AIDS activities.

STRATEGIC ELEMENT II.C.3

Expanding and evaluating HIV counseling and testing and integrating aspects of early intervention.

THE NEED

Of the estimated one million persons in the United States infected with HIV, many are unaware that they are. Counseling, testing, referral, and partner notification (CTRPN) services are unavailable in 95 percent of the community health centers, 40 percent of the sexually transmitted diseases (STDs) clinics, and 80 percent of the tuberculosis clinics. Moreover, as drug-abuse-related transmission of HIV becomes an increasingly important source of transmission, it is important to have drug abuse treatment programs also provide CTRPN services. Though CTRPN services are considered to be key components of an HIV prevention strategy, insufficient studies appear in the published literature to assess behavioral and mental health outcomes associated with HIV counseling and testing. Gaps in knowledge exist regarding the effectiveness of existing HIV counseling programs and in methods for identifying effective counseling interventions for specific populations of HIV seropositive individuals.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) efficiently provide all persons at risk of acquiring HIV infection effective and culturally sensitive counseling and testing services; 2) have available trained health

providers to provide counseling and testing services based on fully researched population-specific model protocols, which will result in curtailing the spread of HIV infection and providing referral for appropriate mental health, medical, and substance abuse treatment. (See page 11 for Year 2000 HIV Infection Objective #8 which relates to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Increase counseling and testing services in community health centers, sexually transmitted disease clinics, tuberculosis clinics; and in communities with a high prevalence or incidence of AIDS, expand by 50 percent the drug treatment programs providing testing and counseling services; in communities with a low prevalence or incidence of AIDS, expand by 25 percent the drug treatment programs providing testing and counseling services; and increase the training of health and mental health care providers in HIV and AIDS-related counseling;
- Improve HIV counseling protocols for specific populations based on research results documenting mental health and behavioral outcomes of various counseling approaches;
- Expand support for State and local efforts in notifying, counseling, and testing of the sex partners and needle sharing partners of individuals with HIV infection;
- Expand support to evaluate the effects of counseling on behavior and subsequent serostatus among high risk persons, and expand and evaluate HIV counseling and testing in STD and tuberculosis (TB) clinics and community health centers; expand and evaluate partner notification services in **STD**, **TB**, and family planning clinics, drug treatment and migrant health centers, and alternative test sites; and develop and evaluate a system for follow up of seropositive persons who do not return for test results and post test counseling; and
- Link counseling and testing programs to health care systems to provide ongoing services for those who are HIV positive, to assess the clinical

status and provide recommendations for early intervention.

STRATEGIC ELEMENT II.C.4

Preventing maternal transmission of HIV and AIDS.

THE NEED

Over 15,000 women with AIDS have been reported in the United States. At least 10 percent of all AIDS cases are among women, and 85 percent of women with AIDS are of childbearing age. The proportion of AIDS cases in women has risen from 7 percent of all cases reported before 1984 to 11 percent in 1990. The prevalence of HIV infection in women of reproductive age is increasing in the U.S. - approximately 100,000 women of childbearing age are believed to be infected with HIV. Intravenous drug abuse and heterosexual contact is primarily associated with and responsible for this steady increase in the proportion of AIDS cases among women, and it is reasonable to conclude that this will lead to a growing problem in newborns.

Based on existing data, an estimated 20-40 percent of infants born to HIV-infected mothers will be infected with the virus at birth. As of July 1990, 80 percent of the reported 2,464 pediatric AIDS cases resulted from maternal and infant transmission. Of infants with AIDS, 60 percent were born to mothers who were IVDUs, and 14 percent were born to mothers who had partners who were IVDUs.

THE LONG-TERM OBJECTIVE

The long-term objective is to better understand the transmission of HIV from mother to child and the progression of HIV-related disease in infants and children, and to then to design surveillance, epidemiologic prevention, outreach, and treatment programs that address the problem. (See page 10 for Year 2000 HIV Infection Objective #2 which relates to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Revise and publish guidelines for prevention of perinatal transmission of HIV;
- Assess the impact of different public health programs promoting HIV testing and counseling and early intervention in women and children;
- Develop new information and intervention models for effective strategies for the reduced spread of HIV among IVDUs, their sexual partners, and their children;
- Develop information on the effectiveness of drug abuse treatment programs for women of child-bearing age, their enrollment and retention in programs, their drug use patterns, and their physical and mental health;
- Include studies of women and children in the “Cooperative Agreement for Multi-Site Trials of Behavior Strategies to Prevent the Future Spread of HIV Infection”;
- Have advanced efficacy trials of therapeutic interventions to prevent perinatal transmission; and
- Conduct studies examining factors (both behavioral and biologic) that influence heterosexual transmission to and from women.

STRATEGIC ELEMENT II.C.5

Preventing HIV Infection in poly-drug and non-IV drug users.

THE NEED

While AIDS research has focused on the IV drug (primarily heroin) user, epidemiologic research and ethnographic studies indicate that many drug abusers are poly-drug rather than single drug users or even “single-route” users.

Cocaine, used alone intravenously, or with heroin, or by smoking (in the form of free base or crack), is becoming a significant drug of abuse, and a form of smokable methamphetamine known as “ice” has been identified as an emerging drug problem. Other drugs, such as benzodiazepines, amphetamines, alcohol, and marijuana, also are used extensively by those in and out of treatment.

Moreover, evidence suggests that injection of such drugs as anabolic steroids and growth hormones by body builders, athletes, and adolescents seeking to enhance their appearance frequently involves needle sharing and sexual behaviors that promote the transmission of HIV. Information regarding the use of these drugs is sparse.

THE LONG-TERM OBJECTIVE

The long-term objective is to conduct systematic surveillance of these “real life” patterns of drug abuse, to understand how these drugs and use patterns affect the vulnerability to and course of HIV infection, and then to develop effective methods to prevent or modify high risk behaviors.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Identify the incidence and prevalence of patterns of poly-drug, and non-IV drug use in groups at risk for AIDS, and determine the prevalence and incidence of HIV infection in these groups;
- Develop and test programs of primary and secondary prevention;
- Improve the ability to predict drug users’ resistance to prevention and intervention efforts and identify causes of relapse; and
- Report on evaluations on the associations and interactions between sexual and drug abuse behaviors.

STRATEGIC ELEMENT II.C.6

Assisting other countries in their AIDS prevention activities.

THE NEED

The World Health Organization (WHO) estimates that by the year 2000 a total of 40 million persons will be infected with HIV, creating a true worldwide pandemic. The HIV epidemic will continue to have far reaching health, social, and economic consequences for all nations. The epidemic places extraordinary demands upon the

health care infrastructure and drains health and human resources throughout the world. Continuing to develop and strengthen HIV and AIDS prevention capacities at the global level is therefore essential.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) promote strong national AIDS programs; 2) control the transmission of HIV by eliminating transfusion of infected blood to the extent possible and develop national transfusion policies, including, where possible both epidemiologic and serologic screening for transfused blood products; 3) establish comprehensive programs in AIDS education; 4) make available health education to pregnant women, and persons with sexually transmitted diseases through national ministries of health; 5) make available commodities to prevent HIV infection (e.g., condoms); 6) improve, in selected countries, the effectiveness of the treatment of sexually transmitted diseases and the treatment of substance abuse as HIV prevention strategies; and 7) develop educational programs targeting high risk populations.

PHS ROLE AND ACTIONS

By 1994, the PHS will:

- Provide, through the United States Agency for International Development (USAID), WHO, the Pan American Health Organization (PAHO), and other international organizations, technical assistance to strengthen foreign AIDS prevention and control programs, including epidemiologic research, surveillance, and intervention programs, and provide information regarding current U.S. developments;
- Assist in the development and implementation of international public health policies for persons with HIV infection and AIDS;
- Collaborate with the WHO to identify and provide infrastructure development to those areas with populations of high seroprevalence that may serve as vaccine testing sites.

STRATEGIC ELEMENT II.C.7

HIV Vaccine liability issues.

THE NEED

There exist concerns among researchers and pharmaceutical companies over potential financial liabilities related to testing and subsequent sales of HIV vaccines. It has been suggested that concerns over the cost and availability of liability insurance might delay or eliminate promising vaccine research, and could result in refusals to manufacture and market an HIV vaccine once it has been approved by the Food and Drug Administration (FDA).

LONG TERM OBJECTIVE

The long term objective for this activity is to ensure that HIV vaccines are developed and marketed.

PHS ROLES AND ACTIONS

By 1994, PHS, in concert with other public and private-sector organizations, will explore whether liability concerns are currently serving as a barrier to the HIV clinical trials, and whether they could have negative impact on potential vaccine availability following FDA approval. This will include discussions of what role, if any, the Federal Government might undertake in the absence of private sector solutions.

STRATEGIC ELEMENT II.D.1

Preventing transmission of HIV in health care settings.

THE NEED

Approximately 6.9 million health care workers in the United States are potentially at risk of blood contact and infection with blood-borne pathogens during their performance of job duties. As the number of persons with HIV infection who require medical care increases, the potential for occupational transmission of HIV will increase. Despite this potential risk, existing data are inadequate to estimate accurately the number who have been infected with HIV through occupational

exposure, to estimate the risk of transmission of HIV and other blood-borne agents in the work place, to identify specific risk factors, or to develop specific preventive strategies for many of these groups of workers. Studies do indicate, however, that risks could be reduced if more health care workers followed recommended precautions and if bio-engineering controls, safer devices, and improved personal protective equipment to protect workers were developed. Additionally, transmission of HIV to patients by an infected health care worker during invasive procedures has been reported.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) establish a national surveillance system for health care workers and others who acquire HIV infection as a result of occupational exposure; 2) design medical devices that are engineered to protect workers from percutaneous injuries caused by unprotected sharp instruments; 3) educate health care workers to understand the concept of “universal precautions”; 4) undertake continuing training and education on how to minimize exposures and practice safe work procedures; 5) have employers set up education and medical management programs that include postexposure management, counseling, and documentation of exposure: define the nature and frequency of worker exposure to blood and other body fluids capable of transmitting HIV, the risk of transmission of HIV-associated with these occupational exposures, and assess the risk of HIV transmission to patient during invasive procedures; and 7) develop and evaluate measures to reduce exposure and infection risks and assure that appropriate medical care is provided to all patients, including those with HIV, by developing practical and effective infection control measures for use by health-care workers. (See page 12 for Year 2000 HIV Infection Objective #14 which relates to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Institute procedures in at least 90 percent of States that allow for the timely, systematic, and uniform collection of data on occupationally related cases of HIV transmission and for

reporting of this data to CDC to supplement established surveillance data on occupational transmission in reported AIDS cases;

- Make available estimates of the risk of transmission following exposure to HIV that occur in the work place (i.e., mucous membrane and skin exposures, in addition to percutaneous exposures);
- Assess the risk of HIV transmission to patients and develop and evaluate methods to prevent such transmission;
- Design and implement new intervention strategies to reduce workers’ risks of occupational exposure to blood, occupational acquisition of HIV infection, and patients’ risk of nosocomial infection (evaluations have already begun to assess the effectiveness of these strategies in reducing risks);
- Make available training in at least 95 percent of medical and professional schools about HIV infection control measures, establish programs for post exposure management, and develop model curricula for various groups of workers; and
- Implement a priority quality control assessment of preventive barrier devices, i.e., gloves, gowns, masks, anti-needle stick devices, and eye protectors; and improve and establish labeling guidelines for preventive barrier devices.

STRATEGIC ELEMENT II.E.1

Expediting the dissemination of the latest information on proven prevention techniques, new therapies, and state-of-the-art health care.

THE NEED

An up-to-date knowledge of what works and what does not work is not generally available to local and community-based health providers and the public at large.

THE LONG-TERM OBJECTIVE

The long-term objective is to rapidly disseminate information on state-of-the-art clinical care; recent research findings; up-to-date information on

investigational treatment INDs; newly approved therapies; current health frauds; and lessons learned from effective alcohol, drug abuse, and HIV prevention programs to the health provider community and the public, urban and rural environments.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with health professional organizations and organizations serving people with HIV infection and AIDS, will:

- Utilize all PHS communications modes (Morbidity and Mortality Weekly Report, FDA Consumer, National Library of Medicine AIDS Bibliography and on-line retrieval services, news releases, video news releases, etc.) to communicate information on HIV infection and AIDS:
- Expand the AIDS Clinical Trials Information Service to include information as soon as it is available for release on results of clinical trials and treatment recommendations;
- Develop and disseminate state-of-the-art guidelines for all aspects of treatment of HIV infection:
- Report on the results of PHS-funded programs, establish a system of identifying exemplary prevention programs, and make use of the Learning Community Conference and other forums which the prevention field recognizes and accepts as important vehicles for the transfer of information;
- Conduct health fraud conferences and establish State health fraud task forces and information exchange networks;
- Continue to support regional, national and international conferences to facilitate the exchange of scientific information: and
- Continue to educate community leaders on community research initiatives.

STRATEGIC ELEMENT II.E.2

Encouraging abstinence or proper and consistent use of condoms.

THE NEED

Abstinence and barrier products can help control the spread of HIV infection as well as other sexually transmitted diseases (STDs) and offer the most available form of protection. Improve public understanding and proper and consistent use of condoms. There is a need to improve barrier methods in conjunction with spermicidal/virucidal formulations for protection against HIV infection and other STDs.

THE LONG-TERM OBJECTIVES

The long-term objective is to encourage abstinence, to promote the proper use of condoms, to develop and market new types of condoms that are widely acceptable (functionally and culturally), to develop a protective device for women that does not depend on a man's decision, to characterize the effectiveness of the existing spermicides/virucides, and to promote the development of new spermicides/virucides that are safe and effective.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Determine the relative risks of HIV infection based upon exchange of body fluids in relation to the presence of various genital lesions;
- Define the major characteristics of condoms and spermicides that different populations find physically and culturally acceptable ;
- Determine, through clinical and laboratory studies, the potential of spermicides as a practical measure to prevent the spread of HIV infection;
- Incorporate research findings into intervention programs targeted at high risk groups;
- Promote development of condoms of new materials and test them for their acceptability.

safety, and efficacy in contraception and disease prevention;

- Conduct research to learn why people do or do not use condoms correctly:
- Design educational materials that can increase abstinence and correct use of condoms among high risk groups: and
- Implement a priority quality control assessment of condoms.

STRATEGIC ELEMENT II.E.3

Encouraging HIV-infected persons to be aware of their infection and to seek early medical care and social services.

THE NEED

Recent evidence has shown that many HIV-infected people could benefit from counseling and prevention oriented medical care. In addition to personal health benefits, delaying the onset of illness through early intervention can extend the period of productive employment for infected persons. Furthermore, early intervention may reduce future transmission of HIV infection, largely by encouraging desirable changes in behavior on the part of those already infected.

At present, however, these potential benefits are not being widely realized for three main reasons: 1) fewer than half of the roughly 1 million HIV-infected people are aware of their HIV status; 2) some have been tested but do not know how to access a system of prevention oriented medical care: and 3) others are economically unable to obtain care in the early stages of infection.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) bring HIV-infected people into culturally sensitive systems that provide health care and social support services in the earliest stage of HIV illnesses: and 2) by the end of the decade, ensure that all infected people are aware of their infection and referred to appropriate prevention oriented medical care and social support services, through community-based systems of care, before developing symptoms of HIV disease.

PHS ROLE AND ACTIONS

Progress needs to be made by many public and private organizations. The PHS, in concert with other public and private-sector organizations, will help facilitate the provision of care by State and local agencies. By 1994, the PHS will:

- Establish working relationships among PHS Service Demonstration projects and HIV testing centers in their cities that provide referral of people to appropriate sources of testing and of prevention oriented medical care and social support services:
- Establish working relationships among at least 25 percent of the federally supported Community Health Centers and HIV testing centers in their cities:
- Develop and test in the PHS Service Demonstration program at least three models of early intervention in HIV infection, including mental health counseling aimed at improving psychological and behavioral outcomes;
- Encourage, in conjunction with the Bureau of Prisons, those responsible for health care of incarcerated individuals to work with State and local organizations to provide prevention and intervention services to HIV-infected and at risk incarcerated individuals: and
- Encourage drug treatment at primary care sites.

STRATEGIC ELEMENT II.F.1

Evaluating the effectiveness of public information programs in preventing HIV infection.

THE NEED

Although public information programs account for a very small percentage of the PHS HIV/AIDS budget, these programs are able to reach more than 200 million Americans every month with prevention promoting messages. The audience for these programs includes persons at high risk of infection as well as persons who exert strong influence on the policies and behaviors within communities, States, and the nation.

Over the past **20** years, health communication programs directed toward cardiovascular disease risk factors have proven increasingly successful. Systematic evaluation of the cardiovascular communications programs has helped program managers understand the conditions that enhance the effectiveness of public communication programs. Lessons learned from these successful public communication programs have compressed the learning curve, thereby allowing for the development of very sophisticated HIV public information programs. These HIV programs need to be evaluated systematically and fine-tuned to assure their effectiveness within target populations.

- Characterize the conditions under which HIV information programs are most effective;
- Assess the effectiveness of clearinghouse and hotline services in providing information to targeted populations; and
- Determine the efficiency of employing paid advertising as a strategy for improving the effectiveness of public service advertising materials.

THE LONG-TERM OBJECTIVE

The long-term objective is to utilize established evaluation methods and systems to ensure maximum benefits from public information programs and to increase understanding of the causal factors associated with producing public health benefits.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Apply systematic, quantitative, formative evaluation in creating information materials and strategies that effect desired changes in target populations;
- Conduct efficacy testing of public information materials and strategies to determine the potential benefits of program efforts under ideal circumstances;
- Systematically track public information programs in sentinel communities to monitor the continuing effects of program and nonprogram activities on the knowledge, attitudes, and practices of target populations, and the degree to which specific interventions are providing change;
- Monitor the knowledge and attitudes of the U.S. adult population regarding HIV transmission, HIV prevention, persons infected with HIV, and programs to prevent or treat HIV infection;

III. PRODUCT EVALUATION, RESEARCH, AND MONITORING

PRODUCT EVALUATION, RESEARCH, AND MONITORING STRATEGY: Evaluate HIV vaccines and AIDS therapeutic drugs and biologic agents and improve blood safety.

PHS is responsible for determining the safety and efficacy of human drugs and biologic products to treat HIV infection, HIV-associated illnesses, and AIDS and for ensuring the safety of the Nation's blood supply. In discharging these responsibilities, PHS reviews new drug applications, monitors the safety of marketed drugs, and inspects blood banks and other blood processing facilities. There is special emphasis on ensuring timely premarketing review of drug products that offer promise for diagnosing, treating, or preventing HIV and HIV-related diseases. PHS also stresses the timely exchange of information among the public, government, and academia regarding drug development strategies and the design and conduct of clinical trials.

STRATEGIC ACTIVITY III.A

Evaluate therapeutic, diagnostic, and preventive agents and regimens.

- III.A.1 Facilitating the clinical testing and approval of promising products.
- III.A.2 Facilitating cooperation between the United States and foreign investigators in conducting clinical trials of AIDS vaccines in an international setting.
- III.A.3 Increasing the participation of urban poor, racial and ethnic minorities, women of childbearing age, children, and rural individuals in clinical trials, and continuing to work with community research studies.

STRATEGIC ACTIVITY III.B

Help ensure the safety of blood supplies, blood products, human organs, and tissues.

- III.B.1 Addressing the safety of the blood supply.

STRATEGIC ELEMENT III.A.1

Facilitating the clinical testing and approval of promising products.

THE NEED

Although zidovudine (AZT) has been shown to delay the progression or onset of AIDS, there is no available treatment that will cure HIV infection. Moreover, as HIV disease progresses, people develop one or more opportunistic infections, many of which are difficult to treat. Rapid development and marketing of safe and effective therapeutic, diagnostic, and preventive agents and regimens is therefore critical.

THE LONG-TERM OBJECTIVES

The long-term objective is to encourage the most timely, effective, and efficient premarket research and to assure the timely review of products that offer promise for diagnosing, treating, curing, or preventing HIV infection or HIV-related disease.

PHS ROLE AND ACTIONS

Over the next several years, the PHS will:

- Increase the current practice of early and continued consultation between the FDA and manufacturers/sponsors to provide guidance on efficient and effective product development;
- Facilitate making investigational therapies more widely available, where appropriate, by working with sponsors on the development of treatment INDs and open safety protocols;
- Approve more drugs and biological products for marketing based on Phase 2 studies when sufficient data are available, and encourage the sponsor to conduct needed postmarketing Phase 4 studies;
- Undertake focused regulatory research on critical rate-limiting aspects of the preclinical, clinical, and manufacturing phases of product development and evaluation;
- Continue a priority review program for new devices with specific AIDS prevention, diagnostic, or therapeutic claims; and

- Offer educational opportunities to health care professionals about the regulatory requirements for conducting clinical trials.

STRATEGIC ELEMENT III.A.2

Facilitating cooperation between the United States and foreign investigators in conducting clinical trials of AIDS vaccines in an international setting.

THE NEED

The HIV pandemic is a conglomerate of many overlapping epidemics spanning national borders. While it is most likely that initial trials to determine safety and efficacy of potential vaccines will be done in developed nations, further demonstrations of effectiveness may require cooperation between U.S. investigators and those in developing countries to test certain population groups in which infection rates of new cases exceed those in the U.S.

THE LONG-TERM OBJECTIVES

The long-term objective is to assure international coordination in vaccine development, research priorities, and identification of optimal sites and programs to undertake the clinical studies. This includes facilitating maximum participation by the private sector in international and national vaccine development.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private sector organizations, will:

- Develop standard assays for SIV and HIV immunologic analysis of vaccine candidates for use by the international biomedical research community;
- Address the economic disincentives (e.g., liability) that inhibit greater participation of the private sector in HIV vaccine development;
- Develop the epidemiologic, clinical, and laboratory infrastructure necessary for implementing vaccine trials in international settings; and

- Maintain effective communications between the PHS and the WHO Global Programme of AIDS, and PAHO, as well as with investigators in foreign countries to further enhance cooperation.

STRATEGIC ELEMENT III.A.3

Increasing the participation of urban poor, racial and ethnic minorities, women of childbearing age, children, and rural individuals in clinical trials, and continuing to work with community research studies.

THE NEED

Epidemiologic studies indicate that HIV infection and AIDS is steadily increasing among the socioeconomically disadvantaged. These populations, however, are under represented in several clinical trials of experimental therapies for HIV infection and AIDS. Community-based research on HIV infection and AIDS has provided community clinicians treating these populations experience with the most current treatment procedures and has helped provide researchers access to populations under represented in clinical trials. Communitybased AIDS research programs, however, are available in a relatively small number of cities.

THE LONG-TERM OBJECTIVE

The long-term objective is to be able to provide patients from economically or geographically disadvantaged areas, including the urban poor, racial and ethnic minorities, children, women of childbearing age and rural HIV-infected individuals access to clinical research studies. This objective can be met in a number of ways, including the professional development of providers and Community and Migrant Health Centers (C/MHCs) through the Community Programs for Clinical Research on AIDS or through accessing patient slots in AIDS Clinical Trials Units (ACTUs), university-based research programs, or community-based clinical trials networks.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Increase the links between ACTUs and community health centers providing primary care or substance abuse treatment for drug users;
- Establish guidelines for inclusion of pregnant women in clinical trials of HIV therapies;
- Conduct specific studies to determine the barriers to women in clinical trials and take steps to remove the barriers; and establish guidelines for the inclusion of pregnant women in clinical trials of HIV therapies;
- Expand the Community Programs for Clinical Research on AIDS;
- Develop model guidelines and methodologies for the successful conduct of community-based clinical research; and provide educational and technical assistance to the regulations for the conduct of studies to support new drug approval;
- Expand the number of pediatric ACTUs for evaluation of therapeutic agents in HIV-infected children and adolescents;
- Ensure the proportional inclusion of underserved populations in the clinical trials; and
- Increase ancillary service programs, including those for substance abusing and mentally ill populations, meeting health care and social service **needs** to ensure participation of HIV-infected underserved populations in clinical trials.

The PHS-funded community health centers have had success in enrolling urban poor, racial and ethnic minorities, and women of childbearing age in a program of comprehensive care, including a range of HIV services, particularly early identification and intervention. Several of these health centers are already either clinical trial grantees or part of a grant consortium. By 1994, the PHS will:

- Have at least percent of the community health centers participating in a clinical trial studies; and identify community health center patients with HIV infection on a routine basis to be enrolled in a clinical trial protocol; and
- Develop a network of primary care providers who are able to give consultation and technical assistance on the development and conduct of clinical trials to ambulatory care organizations; and use the national network of Education Training Centers to enhance the collaboration between community physicians and researchers, thereby increasing the assessment and enrollment of minority and women patients in clinical trials.

STRATEGIC ELEMENT III.B.1

Addressing the safety of the blood supply.

THE NEED

The voluntary deferral of blood donation by donors at risk for HIV infection and the laboratory screening of blood donations for HIV antibody have substantially reduced the risk of transfusion-associated HIV infection. People at risk for HIV infection are requested not to donate, and although most exclude themselves, some do not. Among those who donate, a few are so recently infected with HIV that their blood has not developed antibodies, and, therefore, they appear negative on all available screening tests. The under use of autologous transfusions and potential overuse or inappropriate use of homologous blood compounds the problem.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) have a national surveillance and follow up system in place for those who report acquiring HIV infection from screened blood; 2) continue collection of data to improve understanding of why persons at risk for HIV infection donate blood and to have in place improved methods that result in deferral; 3) improve screening techniques and regularly inspect blood bank operations; and 4) transfuse blood and blood components only when appropriate, and use autologous transfusions and intraoperative salvage procedures when they are

made as safe as possible. (See page 11 for Year 2000 HIV Infection Objective #7 which relates to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Improve reporting and investigation at State and local levels of cases of HIV infection and AIDS purportedly acquired from receipt of blood and blood products;
- Reduce the number of blood donors who are persons at risk of HIV infection, as indicated by a decrease in the number of HIV-seropositive blood donors;
- Collaboration with blood collection centers to develop better methods of deferring persons at risk from donating blood;
- Conduct regular inspections of blood banks and plasmapheresis centers to maintain proper quality control and record keeping procedures;
- Initiate a physician's survey, for possible future education programs, about appropriate blood use to determine physicians' knowledge about the proper use of blood and blood products;
- Disseminate pamphlets about the appropriate use of blood and autologous transfusion to more than 200,000 physicians, and disseminate patient brochures to patients through doctors' offices; and
- Continue to maintain surveillance for HIV-2 in the blood supply and to monitor the prevalence of HIV-2 in the U.S. population.

IV. CLINICAL HEALTH SERVICE RESEARCH AND DELIVERY

PHS manages a variety of service, education, and research programs designed to improve the care of persons with HIV infection. Emphasis is placed on the special needs of populations at substantial risk of HIV infection. These programs include HIV clinical services, demonstration projects, and support of city and State health and social services. PHS supports curriculum development for health profession schools to ensure that students are trained in the diagnosis and treatment of HIV, AIDS and related diseases: it also administers programs to train staff of federally funded health care facilities who are involved in providing care to HIV infected patients. PHS supports clinical research involving the neuropsychiatric, behavioral, and psychological aspects of HIV infection. PHS also supports the development of health services research and patient care guidelines to encourage optimal clinical practice and health care delivery arrangements; those guidelines will be updated routinely on the basis of ongoing analysis of the outcomes of patients with HIV and related conditions.

CLINICAL HEALTH SERVICES RESEARCH AND DELIVERY STRATEGY: Enhance the capacity of organizations serving patients with HIV infections.

STRATEGIC ACTIVITY IV.A

Support community-oriented health care for HIV-infected individuals,

- IV.A.1 Increasing the development of State and local consortia for the planning, assessment, and organization of health care.
- IV.A.2 Encouraging the organization of family-centered and community-oriented health care programs, providing a wide range of medical and social services.
- IV.A.3 Improving the availability, effectiveness, and community acceptance of drug treatment for those at risk of HIV infection.
- IV.A.4 Integrating AIDS services into the framework of existing alcohol and drug abuse treatment and family planning programs

and drug treatment in primary care health systems.

STRATEGIC ACTIVITY IV.B

Provide comprehensive health care services to American Indians and Alaska Natives with HIV infection who are eligible for care from the Indian Health Service.

- IV.B.1 Preventing the spread of HIV and treating AIDS in American Indian and Alaskan Native communities.

STRATEGIC ACTIVITY IV.C

Train health professionals to educate and counsel persons both with and at risk of HIV infection.

- IV.C.1 Training primary care providers in the early diagnosis, treatment, counseling, and referral of high-risk HIV populations, with special emphasis on providers serving minority populations and substance abusers practicing high-risk behavior.
- IV.C.2 Expanding laboratory training and quality assurance programs.

STRATEGIC ACTIVITY IV.D

Support efforts to bring drug users into treatment, to improve drug abuse treatment, and to prevent and alter high-risk drug use behavior.

- IV.D.1 Evaluating street outreach programs and expanding those that are effective in reducing HIV infection.

STRATEGIC ACTIVITY IV.E

Conduct and support research-related activities to improve clinical practice and patient care delivery for persons infected with HIV.

- IV.E.1 Supporting the development of clinical guidelines and health services research.

STRATEGIC ELEMENT IV.A.1

Increasing the development of State and local consortia for the planning, assessment and organization of health care.

THE NEED

The episodic, long-term care needs of HIV-infected people can be met most efficiently and effectively through diverse providers of medical and social care, organized through consortia or coalitions. Such coalitions enhance limited resources through sharing; help define the HIV epidemic as a community problem, thus attracting additional resources and strengthening referral linkages; and provide a vehicle for effective case management and thus continuity of care for HIV infected patients. Groups of individuals and organizations began to form AIDS coalitions in the early days of the epidemic. These consortia have repeatedly demonstrated that cooperative linkages enhance service delivery and availability, leverage funding, and allow for more effective needs assessments and resource allocation. The importance of consortia development and subsequent community partnerships in the epidemic have been recognized and endorsed in several reports, and most recently in the Ryan White Comprehensive AIDS Resources Emergency Act of 1990.

LONG-TERM OBJECTIVES

The long-term objective is to support the continued development of consortia in order to maximize and coordinate community and State health and social care resources directed to HIV care. This objective requires PHS collaboration with concerned national, State, and local organizations to provide guidance, technical assistance, and, if available other resources, to support: 1) consortia development in every major metropolitan statistical area; 2) development of consortia at appropriate levels to lead planning and needs assessment efforts for rural areas that may have few existing community-based organizations; 3) identification and dissemination of technical assistance and information on successful consortia development, particularly those that have successfully included minority and ethnic organizations within their membership; and 4) evaluations of consortia achievements in

bridging resource gaps, particularly with reference to early intervention and continuity of care.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Identify and define elements of a broad based consortia, and disseminate them as part of an overall technical assistance (TA) package; develop a technical assistance program, (including materials developed through a cooperative agreement with Association of State and Territorial Health Officials, Conference of Mayors, and others) to assist in coalition development; and establish technical assistance teams to visit sites requiring assistance;
- Examine the feasibility of requiring that all applicants for HIV service funding, demonstrate their active coordination and collaboration with public and private organizations and providers as evidenced by consortium membership, cooperative agreements, etc.;
- Develop, disseminate, and maintain a geographically indexed agency-specific descriptive listing of HIV service-related programs, and their subsequent HIV direct and related grantees, with an indication of supported and/or anticipated coalitions and consortia; and
- Develop an evaluation plan to determine short and long-term effectiveness of coalitions in enhancing limited resources and improving access to and quality of appropriate care.

STRATEGIC ELEMENT IV.A.2

Encouraging the organization of family-centered and community-oriented health care programs providing a wide range of medical and social services.

THE NEED

It is estimated that approximately 25-30 million people do not have access to routine primary care related to HIV infection and AIDS, including testing and counseling, early intervention, or treatment programs.

LONG-TERM OBJECTIVE

The long-term objective is to expand current Community and Migrant Health Centers (C/MHCs) and to develop new C/MHCs to provide appropriate care for persons with HIV infection and AIDS, specifically in socio-economically depressed areas where the substance abuse, perinatal mortality, HIV infection, and other health related factors are combined to create pockets of greatest need.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private sector organizations, will:

- Identify, with the cooperation of State and local health departments, areas with highest need for services for managing HIV prevention and intervention; include all of the areas with the highest concentration of AIDS in this identification process with appropriate underserved communities within these areas specifically identified for technical assistance;
- Target technical assistance to communities with the highest need to help make grant applications more competitive; and
- Identify and provide technical assistance for communities which do not have C/MHCs and which have an appropriate underserved community with a rapidly increasing number of reported AIDS cases; and, as resources are available, increase the number of users of primary care services in these targeted areas and in other appropriate areas.

STRATEGIC ELEMENT IV.A.3

Improving the availability, effectiveness, and community acceptance of drug treatment for those at risk of HIV infection.

THE NEED

Approximately 32 percent of all reported AIDS cases involve IV drug use, making it the second most common means of transmission of the virus. Drug users who engage in unprotected sexual activity may infect their sexual partners, contributing to the spread of the virus into the

heterosexual, nondrugusing population. Approximately 80 percent of all HIV infection cases attributed to heterosexual transmission have involved sexual contact with intravenous drug abusers. Use of alcohol and other non-injection drugs also has been associated with sexual risk taking.

Increasing retention in treatment, reducing illicit and licit drug use and needle-sharing, improving participation in relapse prevention and aftercare, reducing behaviors that increase the risk of transmitting HIV, and improving acceptance of community drug treatment all are expected to help prevent the spread of AIDS.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) provide immediate drug treatment, matching clients to treatment modalities; 2) provide new pharmacotherapies for the treatment of opiate and cocaine dependence; 3) provide related treatment services (e.g., family counseling, AIDS education) to prevent the transmission of HIV infection through risky sexual practices with drug users; 4) provide aftercare and relapse prevention services to maintain drug abstinence and rehabilitative treatment gains; and 5) achieve broad community-based support of and for referral of high-risk individuals, to drug treatment. (See pages 10 and 11 for Year 2000 HIV Infection Objectives #2, #4, and #5 which relate to this strategic element.)

PHS ROLE AND ACTIONS

By 1994 the PHS, in concert with other public and private-sector organizations, will:

- Carry out PHS responsibilities under the National Drug Control Strategy and participate with the Office of National Drug Control to identify additional initiatives.
- Provide preliminary research results on strategies to increase the effectiveness of treatment outcomes through improved methods of attracting individuals to treatment; through retention of those in treatment; and through creation and enhancement of interventions to treat those who are drug-dependent;

- Increase testing capacity of investigational medications for the treatment of opiate dependence, resulting in four medications under evaluation for the treatment of opiate and cocaine dependence;
- Organize "Treatment Works" community outreach programs and referral to treatment coalitions in areas of high incidence of drug abuse and AIDS;
- Develop a strategy to evaluate nonpharmacologic treatments of drug abuse; and
- Develop ways to promote and gain acceptance of local drug treatment programs, thereby addressing the "not in my back yard" problem.

STRATEGIC ELEMENT IV.A.4

Integrating AIDS services into the framework of existing alcohol and drug abuse treatment and family planning programs and drug treatment in primary care health systems.

THE NEED

Alcohol and drug treatment programs, and family planning clinics may perhaps be the only contact with a health-related agency capable of providing "HIV education" information for many addicts. These programs generally are not organized to focus on AIDS prevention issues and the myriad of physical and mental health problems associated with the care and treatment of HIV-infected people. Counseling and/ or drug treatment capabilities are not available in many primary care locations due to legal, training, and cultural barriers.

THE LONG-TERM OBJECTIVE

The long-term objectives are: 1) Include AIDS prevention services within all alcohol and drug abuse prevention and family planning programs nationwide; and 2) expand training for staff who provide family planning and drug and alcohol services in dealing with AIDS issues.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Double the number of drug treatment programs that offer integrated treatment and prevention services to drug abusers, their sexual partners, and their families;
- Increase by 100 percent the number of drug treatment personnel who are trained to care for patients with HIV infection and AIDS during drug abuse treatment in the 10 cities with the highest incidence of AIDS;
- Develop a national strategy to assure AIDS training, utilizing the model programs developed and implemented by the National Institute for Mental Health, the National Institute on Drug Abuse, and the Office for Substance Prevention (OSAP); develop a national training program that assures access to AIDS training for all OSAP grantees; and provide updated training about HIV infection, AIDS, and drug abuse issues to Title X family planning grantees;
- Establish closer links and better referral networks among family planning clinics and drug abuse facilities;
- Train a higher percentage of primary care providers in high incidence areas of HIV infection and drug abuse in aspects of diagnosis, counseling and management of the dual problems of substance abuse and HIV infection;
- Qualify at least 80 percent of all OSAP High-Risk and Pregnancy and Postpartum Women Grantees to develop AIDS prevention services; and require that grantees who conduct alcohol and drug abuse conferences and workshops incorporate AIDS into their programs;
- Include a focus on AIDS in at least 50 percent of the Community Partnership Grantees funded to bring together public and private-sector organizations to prevent alcohol and drug abuse and involve representatives from agencies whose primary goal is AIDS prevention;

- Integrate AIDS prevention themes in at least 80 percent of the markets targeted for the new urban youth multimedia alcohol and drug abuse campaign; and
- Establish model programs integrating substance abuse care in primary care centers.

STRATEGIC ELEMENT IV.B.1

Preventing the spread of HIV and treating AIDS in American Indian and Alaska Native communities.

THE NEED

The behaviors associated with sexually transmitted disease, teenage pregnancy, and alcohol and substance abuse, which are prevalent in American Indian communities, may predispose American Indians to a rapid spread of AIDS in their communities.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) achieve an HIV seroprevalence rate in American Indian and Alaska Native communities no higher than that of the general population; 2) stabilize sexually transmitted disease rates so that they do not increase in FY 93; and 3) provide all eligible HIV-infected persons with comprehensive health care.

PHS ROLE AND ACTIONS

By 1994, the PHS, through the Indian Health Service, with other public and private-sector organizations, will:

- -Reach individuals on American Indian and Alaska Native reservations and communities with culturally sensitive and effective AIDS prevention messages;
- Establish local AIDS prevention task forces in each American Indian and Alaska Native community;
- Conduct local surveillance efforts which will attempt to identify persons at risk of HIV infection and AIDS;

- Offer voluntary confidential testing to high-risk persons in American Indian and Alaska Native communities;
- Offer early treatment to all identified HIV-infected persons in the American Indian and Alaska Native communities seeking early treatment;
- Provide medical care for all eligible HIV-infected persons, as required by statute; and
- Provide all HIV-infected persons and their families referral assistance to a local support program.

STRATEGIC ELEMENT IV.C.1

Training primary care providers in the early diagnosis, treatment, counseling, and referral of high risk HIV populations, with special emphasis on providers serving minority populations and substance abusers practicing high risk behavior.

THE NEED

Due to the large numbers of HIV-infected people or those at risk in the United States, it is essential for all primary care providers to identify the at-risk patient and provide appropriate counseling, testing, and care for those individuals.

THE LONG-TERM OBJECTIVES

The long-term objective are: 1) increase the involvement of primary care providers in each State who are capable of providing sensitive and appropriate care consonant with the state of the latest scientific knowledge; 2) train all providers to recognize the signs and symptoms of HIV infection and AIDS and substance abuse; and 3) offer educational opportunities (including clinical education) to keep pace with the constantly evolving nature of the HIV epidemic and the knowledge-related available treatments. (See page 12 for Year 2000 HIV Infection Objective # 9 which relates to this strategic element.)

PHS ROLE AND ACTIONS

Over the next several years, the PHS will continue to work in conjunction with national and State

professional organizations and health professional training centers to develop training programs, as well as work with State and local health departments to integrate more fully the CDC sexually transmitted disease training capabilities with the Education Training Center (ETC) activities. The PHS will also develop networks with minority health care providers, minority health professional associations, and with community-based professionals who are playing a major role in the early detection and treatment of HIV-infected individuals. By 1994, the PHS will:

- Develop an expert quality clinical training site at each of the ETC sites;
- Develop a network of expert panel rosters (including accessible telephone numbers) for community consultation for providers within the funded ETCs;
- Have at least 75 percent of the community/migrant health centers working with the ETCs on staff education;
- Have established relationships between the ETCs to assist providers in obtaining information about pertinent clinical trials and studies available in their respective regions;
- Define and demonstrate model clinical training programs for health, mental health, and substance abuse professionals in HIV infection and AIDS;
- Develop models to be used by a cadre of academically, clinically, and community-based professionals who will incorporate AIDS and drug abuse instruction as part of practice and training responsibilities; and
- Improve the assessment and evaluation of education and training needs of primary care providers in order to provide more accurate projections of future supply to meet the needs of the AIDS epidemic.

STRATEGIC ELEMENT IV.C.2

Expanding laboratory training and quality assurance programs.

THE NEED

To respond to increasing demands for highly accurate and reliable laboratory testing in support of HIV prevention, counseling, and treatment programs, expanded laboratory training and quality assurance programs are needed. The focus must be on new tests for HIV-1 and other retroviruses, tests for opportunistic pathogens, tests for assessing and monitoring disease progression (e.g., CD4+ cell testing), and quality assurance methods for identifying and resolving problems in the pre- and postanalytic steps of the laboratory testing process.

THE LONG-TERM OBJECTIVE

The long-term objective is to have sufficient numbers of appropriately trained laboratory workers.

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Have a majority of laboratories that perform Western blot confirmatory testing be familiar with the CDC-endorsed criteria for interpretation in clinical and public health settings;
- Have a majority of laboratories that perform serologic testing for HIV infection participate in voluntary performance evaluation programs which offer them opportunities for problem detection, problem resolution, and self-improvement; and
- Have a majority of laboratories that perform serologic testing for HIV infection participate in laboratory training, and establish and maintain quality assurance in CD4+, as well as, other immune function assays and detection of HIV antibody, antigen, and opportunistic pathogens.

STRATEGIC ELEMENT IV.D.1

Evaluating street outreach programs and expanding those that are effective in reducing HIV infection.

THE NEED

Most drug users are not currently undergoing treatment for drug abuse. For example, 80 percent of intravenous drug users (IVDUs) are not currently undergoing treatment for their addiction. Peer education has been successful in encouraging IVDU's to decrease needle-sharing, to disinfect their drug paraphernalia with bleach, to seek HIV antibody counseling and testing, and to enroll in drug treatment. Street outreach, therefore, has become an important strategy for contacting and educating intravenous drug users who are not in treatment.

THE LONG-TERM OBJECTIVE

The long-term objective is to reach the estimated 80 percent of drug users who are not in treatment with HIV prevention services which would include services for sexually transmitted diseases and tuberculosis. (See pages 11 and 12 for Year 2000 HIV Infection Objectives #6 and #12 which relate to this strategic element.)

PHS ROLE AND ACTIONS

By 1994, the PHS, in concert with other public and private-sector organizations, will:

- Evaluate the effectiveness of street outreach programs in reducing rates of HIV infection in IVDUs and their partners;
- Evaluate the impact on behavior of HIV counseling and testing in drug treatment centers and in STD clinics; and
- Support programs which have demonstrated effectiveness in providing street and community HIV prevention outreach services for IVDUs who are not in drug treatment.

STRATEGIC ELEMENT IV.E.1

Support the development of clinical guidelines and health services research.

THE NEED

Recent research has pointed to differences in outcomes for hospitalized AIDS patients that may be associated with variations in therapeutic and patient management. Researchers also point to the potential effects of increased longevity in individuals with HIV infection and AIDS, including enhanced provision of long-term care and pharmaceuticals. The potential burden to society for delivering care to individuals with HIV infection and AIDS is likely to be immense and provides the impetus for assuring the provision of cost-effective and appropriate care.

This need becomes particularly important as the number of persons with HIV infection and AIDS who require medical care expands, resulting in an increased role for primary care providers in patient management.

THE LONG-TERM OBJECTIVES

The long-term objectives are: 1) collaborate with specialty boards and individual health care practitioners in developing and continually updating clinical guidelines for primary care physicians, reflecting the emerging science knowledge base and professional judgment about optimal clinical practice and health care delivery arrangements; 2) disseminate these guidelines to health care providers, policy makers, and the public; and 3) conduct health services research which addresses issues appropriate for the effective and efficient delivery of health care for persons infected with HIV.

PHS ROLE AND ACTIONS

Over the next several years, the PHS will create an AIDS Medical Care Effectiveness Program

involving three interrelated components: 1) clinical guideline development and dissemination; 2) data development; and 3) health services research.

The PHS will focus on diagnostic workup and early intervention, as well as the management of HIV-associated opportunistic infections and health systems issues important in the delivery of care. By 1994, the PHS will:

- Support the completion, pilot testing, and dissemination of an initial set of clinical guidelines for primary care practitioners and initiate the development of a second set;
- Expand medical effectiveness research based on the gaps identified in the clinical guideline process;
- Expand health services research on HIV and AIDS to address the complex array of problems experienced by different population groups in the organization of health care, health care decision making, ethical issues in the delivery of patient care, and the impact of HIV infection and AIDS on society;
- Continue to expand data gathering and analytic activities that focus on health resources utilization, financing of care, barriers to care, and quality of life and disability among individuals with HIV infection and AIDS;
- Disseminate the information collected on research, clinical care and patient care delivery mechanisms using information delivery systems that have the capability of reaching community HIV health care providers; and
- Have the Educational Training Centers (ETC) program use its national networks to expedite the dissemination of state-of-the-art clinical guidelines to primary care providers.

TRACKING

The Assistant Secretary for Health has made the National AIDS Program Office responsible for monitoring PHS' progress with regard to the AIDS strategies described above. Accordingly, NAPO will report regularly on the status of each strategic activity.

The lead agency for each activity will report its achievements to NAPO every six months. The following month, NAPO will summarize the current status of each activity. In November 1992 and every year thereafter, NAPO will prepare a report for the Assistant Secretary for Health on PHS' achievements in combatting the AIDS epidemic during the preceding fiscal year.

APPENDIX 1:
HIV/AIDS TOTAL FEDERAL SPENDING (by Agency)
(in millions of dollars)

	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993*
HHS:												
Public Health Service	\$6	\$29	\$61	\$109	\$234	\$502	\$962	\$1,301	\$1,590	\$1,888	\$1,968	\$2,069
Medicaid (Federal Share)	---	10	30	70	130	200	330	490	670	870	1,080	1,290
Medicare	---	--	--	5	5	15	30	55	110	180	280	385
Social Security -DI	---	---	5	10	25	45	80	125	185	240	310	385
Social Security -SSI	---	---	1	3	8	15	18	28	39	65	100	125
Office for Civil Rights	---	---	---	---	---	---	---	3	3	3	3	3
Subtotal, HHS	6	39	91	197	402	777	1,420	2,002	2,597	3,246	3,741	4,257
(Non-PHS: non-add)	0	(10)	(36)	(88)	(168)	(275)	(458)	(701)	(1,007)	(1,358)	(1,773)	(2,188)
OTHER:												
Veterans Affairs Department	2	5	7	11	23	55	84	142	208	217	375	443
Defense Department	---	---	---	---	79	74	53	86	125	127	97	94
Agency for Internat'l Development	---	---	---	---	2	17	30	40	41	50	56	71
Justice/Bureau of Prisons	---	---	---	---	1	1	1	2	4	6	1	9
State Department	---	---	---	---	---	1	1	1	1	1	1	1
Labor Department	---	---	---	---	---	1	1	1	1	1	2	2
Education Department	---	---	---	---	---	---	1	---	---	---	---	---
Housing and Urban Development	---	---	---	---	---	---	1	---	---	---	67	40
Subtotal, Other	2	5	7	11	105	149	172	272	380	402	605	660
TOTAL	\$10,88	\$44	4	\$208	\$507	\$926	\$1,592	\$2,274	\$2,977	\$3,648	\$4,346	\$4,917

*President's Proposed Budget

APPENDIX 2: HIV/AIDS TOTAL FEDERAL GOVERNMENT SPENDING (by Function)

(in millions of dollars)

	FY 1991					FY 1992					President's Proposed Budget - FY 1993				
	Research	Prevention	Treatment	Income Support	Total	Research	Prevention	Treatment	Income Support	Total	Research	Prevention	Treatment	Income Support	Total
HHS:															
Public Health Service	\$1,230	\$400	\$258	---	\$1,888	\$1,263	\$393	\$312	---	\$1,968	\$1,310	\$419	\$340	---	\$2,069
Medicaid (Federal Share)		---	870		870		-	1,080		1,080	---	---	1,290	-	1,290
Medicare	---		180	---	180	---	---	280	---	280	---		385	---	385
Social Security DI				240	240			---	310	310	---	---		385	385
Social Security - SSI		---	---	65	65	---			100	100	---			125	125
Office for Civil Rights	---	3		---	3		3		---	3	---	3	---	---	3
Subtotal, HHS	1,230	403	1,308	305	3,246	1,263	396	1,672	410	3,741	1,310	422	2,015	510	4,257
(Non-PHS: non-add)	0	(3)	(1,050)	(305)	(1,358)	0	(3)	(1,360)	(410)	(1,773)	0	(3)	(1,675)	(510)	(2,188)
OTHER:															
Veterans Affairs Department	8	29	180	---	217	8	30	337		375	8	31	404		443
Defense Department	44	19	64		127	17	18	62	---	97	18	15	61		94
Agency for Internat'l Development	---	50	---		50	---	56		---	56		71	---	---	71
Justice/Bureau of Prisons	---	1	5	---	6	---	1	6		7	---	1	8		9
State Department		1			1		1	---		1		1			1
Labor Department		1	---		1	---	2		---	2		2		---	2
Education Department	---			---	0	---				0	---		---	---	0
Housing and Urban Development					0			---	67	67				40	40
Subtotal, Other	52	101	249	0	402	25	108	405	67	605	26	121	473	40	660
TOTAL	\$1,282	\$504	\$1,557	\$305	\$3,648	\$1,288	\$504	\$2,077	\$477	\$4,346	\$1,336	\$543	\$2,488	\$550	\$4,917
Change from Previous Year	\$118	\$34	\$437	\$81	\$670	\$6	\$0	\$520	\$172	\$698	\$48	\$39	\$411	\$73	\$571
% Chg from Previous Year	10%	7%	39%	36%	22%	0%	0%	33%	56%	19%	4%	8%	20%	15%	13%



APPENDIX 3

FEDERAL AIDS PROGRAMS AND ACTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

HCFA administers the Medicare and Medicaid programs, which finance, along with the States, medical care for eligible people. It is estimated that approximately 40 percent of all AIDS patients are eligible for Medicaid coverage and one to two percent are eligible for Medicare coverage. In 1990, HCFA spent \$780 million on AIDS related health care.

PUBLIC HEALTH SERVICE

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

AHCPR supports activities designed to enhance the quality, appropriateness, and effectiveness of health care services and to improve access to that care through various programs including its AIDS Medical Care Effectiveness Program (AMCEP). The program emphasizes three activities: 1) clinical guideline development and dissemination; 2) data development; and 3) outcomes research.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

ADAMHA supports research on the neurological, neuroimmunological, psychiatric, behavioral and psychosocial aspects of HIV infection. Drug abuse treatment is also a primary HIV prevention strategy. ADAMHA's alcohol and other drug abuse research focuses on natural history and etiology, immunology,

drug abuse treatment and prevention strategies. ADAMHA also administers the Alcohol, Drug Abuse, and Mental Health Services Block Grant and other grant programs providing States and localities with support for substance abuse and mental illness treatment and prevention programs.

CENTERS FOR DISEASE CONTROL

CDC assesses the status and characteristics of the AIDS epidemic and prevalence of HIV infection and supports via financial and technical assistance the design, implementation and evaluation of prevention activities. CDC develops and tests diagnostic and prevention technologies for HIV and provides guidelines for the transfer of appropriate methodologies into clinical and public health practice. CDC also works with outside agencies and organizations to build or strengthen HIV prevention capacities and collaborative efforts at the local, State, national and international levels.

FOOD AND DRUG ADMINISTRATION

FDA is responsible for assuring the safety and effectiveness of drugs, biologics, vaccines, and medical devices used in the diagnosis, treatment and prevention of HIV infection, AIDS, and AIDS associated opportunistic infections. The FDA also works with the blood banking industry to safeguard the Nation's blood supply.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

HRSA administers education and training programs for health care providers and community service workers who care for AIDS patients. It also administers programs to demonstrate how communities can organize their health care resources to develop an integrated, comprehensive system of care for those with AIDS and HIV infection.

INDIAN HEALTH SERVICE

IHS provides a comprehensive health services delivery system for American Indians and Alaskan Natives, and integrates its AIDS prevention and treatment program with this system. The IHS focuses its efforts primarily on the prevention of the spread of AIDS in Indian and Alaskan Native communities.

NATIONAL INSTITUTES OF HEALTH

NIH supports research to provide insight into the nature of HIV infection and its sequelae, the genetic and biological properties of the virus, immunopathogenesis, the natural history of HIV consequences of HIV infection on the central nervous system, risk factors and various modes of transmission. NTH supports a major effort to develop vaccines and to develop and test new agents for the treatment of AIDS and HIV infection, including opportunistic infections and HIV-associated malignancies.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The Office of the Surgeon General and six staff offices in the Office of the Assistant Secretary for Health (ASH) conduct the following AIDS activities:

- **OFFICE OF THE SURGEON GENERAL**
OSG co-chairs and staffs the PHS Panel on Women, Adolescents and Children with HIV Infection and AIDS. The panel is charged with overseeing and

implementing recommendations of the Secretary's Work Group on Pediatric HIV Infection and Disease and is the group responsible for women and AIDS issues for the Assistant Secretary for Health's Committee on Women's Health Issues.

- **NATIONAL AIDS PROGRAM OFFICE**

NAPO serves as the staff office responsible for coordinating and integrating all PHS AIDS-related activities. It advises the Assistant Secretary for Health on the development of policy, the setting of priorities, and on the guidance of implementation of PHS AIDS-related activities.

- **OFFICE OF HEALTH PLANNING AND
EVALUATION**

OHPE serves as the principal staff office within the PHS to coordinate development and analysis of overall PHS programmatic, regulatory, legislative and data policy, as well as planning and evaluation efforts. In addition, OHPE has played a role on selected AIDS policy issues.

- **OFFICE OF MINORITY HEALTH**

OMH coordinates activities as they relate to racial and ethnic populations in the U.S. These populations often have a shorter life expectancy and a poorer health status. AIDS has been added to the list of health conditions targeted for improvement that have disproportionately impacted the health status of minorities in the U.S.

- **OFFICE FOR DISEASE PREVENTION
AND HEALTH PROMOTION**

ODPHP coordinates the development and monitoring of the national health promotion and disease prevention objectives, including those on health status improvement and risk reduction.

■ OFFICE OF INTERGOVERNMENTAL AFFAIRS

OIA coordinates the AIDS activities of the ten Regional Health Administrators in conjunction with a Memorandum of Understanding with NAPO. AIDS coordinators in each region convene, exchange information and conduct joint activities with State and local health officials and organizations representing or serving people with AIDS or HIV infection.

■ OFFICE OF POPULATION AFFAIRS

OPA provides grants to public and private non-profit agencies to support voluntary family planning projects and a broad range of reproductive health services and screening for other health problems, including HIV.

SOCIAL SECURITY ADMINISTRATION

The Social Security Administration administers the Disability Insurance and the Supplemental Security Income programs which provide cash assistance to eligible persons with AIDS or HIV-related illnesses. In 1990, the Social Security Administration spent \$219 million on AIDS related benefits.

OFFICE FOR CIVIL RIGHTS

The Office for Civil Rights investigates claims of AIDS-related discrimination in HHS-conducted programs. It received 160 AIDS-related complaints in 1989. In 1990, OCR spent \$3 million on AIDS activities.

DEPARTMENT OF VETERANS AFFAIRS

The Department of Veterans Affairs (VA) conducts AIDS prevention programs and provides medical care to veterans with AIDS. It is estimated that approximately 7 percent of all AIDS patients receive care from the VA. In 1990, the VA spent \$208 million on AIDS related programs.

DEPARTMENT OF DEFENSE

The Department of Defense conducts an HIV testing program, research, HIV prevention programs, and provides medical care to HIV-infected active-duty and retired military personnel. In 1990, the DOD \$125 million on AIDS programs.

DEPARTMENT OF STATE

The Department of State provides technical assistance to its embassies and oversees compliance with HIV screening for immigrants, refugees, and travelers in accord with the Immigration and Nationality Act. In 1990, the Department of State spent \$2 million on AIDS programs.

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

The U.S. Agency for International Development provides technical assistance to developing countries to improve the monitoring and surveillance of HIV infection, design and implement HIV prevention programs, and evaluate the impact and effectiveness of programs. In 1990, USAID spent \$41 million on AIDS related activities.

DEPARTMENT OF JUSTICE

The Department of Justice conducts an HIV testing program and provides medical care to prisoners with HIV-related diseases. In 1990, the Department of Justice spent \$4 million on AIDS programs.

Under this program capital advances and contracts for project rental assistance are provided to expand the supply of supportive housing that is designated to accommodate the special needs of HIV-infected persons.

DEPARTMENT OF LABOR

The Department of Labor administers the Job Corps, which conducts an HIV testing program, HIV prevention programs, and provides limited medical care to Job Corps participants. The Occupational Safety and Health Administration, within the Department of Labor, monitors workplaces for safety hazards, which include practices that may expose workers to HIV. In 1990, the Department of Labor spent \$1 million on AIDS programs.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

The Department of Housing and Urban Development (HUD) conducts the Housing Opportunities for Persons with AIDS (HOPWA) Program which funds two types of grants for housing assistance and supportive services for low-income persons with AIDS and related-diseases:

(1) entitlement grants awarded by formula to States and eligible metropolitan areas with the largest number of cases of AIDS; and (2) competitively awarded grants. The purpose of the HOPWA is to provide States and localities with the resources and incentives to devise long-term comprehensive strategies for meeting the housing needs of low-income persons with AIDS and related diseases.

In addition to HOPWA, HUD also administers the Supportive Housing for Persons with Disabilities Set-Aside for Persons Disabled as a Result of Infections with HIV Program (Sec. 811) through the Office of Housing Assistance.

APPENDIX 4:
PUBLIC HEALTH SERVICE HIV/AIDS BUDGETS

FUNCTIONAL CATEGORY (in thousands)	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
I. Basic Science Research			
A. Biomedical Research			
1. HIV and HIV Genome	\$82,403	\$87,628	\$92,524
(CDC)	1,394	1,333	1,343
(NIH)	81,009	86,295	91,181
2. Immunology	104,342	106,565	115,274
(CDC)	1,187	1,135	1,143
(NIH)	78,826	81,576	89,386
(ADAMHA)	24,329	23,854	24,745
3. Blood and Blood Products	8,476	7,794	7,136
(NIH)	8,476	7,794	7,136
4. Diagnostic Methods/Reagents Development	14,033	14,093	14,778
(CDC)	2,098	2,005	2,020
(NIH)	11,935	12,088	12,758
5. Animal Models and Related Studies	31,312	33,314	34,816
(CDC)	700	669	674
(NIH)	27,421	28,879	30,237
(ADAMHA)	3,191	3,826	3,905
Subtotal, Biomedical Research:	240,566	249,454	264,528
B. Neuroscience & Neuropsychiatric Research	44,724	47,313	50,244
(NIH)	22,294	23,088	24,719
(ADAMHA)	22,430	24,225	25,525
C. Behavioral Research			
1. Mechanisms of Behavioral/Behavior Change	19,057	22,709	23,840
(NIH)	1,716	1,574	1,625
(ADAMHA)	17,341	21,135	22,215
2. Prevention of High-Risk Behaviors	111,268	104,997	112,269
(NIH)	1,531	1,873	2,041
(ADAMHA)	109,737	103,124	110,228
Subtotal, Behavioral Research:	130,325	127,706	136,109
D. Therapeutic Agents			
1. Development	144,719	150,991	157,636
(NIH)	143,519	150,178	156,785
(ADAMHA)	1,200	813	851
2. Clinical Trials	218,806	226,594	232,095
(NIH)	218,806	226,594	232,095
Subtotal, Therapeutic Agents:	363,525	377,585	389,731

FUNCTIONALCATEGORY	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
E. Vaccines			
1. Development	48,926	53,517	55,803
(NIH)	48,926	53,517	55,803
2. Clinical Trials	11,000	17,294	18,114
(NIH)	11,000	17,294	18,114
Subtotal, Vaccines	59,926	70,811	73,917
F. Research Enhancement			
1. Training	16,792	15,835	16,766
(NIH)	11,467	10,567	11,377
(ADAMHA)	5,325	5,268	5,389
2. Construction (Extramural)	111	117	120
(NIH)	111	117	120
Subtotal, Research Enhancement	16,903	15,952	16,886
<i>Total, Basic Science Research</i>	855,969	888,821	931,415
II. Risk Assessment and Prevention			
A. Surveillance			
1. Diseases Associated with HIV	27,077	26,923	27,256
(CDC)	24,111	23,865	24,042
(NIH)	2,966	3,058	3,214
2. HIV Surveys	68,375	65,337	65,956
(IHS)	50	840	884
(CDC)	67,125	64,297	64,772
(ADAMHA)	1,200	200	300
3. Knowledge, Attitude, and Behaviors	4,382	4,268	4,389
(CDC)	2,882	2,868	2,889
(ADAMHA)	1,500	1,400	1,500
Subtotal, Surveillance	99,834	96,528	97,601
B. Pop.-Based Res: Nat Hist, Trans, Risk Factors			
1. Transmission			
a. Sexual	26,159	24,399	25,454
(CDC)	3,434	3,283	3,307
(NIH)	22,725	21,116	22,149
b. Intravenous Drug Abusers	12,989	13,355	13,625
(CDC)	2,382	2,277	2,294
(NIH)	3,377	3,182	3,333
(ADAMHA)	7,230	7,896	7,998
c. Hemophilia Populations	4,237	6,437	6,682
(CDC)	947	905	912
(NIH)	3,290	5,532	5,770

FUNCTIONAL CATEGORY	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
d. Blood Recipient/Donor Studies	14,464	12,574	12,806
(CDC)	3,849	3,679	3,706
(NIH)	10,615	8,895	9,100
e. Perinatal Infection	42,167	43,155	45,621
(CDC)	9,159	8,755	8,820
(NIH)	33,008	34,400	36,801
f. Occupationally Related	7,875	7,893	7,950
(CDC)	7,756	7,718	7,775
(NIH)	119	175	175
g. Other/Miscellaneous	11,912	11,725	12,017
(CDC)	6,879	6,635	6,684
(NIH)	5,033	5,090	5,333
Subtotal, Transmission	119,803	119,538	124,157
2. Natural History and &factors	67,880	64,971	68,017
(CDC)	8,498	8,456	8,518
(NIH)	41,882	42,510	44,654
(ADAMHA)	17,500	14,005	14,845
Subtotal, Population Based Research	187,683	184,509	192,174
C. Information & Education/Preventive Services			
1. High Risk or Infected Persons			
a. Health Education/Risk Red	27,153	26,942	30,765
(CDC)	24,023	23,689	27,260
(NIH)	2,633	2,762	2,987
(IHS)	497	491	518
b. Counseling, Testing & Partner Notification	97,549	96,855	97,598
(CDC)	96,992	96,188	96,899
(NIH)	457	470	492
(IHS)	100	197	207
c. Women & Infants HIV Prevention	20,003	17,991	23,124
(CDC)	20,001	17,989	23,122
(NIH)	2	2	2
d. HIV Prevention Among Drug Abusers	30,659	40,278	37,509
(CDC)	29,334	28,611	25,426
(ADAMHA)	1,325	11,667	12,083
e. Special Projects			
(1) Conference of Mayors	415	413	416
(CDC)	415	413	416
(2) HIV Related TB Demo Projects	8,743	8,956	24,021
(CDC)	8,743	8,956	24,021
(3) National Hemophilia AIDS/HIV Projects	11,947	11,888	12,976

FUNCTIONAL CATEGORY	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
(CDC)	11,947	11,888	12,976
(4) Community-Based Demo. Projects	4,600	4,012	4,042
(IHS)	0	0	0
(CDC)	4,600	4,012	4,042
(5) Rural Areas	0	0	0
(CDC)	0	0	0
Subtotal, Special Projects	25,705	25,269	41,455
f. Early Intervention Services (CARE)	0	0	0
(CDC)	0	0	0
g. Technical Assistance and Evaluation	0	0	0
Subtotal, High Risk or Infected Persons	201,069	207,335	230,451
2. Special Minority Initiatives	52,090	50,259	50,659
(HRSA)	0	350	350
(IHS)	646	639	676
(CDC)	49,295	47,195	47,543
(OASH)	2,149	2,075	2,090
3. School and College Aged Youth			
a. National Efforts	17,780	15,720	15,844
(CDC)	17,572	15,506	15,620
(NIH)	208	214	224
b. State and Local Projects	22,782	22,669	22,837
(CDC)	22,782	22,669	22,837
c. Program Development & Training	7,049	7,112	7,173
(IHS)	100	197	207
(CDC)	6,949	6,915	6,966
d. Evaluation Activities	3,726	3,708	3,735
(CDC)	3,726	3,708	3,735
Subtotal, School and College Aged Youth	51,337	49,209	49,589
4. General Public & Special Programs			
a. National			
(1) Clearinghouse	8,606	8,564	8,627
(CDC)	8,606	8,564	8,627
(2) Hotline	5,928	5,899	5,942
(CDC)	5,928	5,899	5,942
(3) Treatment Trials & Therapy Info.	5,899	4,407	4,394
(NIH)	2,549	3,157	3,094
(ADAMHA)	3,350	1,250	1,300
(4) Other	18,406	15,808	15,926
(CDC)	18,406	15,808	15,926
Subtotal, National	38,839	34,678	34,889

FUNCTIONAL CATEGORY	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
b. Regional, State, and local	12,455	12,121	12,832
(IHS)	50	313	329
(CDC)	12,405	12,344	12,435
(NIH)	0	70	68
Subtotal, General Public & Special Programs	51,294	47,405	47,721
5. Health-Care Workers & Providers			
a. Education Training Centers	17,985	17,982	18,236
(HRSA)	17,029	16,984	16,984
(NIH)	956	998	1,252
b. Other types of Training	9,760	6,713	6,923
(IHS)	60	197	207
(NIH)	0	0	0
(ADAMHA)	9,700	6,516	6,716
Subtotal, Health-Care Workers & Providers	27,745	24,695	25,159
6. Prevention Capacity Enhancement	12,835	11,898	11,986
(IHS)	0	0	0
(CDC)	12,835	11,898	11,986
(NIH)	0	0	0
Subtotal, Information & Ed./Preventive Serv.	396,370	390,801	415,565
Total, Risk Assessment and Prevention	683,887	671,838	705,340
XI. Product Evaluation, Research, and Monitoring			
A. Therapeutic Agents	20,921	25,675	26,773
B. Vaccines	10,143	11,583	12,078
C. Diagnostic Reagents and Test Kits	8,241	8,423	8,783
D. Blood and Blood Products	15,215	16,879	17,604
E. Medical Devices	8,875	9,742	10,159
Total, Product Evaluation, Research & Monitoring (FDA)	63,395	72,302	75,397
V. Clinical Health Services Research & Delivery			
A. Services			
1. Drug Subsidy Programs	0	0	0
(HRSA)	0	0	0
2. Community Health Care Services	8,746	8,279	8,563
(HRSA)	0	0	0
(IHS)	300	296	313
(ADAMHA)	8,446	7,983	8,250
3. HIV Health Service Grants	0	0	0
(HRSA)	0	0	0
4. Demo Projects Sub-Acute Care	0	0	0
(HRSA)	0	0	0

FUNCTIONAL CATEGORY	FY 1991 Expenditure	FY 1992 Appropriation	FY 1993 Pres. Budget
5. Formula Grants to States for home Hlth Services (HRSA)	0	0	0
6. Emergency Care - Title I (HRSA)	87,831	121,663	148,663
7. Comprehensive Care - Title II (HRSA)	87,831	107,704	107,704
8. Early Intervention - Title III (HRSA)	44,891	49,862	49,862
9. Mental Health Services - Title III (HRSA)	0	0	0
10. Serv & Research for Women & Children - Title IV (HRSA)	0	0	0
11. Program Management (HRSA)	4,786	4,621	4,996
Subtotal, Services	8,746	8,279	8,553
B. Pediatric Demonstrations (HRSA)	19,518	19,747	19,747
C. Construction (HRSA)	4,029	0	0
D. Research (ADAMHA)	12,458	12,968	12,967
(AHCPR)	1,100	1,481	1,740
(NIH)	10,252	10,135	9,875
	1,106	1,352	1,352
Total, Clinical Health Services Research & Delivery	270,090	324,844	352,502
V. PHS-wide Activities			
A. OASH/NAPO	3,789	2,452	3,958
B. Contingency Fund (NIH Program Management)	0	0	0
C. Construction (PHS Facilities) (NIH)	11,102	7,000	0
(ADAMHA)	9,502	7,000	0
	1,600	0	0
Total, PHS-Wide Activities	14,891	9,452	3,958
PHS TOTAL	\$1,888,232	\$1,967,257	\$2,068,612

NOTE: Budget subject to minor reprogramming and administrative adjustments