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RESEARCH

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

I Record of Accomplishment

Since the epidemic began in 1981, the Nation has made significant advances in HIV-related research advances. Sentinel points of that progress include:

- Identification in April 1984 of HIV as the **[causal agent?]** of AIDS;
- Development in March 1985 of an accurate test to determine exposure to HIV;
- Approval in September 1986 of of zidovudine (AZT), the first **[what do they call them?]** for treatment of HIV disease;
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV;
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Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent;
- Signing the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan;
- Accelerating AIDS drug approval to record times. (Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and two new diagnostic tests.)
- Supporting research that led to finding that use of AZT during

pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds;

- Launching a four-year, $100 million research effort to develop effective topical microbicides;

- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

Beyond the impact that AIDS research has had on the epidemic, the Nation has realized additional benefits of supporting such research. Several Federal Agencies play a significant role in AIDS research (See Appendix B). The effort to understand HIV and AIDS has produced scientific advances that benefit research on many other diseases. For example, AIDS research has accelerated study of the human immune system, which helps us to better understand and treat many other diseases, such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

Advances made in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, or the treatment of diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to Federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One of the recent research advances has been the development of a new class of drugs, known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream and possibly improve a person's clinical status and reduce the risk of HIV transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various Federal Agencies, such as the annual NIH plan for HIV-related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

II Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. We must ensure that the Nation capitalizes on the most promising scientific opportunities.

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing a Federal effort of this magnitude requires coordinating efforts at two levels: First, within NIH and second among the Departments and

Agencies supporting HIV research.

Within NIH, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the NIH Revitalization Act Amendments of 1993 established a permanent Office of AIDS Research (OAR) and provided it with new oversight and budget authorities. It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be maintained.

Add RS language about the Levine Report

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy created an inter-departmental working group, chaired by the Director of the Office of AIDS Research, charged with developing a coordinated plan and budget for HIV and AIDS research across all Agencies.

On December 6, 1996, at the White House Conference on HIV and AIDS, President Clinton directed OAR Director Dr. William Paul to develop the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS. This plan was completed in April, 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides a blueprint to focus and coordinate all Federal HIV/AIDS research initiatives and serves as a foundation for continued planning and evaluation.

Vaccine Development. Several major challenges currently face the U.S. and the world in the development of an effective HIV vaccine or vaccines. The first is to surmount the daunting scientific and social challenges and the second is to ensure the development and testing of promising vaccine candidates.

On the scientific level, researchers are pursuing two approaches to vaccine development. One approach is based on the belief that additional basic science information will guide us in vaccine development. The second approach involves conducting clinical efficacy trials in humans to find answers that will lead to the development of a successful candidate.

Developing a vaccine cannot be accomplished by the government or the private sector working apart: a continuing public-private

partnership is needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, in February 1996, Vice President Gore convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

Microbicides. In the absence of an effective vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV.

Condoms, the barrier methods that are currently available, have limitations. Most require consent, if not active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

The development of this important prevention option will depend on strong and continuing support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where pharmaceutical or biotechnology companies can assume a lead role. Discussions among Federal Agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development.

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. There is evidence indicating that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine

HIV/AIDS Research Network[3] are important in improving our understanding of HIV disease in adolescents.

New and More Effective Therapies. Strong and continuing research to develop new and more effective therapies for HIV infection and its associated conditions must be a priority if we hope to transform HIV disease into a chronic, manageable condition. Due to the FDA's accelerated approval program[4], the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for patients. While some treatments have shown promise based on surrogate markers and/or laboratory tests data regarding long-term clinical effectiveness are unavailable. Patients may be receiving less effective treatments or combinations of treatments, and private insurers and Federal programs such as Medicaid and Medicare may be paying for treatment strategies that are not optimally effective.

It is incumbent upon the government and the private sector to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it is necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. Through the efforts of Vice President Gore, the Forum for Collaborative HIV Research has been established to assess approaches for accelerating clinical effectiveness research.

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[3] The Adolescent Medicine HIV/AIDS Research Network is cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA).

[4]The accelerated approval regulation permits companies to seek approval of drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

Public-Private Partnerships. A key role for the Federal government is to act in partnership with the private sector and support areas where industry is unlikely to pursue research that would be beneficial to the public health. For example, it is unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is critical to improving patient care. The National Institutes of Health (NIH) and the Department of Veterans Affairs (VA) have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships that include the NIH, studies of alternative therapies have been and will continue to be conducted.

It also is cost-effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

Continued Investment. Research is an investment in our future and it must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine. At present, NIH receives many more outstanding AIDS research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment.

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Members of the Interdepartmental Task Force on HIV and AIDS

NAS Re-write
August 8, 1996, 5:30 pm (n:\text5.g96)

[Note: This could be reworked as a message from the President to the world or as a letter from Patsy to the President presenting the draft Strategy to him.]

> *"We must develop a clear, well-articulated national plan for confronting AIDS."*
> *The Final Report of the National Commission on AIDS*
> *June 1993*

Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National AIDS Strategy that would detail the Federal government's long-term approach in responding to this epidemic. The National AIDS Strategy has been developed by the Clinton Administration to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, businesses, schools, churches, families, and individuals.

The President has identified the following national goals to guide our efforts against HIV:

- **To provide strong continuing support for AIDS-related research in order to find additional treatments, a preventive vaccine to protect the uninfected, and a cure for those currently infected;**

- **To provide strong continuing support for effective AIDS prevention strategies to continue to reduce the number of new HIV infections in the U.S.;**

- **To ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs; and,**

- **To ensure that people living with HIV are not subject to unlawful discrimination.**

This document is a snapshot of where we are as a Nation and where we need to go in achieving these national goals. ~~This document is a~~

~~snapshot of where we are as a Nation and where we we need to go in achieving these national goals.~~ It summarizes some of the key accomplishments of our Nation's scientific and public health professionals and identifies key areas for further effort. In addition, the appendices to this report lay out, for the first time, detailed descriptions of the objectives, goals, and budgets of all Agencies involved in the Federal response to HIV in the five key areas of HIV policy: prevention, ~~and budgets of all Agencies involved in the Federal response to HIV/AIDS in the areas of HIV prevention,~~ research, care, civil rights, international activities, and translation of research into practice.

The National AIDS Strategy is intended to be a working document that requires regular updating and adjustment as goals are reached and new challenges emerge. This Strategy provides a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives. ~~This Strategy should provide a reference point for continuing dialogues and collaborative efforts between the public and private sectors that are necessary to meet our national goals and objectives.~~

In that light, the Office of National AIDS Policy is seeking direct input from the Presidential Advisory Council on HIV/AIDS, national and community-based organizations, ~~the Office of National AIDS Policy is seeking direct input from national and community-based organizations,~~ **state and local government, clinicians and researchers, members of the infected and affected community, and other individuals and organizations who can contribute to this historic document. This Strategy is being released, first, in draft form to allow for maximum input to the first of an ongoing national effort to chart and plan Federal efforts in response to the epidemic of HIV/AIDS.**

The development of a National AIDS Strategy is an historic undertaking. No previous Administration has undertaken so broad a planning effort that: (1) involves all Federal Departments and Agencies that engage in HIV-related efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the Federal government should focus its efforts.

The National AIDS Strategy was drafted in consultation with, and with guidance from, numerous groups and individuals. Within the Federal government, this effort began at the Agency level. Members of the Interdepartmental Task Force on HIV and AIDS (IDTF) representing all Federal Agencies involved in the national response to HIV and AIDS, identified their HIV-related goals, objectives, and highlighted areas requiring special attention.

Individuals living with HIV and AIDS, ~~Individuals living with HIV/AIDS,~~ their families, friends, loved ones, and care givers made vital contributions to this Strategy. Numerous non-governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS, ~~Numerous non governmental groups and organizations have also been consulted including the Presidential Advisory Council on HIV/AIDS,~~ participants in the historic White House Conference on HIV and AIDS, the ONAP-sponsored regional briefings, patient and consumer advocates, health care professionals, community-based organizations, educators, religious leaders, and business leaders. The earlier insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

As a Nation, we face great challenges, but we are also facing equally great opportunities. ~~but we are also facing equally challenging opportunities.~~ After fifteen years, AIDS remains a terrible national tragedy that has affected -- and will continue to affect -- far too many people in this Nation and around the world. But we have made tremendous progress in our understanding of HIV and HIV disease, ways we can treat those who are infected, ~~ways in which we can treat those who are infected,~~ and means by which we can prevent infection. Ultimately, HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from the western hemisphere. ~~HIV is a disease that we can defeat -- just as we have eradicated smallpox from our planet and polio from our hemisphere.~~ The National AIDS Strategy provides a foundation for the continuing public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will win the battle against HIV and AIDS.

Patricia S. Fleming
Director, Office of National AIDS Policy

or

William J. Clinton

> *"For nearly every American with eyes and ears open, the face of AIDS is no longer the face of a stranger. Millions and millions of us have now stood at the bedside of a dying friend and grieved. Millions and millions of us now know people who have had AIDS and who have died of it who are both gay and heterosexual. Millions and millions of us are now forced to admit that this is a problem which has diminished the life of every American."*
> *President Clinton, December 1, 1993, Georgetown University*

I. INTRODUCTION

Scope of the HIV/AIDS Epidemic

The epidemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and around the world. While significant progress has been made in understanding the disease and developing treatments since the first case was reported in the U.S. in June 1981, HIV remains a deadly infection for which there is no vaccine, ~~HIV remains a **[usually fatal??]**deadly infection for which there is no vaccine,~~ no cure, and for which there is an expanding but still limited inventory of available treatments. An average of 100 Americans are diagnosed with AIDS every day and a similar number of men, women, and children become infected with HIV every 24 hours. **[Richard -- are you certain these numbers are correct?]** Globally, 7,500 people become infected each day.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) had received reports of 513,486 cases of AIDS among persons in the U.S. and 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has risen from being the 15th cause of death among all Americans to the 8th. AIDS is now the leading cause of death among Americans aged 25 to 44 (See Figure 1). In 1995 alone, approximately 74,000 new cases of AIDS were reported in the U.S. and more than 46,000 AIDS related deaths were reported to the CDC in 1994.~~000 AIDS related deaths were reported to the CDC in 1994**[why mix 1994 and 1995???].**~~ CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 650,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has expanded, the demographics

of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers (i.e., New York, San Francisco, and Los Angeles). Today, this group represents less than half of all new cases. ~~the demographics of the epidemic have shifted. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers. Today, men having sex with men represent **[slightly?]** less than half of all new cases **[anything on infections? i.e., and less than half of all new infections]**.~~ Among the populations that are more heavily affected today are young gay men, women, and injecting drug users and their sexual partners as well as users of non-injecting drugs (i.e., crack cocaine and alcohol). Although gay and bisexual men no longer represent the majority of new cases, this group still represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported to CDC as having been diagnosed with AIDS. Women now comprise 14 percent of cumulatively reported AIDS cases. If this trend continues, it is estimated that 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new cases of pediatric AIDS cases were reported. (Footnote a)
~~approximately 800 new cases of AIDS were reported among **[infants?]**.~~[1]

Adolescents (age 13-19) are at increased risk for HIV infection. CDC estimates that one-quarter of new HIV infections in the U.S. occur among people under age 21. A significant number of young people are engaging at earlier ages in sexual intercourse and drug and alcohol use. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color <u>OR</u> racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS.~~Racial and ethnic minorities have been disproportionately affected by the epidemic of HIV and AIDS.~~ African-Americans, who represent approximately 12 percent of the U.S. population, accounted for 40 percent of newly reported AIDS cases in 1995. Hispanics, who account for about 9 percent of the general population, represented 19 percent of new cases reported in 1995. The number of African-Americans and Hispanics affected by HIV and AIDS has risen

~~[1] It is, however, believed that with greater use of AZT by HIV positive pregnant women, the number of new cases in newborns can be reduced.~~

dramatically. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995, these groups comprised 52 percent of cumulative AIDS cases.

The HIV epidemic continues to spread into suburban and rural areas, with especially dramatic increases in certain regions of the South and Midwest. Between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South. (Endnote 1)[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing more rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories (See Figure 2).

AIDS is an expensive disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (Footnote b). ~~000 (re-add footnote; check for Vancouver numbers).~~ **People living with HIV are disproportionately dependent on the public sector for their health care. Over 50 percent of people living with AIDS are enrolled in Medicaid,** ~~Nearly 50 percent of people living with AIDS are enrolled in Medicaid,~~ **including more than 90 percent of children with AIDS. In FY 1996, the Federal government spent $1.9 billion on Medicaid benefits for people living with HIV and AIDS and another $690 million on Medicare benefits.** ~~8 billion on Medicaid benefits for people living with HIV and AIDS and another $690 milllion on Medicare benefits.~~ **Social Security benefits for people disabled by HIV/AIDS total $1.1 billion in FY 1996.**

Globally, the toll of the epidemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that 27. ~~the toll of the pandemic is much greater and threatens to reverse decades of economic and public health progress in developing countries. The Joint United Programme on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) estimate that since the beginning of the pandemic, 6 million people have been diagnosed with AIDS worldwide and 27.~~**9 million people have been infected with HIV. Since the beginning of the pandemic,** ~~[is this part of the 6 million? If so, the sentence should say "Since the beginning of the pandemic,~~ **6 million people, including 1.6 million children, have been diagnosed with AIDS.**~~]and more than 1.6 million children have been developed AIDS.~~ By the year 2000, WHO projects that between 30 million and 40 million people will have been infected with HIV and 10 million to 15 million children will be orphaned due to AIDS.

II. OVERVIEW OF FEDERAL EFFORTS

The scope and nature of the HIV/AIDS epidemic have drawn States, local governments, academic institutions, private foundations, health care institutions and community-based organizations and the Federal government into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In FY 1985 the Federal government spent $212 million for AIDS research, surveillance, ~~In [FY?]1985 the Federal government spent $212 million for AIDS research, [prevention?] surveillance,~~ and care. By FY 1995 that figure reached $6.8 billion. ~~By [FY?]1995 that figure reached $6.8 billion [I assume this includes entitlement spending. Does the FY85 include such spending?].~~ (See Appendix G).

In the past four years, under the leadership of President Clinton, spending for AIDS research, prevention, and care has increased by 47 percent. Funding for the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act alone has increased by 151 percent. Support for housing for people living with AIDS has increased by 91 percent. AIDS-related research funding has increased by 34 percent and AIDS prevention funding has increased by 24 percent. The National Institutes of Health Revitalization Act of 1993 created a permanent Office of AIDS Research with enhanced authority to prepare and carry out an annual AIDS research budget and plan. Approval of AIDS drugs by the Food and Drug Administration has been accelerated to record times. A community-based planning process has empowered local communities to develop innovative AIDS prevention programs. Eligibility for Social Security disability benefits for people with AIDS have been simplified and Federal laws prohibiting discrimination against people living with HIV and AIDS have been vigorously enforced.

As the epidemic continues, we must renew our vision for ending this epidemic. The sections that follow focus on six major policy areas: prevention, research, care and services, ~~Prevention, research, care,~~ civil rights, international activities, and the translation of research into practice. They identify recent progress and future opportunities for further progress.

~~*PREVENTION*~~

~~THE FOLLOWING TEXT WAS MOVED~~

A. PREVENTION

~~Improving Understanding of Modes of Transmission~~

~~THE PRECEDING TEXT WAS MOVED~~

> *"We have to set a goal. . .We have to reduce the number of new infections each and every year until there are no more new infections."*
> *President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS.*

1. Record of Accomplishment
~~*I Record of Accomplishment*~~

Since the epidemic began, the Nation has made important progress in prevention of HIV infection. In the early years of the epidemic, it was estimated that more than 100,000 Americans were becoming infected with HIV each year. Today, that total is between 40,000 and 60,000 people each year.

Sentinel accomplishments in prevention of HIV include:

- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the first cases of AIDS;
- Identification in 1981 by the Centers for Disease Control and Prevention (CDC) of the risk factors associated with HIV infection; and
- Through successful implementation of CDC-sponsored prevention strategies, a slowing the growth of the epidemic.
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Since President Clinton took office in 1993, efforts in HIV/AIDS prevention have been accelerated. Actions include:

- Increasing funding for AIDS prevention by 24 percent;
- Launching the community planning partnership, which empowers local communities to make decisions about the development of

innovative prevention efforts;

- Launching the Prevention Marketing Initiative, focusing on the risk to young adults (18 to 25) with frank public service announcements advocating sexual abstinence and the correct and, for the first time in the epidemic, the consistent use of latex condoms; and,

- Reorganizing AIDS prevention efforts at the Centers for Disease Control and Prevention to foster greater coordination with efforts to reduce sexually transmitted diseases and tuberculosis.

The efforts of Federal Agencies (see Appendix A) have been instrumental in expanding our knowledge base about HIV prevention. The CDC, the agency with primary Federal HIV surveillance and prevention responsibilities, has been pivotal in identifying risk factors associated with HIV transmission, seroprevalence of HIV in society, and trends in HIV infection.

Federal efforts have shown that HIV prevention programs can be effective. CDC's prevention projects, many in partnership with States, local governments, and community-based organizations, have demonstrated that prevention programs are most effective when designed and implemented at a local level. Biomedical, behavioral, and social science prevention research conducted and supported by the National Institutes of Health (NIH) has expanded and will continue to expand our understanding of the determinants of HIV-related risk behavior.

The Nation has also combatted the duel epidemics of HIV and drug abuse. The National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) support efforts to prevent HIV infection among drug users. The Office of National Drug Control Policy has pursued efforts to counter the problem of substance abuse and its devastating consequences.

There have been advances in integrating primary prevention into health care service systems. The Health Resources and Services Administration (HRSA) and the Department of Veterans Affairs (VA) have encouraged broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training

Centers program.

2. Future Opportunities for Progress ~~*II. Future Opportunities for Progress*~~

Significant challenges remain if we are to reach the Nation's prevention goal -- no new infections. Primary to this progress are efforts to:

- Improve our understanding ~~about~~ the major trends in transmission and seroprevalence of HIV transmission; ~~Improve our understanding about the major modes of HIV transmission;~~
- Close gaps in scientific knowledge, which includes identifying additional effective prevention models and strategies; and
- Eliminate gaps in HIV prevention program areas.

a. Improving Understanding of Trends in the Epidemic

An important aspect of strengthening prevention activities is to have a clearer understanding of those who are becoming infected and what behaviors are placing people at risk. Recent epidemiologic data show that the HIV epidemic continues to spread most rapidly among people who engage in injection drug use and their sexual partners, women, young and minority men who have sex with men, heterosexuals and infants who are infected through perinatal transmission. These trends must be considered when prioritizing prevention research and service programs.

A crucial element of effective prevention strategies is support for adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic and assess the effectiveness of prevention interventions. CDC's AIDS case and case death reporting system provides important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure.

Effective prevention interventions begin with sound information about who is at risk. However, ~~However,~~ current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV prior to an AIDS diagnosis in the population and trends in modes of transmission and new infections. These data must be collected with appropriate confidentiality protections for the identity of those who are living with HIV. CDC

is exploring additional innovative approaches for collecting HIV incidence information. These effort must continue. Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting as well as in the design and evaluation of HIV prevention programs.

The CDC has incorporated data collection design into its community planning process. Shifts in data needs may also require that CDC reevaluate and reconfigure certain of its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies[2], CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes.

b. Prevention Research: Closing Gaps in Scientific Knowledge (Footnote c)
~~Closing Gaps in Scientific Knowledge~~
[2]

Factors that place individuals at risk for acquiring HIV infection entail a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity, we must not *assume* to intuitively know which interventions will work, but instead base our efforts on research findings. Development of effective interventions are based on sound research findings and evaluation. The three main gaps in current knowledge are: basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by basic behavioral research serves as the foundation for prevention programs. To capitalize on what is known and to improve HIV prevention programs that are targeted to reach diverse populations of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying approaches that may be most effective for an individual or a community.[3]

Intervention Research. Research to improve prevention interventions concentrate on modifying behaviors, such as those related to drug use and sex. Intervention research can focus on both individuals and communities, each of which often adhere to norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that

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~~[2]Information on NIH supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.~~

are relevant to the design of intervention programs intended to reduce rates of HIV infection. There is more that we need to know if we are to develop more effective prevention programs. We must incorporate findings from basic behavioral research into effective prevention interventions. Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Intensifying the dialogue between researchers in these two related fields will improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research serve as a foundation for prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. As these models are developed, community-based organizations will require additional technical assistance and training in order to test those models in a "real-world" setting. ~~**[I would suggest replacing the rest with: "Once such models are developed,**~~

c. Strengthening Prevention Programs

~~"]Given the highly innovative nature of these endeavors, CDC must consider providing broader technical assistance and training to community organizations. Moreover, a community based effort that would test prevention models in a real world setting should be carefully considered.~~

~~**C.**~~

For prevention interventions to be effective they must reach people at risk and be responsive to their needs. ~~**[This paragraph seems redundant of the above. If you agree, I'd cut it and begin with the next paragraph.]**~~ ~~In order to stop new infections, the results of basic behavioral, intervention, and social marketing research must serve as a foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. It is therefore important that prevention planners carefully prioritize local efforts based on who is and who is becoming infected.~~

For individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves. It is important that prevention planners carefully prioritize local efforts based on who is and who is becoming infected.

One of the most important innovations in HIV/AIDS prevention is the creation of community planning. Through this public-private partnership it has been possible to establish joint goals for the prevention of HIV that are responsive to local needs. However, this process is early in its development and requires continuing significant leadership and technical assistance.

It is crucial that prevention research results be disseminated and incorporated into prevention programs. Models of effective prevention interventions have been developed but often this valuable information is not reaching those people developing, ~~It is crucial that prevention research~~ **[results?]** ~~advances be disseminated and incorporated into prevention programs.~~ implementing, and evaluating prevention programs. (See Section on Translation of Research into Practice.)

~~)~~

Small, new, community-based organizations -- especially those serving minority populations -- often require additional technical assistance in order to compete for available resources. The CDC and other Agencies provide such assistance and will continue to do so.

~~The CDC and other Agencies provide such assistance and must continue to do so.~~

~~Insert RS language on minority CBOs and technical assistance.~~

Substance Abuse Prevention and Treatment. Injection drug use is one of the major forces driving the epidemic. One third of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of substance abuse on the epidemic will require efforts on several fronts.

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated, however, many care and prevention service programs for HIV and substance are not optimally integrated. It is vital to continue and strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

A key to controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a major form of HIV prevention. **[add some stuff about what we've done to increase treatment slots,** ~~Injection drug abuse is a major force driving growth in the epidemic. Approximately one third of all new AIDS cases~~ **[not infections?]** ~~are directly or indirectly related to this mode of transmission. Moreover,~~

~~THE FOLLOWING TEXT WAS MOVED~~

etc. ... Richard -- there' no specific reference in the text because we haven't done much to increase treatment slots, if anything they have decreased. Also, "treatment slot" is an OMB forbidden word.] Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use;]

~~We need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV infection are overlapping and highly interrelated, however, many care and prevention service programs for HIV and substance are not similarly integrated. It is vital to further strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention efforts.~~
~~THE PRECEDING TEXT WAS MOVED~~
use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. The efforts of the Office of National Drug Control Strategy to motivate Americans to reject illegal drugs and substance abuse are an important element in controlling the epidemic.

Work on these issues has begun and will continue. CDC has initiated State-by-State discussion, including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.
~~Limiting the impact of substance abuse on the epidemic requires efforts on several fronts.~~

~~A central element to controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a highly effective form of HIV prevention.~~
CDC has initiated discussions on this topic, including meetings with State officials regarding HIV and substance abuse prevention issues. SAMHSA's new "Knowledge Development Application (KDA) Program" will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. CDC, HRSA, NIDA, and SAMHSA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of other sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, by as much as twenty-fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups. ~~by as much as **[2000 percent?]** twenty-fold.~~[4,5] These data suggest treating STDs can be a very effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH-supported research to further understanding of the effect of STD treatment on HIV transmission is underway and will continue.

~~NIH supported research to further understanding of the effect of STD treatment on HIV transmission is underway and should **[will?]** continue.~~

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element and that HIV prevention programs incorporate STD prevention and treatment efforts. The traditional model of targeting most STD prevention efforts towards individuals who have already contracted an STD is not necessarily effective for HIV prevention. Linkages between STD and HIV prevention efforts need to be established and, ~~The traditional model of targeting most STD prevention efforts towards individuals who have already contracted an STD is not necessarily **[particularly?]** effective for HIV prevention.~~ where they do exist, enhanced.

People living with HIV are at very high risk for developing active tuberculosis (TB) disease. Studies suggest that the risk of developing active TB disease is 7-to-10 percent per year for persons who are infected with both TB and HIV, ~~People living with HIV are at very high for developing active tuberculosis (TB) disease.~~ whereas the risk is 10 percent per lifetime for persons not infected with HIV.[6] In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with a person with active TB.

The newly organized National Center for HIV, STD, and TB Prevention at CDC demonstrates the importance of integrating the interdependent aspects of the epidemic and illustrates the determination to integrate and coordinate HIV, STD, and TB prevention efforts.

Integration of Prevention Into Primary Care. To reach our prevention goal, ~~**Integration Into Primary Care.**~~ **we must also improve the integration of prevention activities and messages into primary**

health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at-risk persons. To assure that all persons seeking HIV testing can have access to such services, CDC's counseling and testing guidelines must acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a person's sexual and drug use history when a medical history is taken, offering HIV-related counseling and voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. In addition, to reduce perinatal transmission, all pregnant women should be offered HIV counseling and voluntary testing as well as information about and access to AZT. Training should be made available to improve primary care providers' skill, comfort level, and sensitivity in these areas.

Achieving this level of integration requires active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments. Presently HRSA's primary care, RWCA, and professional training programs emphasize the value of integrating prevention into primary care. These are important efforts and that will continue.

Prisoners. Those in prison are at high risk for both substance abuse and HIV infection. There is often a high prevalence of both behaviors that lead to substance abuse and HIV infection in people entering prison. Given that prisoners often are at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Research has shown that individuals who are well informed about HIV and substance abuse issues modify their risk-taking behaviors. It is important that the Federal government build upon the knowledge and opportunity that currently exists to further improve HIV prevention efforts for incarcerated persons.

Evaluation. It is important to assess the effectiveness of the HIV/AIDS prevention interventions. Prospectively set performance measures can be used as a basis for evaluation and program improvement and must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. ~~Performance measures can be used as a basis for evaluation and program improvement and must become a routine part of all Federally funded programs.~~

B. ~~RESEARCH~~

~~THE FOLLOWING TEXT WAS MOVED~~
RESEARCH

~~THE PRECEDING TEXT WAS MOVED~~

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect us from the virus."
President Clinton, December 5, 1995, to the White House Conference on HIV and AIDS

1. Record of Accomplishment

~~*I Record of Accomplishment*~~

Since the epidemic began in 1981, the Nation has made significant advances in HIV-related research advances. Sentinel points of that progress include:

- Identification in April 1984 of HIV as the etiologic agent for AIDS;
- Development in March 1985 of a reliable test to determine exposure to HIV;
- Approval in September 1986 of zidovudine (AZT), the first treatment of HIV primary infection; and
- ~~Identification in April 1984 of HIV as the **[causal agent?]** of AIDS;~~
- ~~Development in March 1985 of an accurate test to determine exposure to HIV;~~
- ~~Approval in September 1986 of of zidovudine (AZT), the first **[what do they call them?]** for treatment of HIV disease;~~
- Development by the Food and Drug Administration of a system of expedited review of treatments for life-threatening diseases, including HIV.

~~including HIV;~~

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Since he took office in 1993, President Clinton has escalated our AIDS research efforts by:

- Increasing AIDS research funding by 34 percent;

- Signing the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH and vesting it with new authority to plan and implement an annual AIDS research plan;

- Accelerating AIDS drug approval to record times. (Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and three new diagnostic tests.)

~~- the Food and Drug Administration has approved 12 new AIDS drugs and two new diagnostic tests.~~

- Supporting research that led to finding that use of AZT during pregnancy, childbirth, and the first six weeks of life can reduce the transmission of HIV from mother to child by two-thirds;

- Launching a four-year, $100 million research effort to develop effective topical microbicides;

- Facilitating creation of the Forum for Collaborative HIV Research to identify opportunities for clinical effectiveness research to improve care for HIV-positive individuals.

Contributions of AIDS Research

Beyond the impact that AIDS research has had on the epidemic, the Nation has realized additional benefits of supporting such research. Several Federal Agencies play a significant role in AIDS research (See Appendix B). The effort to understand HIV and AIDS has produced scientific advances that benefit research on many other diseases. For example, AIDS research has accelerated study of the human immune system, which helps us to better understand and treat many other diseases, such as cancer; autoimmune diseases, including systemic lupus erythematosus; type I diabetes mellitus; rheumatoid arthritis; and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and provides a new paradigm for treatment of viral diseases.

Advances made in the treatment and prevention of HIV-related opportunistic infections have had an enormous impact on the care of patients with other immunodeficiency conditions who are susceptible to many of the same pathogens. This research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, or the treatment of

diseases caused by elevated immune responses (i.e., allergies and lupus).

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent for Kaposi's sarcoma. These findings may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of additional viral diseases and led to development of treatments.

Efforts to develop drugs for the treatment of HIV have accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances have implications for drug design for virtually all disorders. Comparative clinical trials of poxvirus vectors and vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccines. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Due in great part to Federally-sponsored AIDS research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. One of the recent research advances has been the development of a new class of drugs, known as protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream and possibly improve a person's clinical status and reduce the risk of HIV transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs.

In addition, the Food and Drug Administration through its expedited review and accelerated approval programs is now approving drugs more rapidly than ever before. Recent planning efforts on the part of various Federal Agencies, such as the annual NIH plan for HIV-

related research and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS have greatly improved the coordination of HIV research.

II Future Opportunities for Progress

Despite these advances, many complex biomedical and behavioral challenges remain. We must ensure that the Nation capitalizes on the most promising scientific opportunities.

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing a Federal effort of this magnitude requires coordinating efforts at two levels: First, within NIH and second among the Departments and Agencies supporting HIV research.

Within NIH, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. It is crucial that the authority granted OAR in the revitalization legislation, ~~and fund the AIDS research activities of these ICDs the NIH Revitalization Act Amendments of 1993 established a permanent Office of AIDS Research (OAR) and provided it with new oversight and budget authorities.~~ including the consolidated appropriation, be maintained.

Add RS language about the Levine Report

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy created an inter-departmental working group, chaired by the Director of the Office of AIDS Research, charged with developing a coordinated plan and budget for HIV and AIDS research across all Agencies.

On December 6, 1996, at the White House Conference on HIV and AIDS, President Clinton directed OAR Director Dr. William Paul to develop the first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS. This plan was completed in April, 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans

Affairs. This plan provides an blueprint to focus and coordinate all Federal HIV/AIDS research initiatives and serves as a foundation for continued planning and evaluation.
~~This plan provides a blueprint to focus and coordinate all Federal HIV/AIDS research initiatives and serves as a foundation for continued planning and evaluation.~~
Vaccine Development. Several major challenges currently face the U.S. and the world in the development of an effective HIV vaccine or vaccines. The first is to surmount the daunting scientific and social challenges and the second is to ensure the development and testing of promising vaccine candidates.

On the scientific level, researchers are pursuing two approaches to vaccine development. One approach is based on the belief that gathering additional basic science information offers the best hope in steering vaccine development. The second approach is guided by the belief that data gathered from clinical efficacy trials in humans can lead to the development of a successful candidate. This group maintains that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding with human trials, and, that in the face of a global emergency, testing in people should be begin immediately. Both approaches have valid arguments.
~~One approach is based on the belief that additional basic science information will guide us in vaccine development. The second approach involves conducting clinical efficacy trials in humans to find answers that will lead to the development of a successful candidate.~~
Developing a vaccine cannot be accomplished by the government or the private sector working apart: a continuing public-private partnership is needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, in February 1996, Vice President Gore convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

Microbicides. Many scientists believe that in the absence of a vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs[7].

Condoms, the barrier methods that are currently available, have limitations. Most require consent, if not active participation of both partners and therefore cannot be independently used at the discretion of one partner. An easily available and inexpensive microbicide could provide a prevention option for millions of people worldwide.

The development of this important prevention option will depend on strong and continuing support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where pharmaceutical or biotechnology companies can assume a lead role. Discussions among Federal Agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development.

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. There is evidence indicating that HIV may behave differently in infected adolescents. We need more information on impact of puberty on the course of HIV infection and behavioral trends that play a key factor in HIV treatment and prevention. Adolescents also must factor more significantly into the research process. NIH and the Food and Drug Administration (FDA) are examining options for lowering barriers to participation of adolescent in clinical trials and research protocols and will continue to encourage sponsors to enroll adolescents when feasible and appropriate, in such trials. The efforts of the collaboratively-funded Adolescent Medicine HIV/AIDS Research Network (Footnote D) are important in improving our understanding of HIV disease in adolescents and will continue. ~~The efforts of the collaboratively funded Adolescent Medicine HIV/AIDS Research Network~~[3] ~~are important in improving our understanding of HIV disease in adolescents.~~**New and More Effective Therapies.** Strong and continuing research to develop new and more effective therapies for HIV infection and its associated conditions must be a priority if we hope to transform HIV disease into a chronic, manageable condition. Due to the FDA's accelerated approval program (Footnote E), the Federal government is now approving new treatments in

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~~[3] The Adolescent Medicine HIV/AIDS Research Network is cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA).~~

record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for patients. ~~Due to the FDA's accelerated approval program[4],~~ While some treatments have shown promise based on surrogate markers and/or laboratory tests data regarding long-term clinical effectiveness are unavailable. Patients may be receiving less effective treatments or combinations of treatments, and private insurers and Federal programs such as Medicaid and Medicare may be paying for treatment strategies that are not optimally effective.

It is incumbent upon the government and the private sector to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as possible, it is necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. Through the efforts of Vice President Gore, the Forum for Collaborative HIV Research has been established to assess approaches for accelerating clinical effectiveness research.

Public-Private Partnerships. A key role for the Federal government is to act in partnership with the private sector and support research that would be beneficial to the public health in areas where there is a market failure.
~~**Public-Private Partnerships.**~~ **For example, it is unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development.** ~~A key role for the Federal government is to act in partnership with the private sector and support areas where industry is unlikely to pursue research that would be beneficial to the public health.~~ However, information about these therapies is critical to improving patient care. The National Institutes of Health (NIH) and the Department of Veterans Affairs (VA) have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry. It is unlikely

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~~[4]The accelerated approval regulation permits companies to seek approval of drugs for serious or life threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.~~

that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships that include the NIH, studies of alternative therapies have been and will continue to be conducted.

It also is cost-effective for the government to provide access to sophisticated equipment and personnel that can be shared among many researchers in both the private and public sectors. The Department of Energy (DOE) has made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

Continued Support for Research. Research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.~~**Continued Investment.** Research is an investment in our future and it must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure,~~ At present, NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, ~~NIH receives many more outstanding AIDS research applications than it is able to fund;~~ such as DOD and VA, also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue to make this investment.

C. CARE & SERVICES

~~*CARE & SERVICES*~~

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."

President Clinton, May 20, 1996
Signing of the Ryan White CARE Act Reauthorization

Another quote for C&S?

Insert 'vision language'.

1. Record of Accomplishment

The Nation has made significant efforts to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs. As the number of people with HIV has increased, so did their need for care. In 1985, Federal expenditures for HIV-related care and services were $xxx, by 1995 the Federal share reached $xxx. The Federal government has continued to respond this expanding need by:

~~The Federal governmet has continued to respond this expanding need by:~~

- Increasing funding for the Ryan White CARE Act 134 percent in four years;
- Doubling funding for the AIDS Drug Assistance Program in the last two years;
- Increasing funding for Housing Opportunities for People with AIDS 96 percent in four years;
- Preserving the Medicaid guarantee of coverage for the nearly 50 percent of people with AIDS and 92 percent of children with AIDS rely on this health coverage; and
- Revising eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits.

Background

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accommodate the health care needs of persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system

~~of care. the health care infrastructure was particularly unprepared to accomodate the health care needs of persons with HIV.~~ There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services were often directed towards meeting the acute care needs of persons diagnosed with AIDS, rather than the early stages of HIV disease. While we still have far to go, the quality and availability of services for HIV-positive persons has improved significantly.

~~the quality and availabilty of services for HIV postive persons has improved significantly.~~People living with HIV now access finance necessary health care services in a variety of ways. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care.[5] However, for a disproportionate umber of people living with HIV and AIDS, their lives often depend on the Federal health care safety net.

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community, that have admirably served those living with HIV. Taken together, these efforts form a valuable, if yet incomplete, safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of the national safety net consists of programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). The CARE Act programs were was established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based

[5] JL cite. Add Vancouver numbers.

family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service (IHS) which provides health care for HIV-positive Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive people in Federal prisons. ~~and the Indian Health Service (IHS) which provides health care for HIV postive Native Americans and Alaska Natives.~~

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

2. Future Opportunities for Progress

The challenge before us today is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually re-examine the range of service that are needed.

The Health Care Safety Net. The cornerstone of care for people living with AIDS in the U.S. is Medicaid. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at $1.9 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV and AIDS. The 30-year State partnership in Medicaid also must be maintained while the program is made more flexible for State innovations. It is also vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV-positive people rests in providing people access to an

integrated continuum of health care services. One of the more powerful methods of recruiting people into primary care is knowledge of HIV serostatus since people who know they are HIV-positive are more likely to seek health care. Counseling and testing services can serve as a gateway to accessing this care. Linking HIV-positive people with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others.

Again, as was true in terms of prevention, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, ~~acheiving this level of integration will require active collaborative efforts on the part of individual physicians,~~ managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for people living with HIV. Without stable housing, a person living with HIV has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.[8]

People living with HIV and their families face significant obstacles locating affordable housing. The HOPWA program was created in 1992 to assist communities meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems that address homelessness.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

Providing consistent funding for the housing component of the safety net must be a Federal priority. Integrating housing services into other programs and ensuring a shared responsibility among Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens. Efforts are underway to improve inter- and intra-departmental

coordination and should continue.

Prisoners. Another group of people frequently underserved are prisoners. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level, significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons and strengthening linkages between prisons and outside public health Departments. Success at these efforts can serve to improve discharge planning for HIV-positive prisoners at the time of their release from prison.

Program Coordination. For HIV care and services to have the most beneficial impact, they should be part of a continuum of care. For organizations at the front lines of the epidemic, building a comprehensive integrated program requires support from numerous Federal Agencies. For example, creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance would require separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

Efforts to simplify federal funding applications that facilitate improved integration of service programs have already begun. For example, HRSA and SAMHSA have issued joint announcements and the HUD and HRSA have issued a joint announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration should be continued and expanded.

Quality of Care. Federally supported programs can and should consistently provide quality care. Quality care for HIV-positive people is possible, but quality care is not consistently available throughout the health care system. Ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care. Again, goal attainment will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority

setting. Evaluating current activities can provide valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV. In an era of limited resources, coupled with a demand for cost-effective services of high quality, we must use all the tools available to us to the benefit of HIV-positive people.

D. CIVIL RIGHTS

> *"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."*
> *President Clinton, May 20, 1996*
> *Signing of the Ryan White CARE Act Reauthorization.*

One of the national goals is to ensure that people living with HIV are not subject to unlawful discrimination. Discrimination based on HIV status is illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. This fear can also cause HIV-positive people to delay treatment. Opportunities to educate people are lost as people at-risk avoid prevention programs because of the stigma associated with HIV. Discrimination can also wrongfully deny people access to housing, insurance, employment, and health care.

1. Record of Accomplishment

The Federal government has vigorously enforced the Americans with Disabilities Act of 1990 (ADA), the primary source of Federal statutory protection for people living with HIV. It has resolved nearly 800 charges alleging employment discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million.

The Federal government has strongly enforced protections provided under Section 504 the Rehabilitation Act of 1973, which prohibit Federal Agencies and recipients of Federal funds from discriminating against people with disabilities. The DHHS Office of Civil Rights enforces Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. And the Health Care Financing Administration (HCFA) enforces regulations regarding the treatment of HIV-infected people.

The Administration has also spoken out frequently against discrimination. We led the fight to repeal the discriminatory "Dornan Amendment," which would have discharged all HIV-positive

military personnel. And we .... other public statements/acts?

2. Future Opportunities for Progress

Enforcement of Federal Laws. The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including those against clinicians who have refused to care for HIV-positive patients and employers who have dismissed people based on their actual or perceived HIV status. In addition to ongoing efforts, a joint Department of Justice and Health and Human Services program will seek to combat nursing home discrimination against people living with AIDS.

Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. The Director of the Office of National AIDS Policy is working with Federal Agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

Leadership. The United States has made progress in fighting discrimination. However, the enactment of laws is insufficient to end discrimination. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal Agencies, States, communities, and the citizens of this country.

E. INTERNATIONAL ACTIVITIES

Insert quote:

Insert 'visionary language'

AIDS is a global pandemic. In the United States it is estimated that between 650,000 and 900,000 people are currently infected with HIV. The World Health Organization (WHO) estimates that 27.9 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened and in some cases may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.[9] In many countries governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

1. Record of Achievement

At present several Federal Agencies are working at slowing the AIDS epidemic internationally. (See Appendix D.) The Department of State works with other Departments, Agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas of U.S. leadership in the HIV arena are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the

epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS. The Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement.

In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

2. Future Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).[10] Moreover, the U.S. is a member of the governing body of UNAIDS and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV/AIDS Initiative (GIPA).

The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP, the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' goal of working to increase the availability of therapeutics (and vaccines when developed) to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs and funds for HIV activities. We must reverse the current trend to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found. The impact of strong USAID HIV/AIDS program on the global stage can not be undermined. OK??—OK??? LR added.

Sharing Technology and Bringing Lessons Home. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations. The "Lessons without Borders

Project" initiative brings lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of Agencies with varied missions and activities. The State Department and Agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Other Agencies, such as NIH and CDC, also support international activities.

Effectively planning, coordinating, and evaluating the overall U.S. international effort requires organizational efforts. In order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort in a systematic and timely way.

F. TRANSLATION OF RESEARCH INTO PRACTICE

Insert Quote

Insert 'vision language'

An important element in our fight against AIDS is ensuring that hard won research advances are translated into practice (i.e., ensuring that new knowledge is incorporated into the standard practice of clinicians, service providers, and health educators caring for people living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for people with HIV.

1. Record of Achievement

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. Ensuring dissemination of HIV-related information falls under the missions of several Agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio tele-conferencing.

NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients. The Health Resources and Services Administration has also developed guidances for its CARE Act grantees, funds an AIDS warmline that responds to questions from clinicians across the country, and directs a nationwide system

of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

2. Future Opportunities for Progress

Despite these advances, there are opportunities for improvement. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[11] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[12] Reference Kittahare (sp?) article.

State of the Art Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government currently supports a number mechanisms for periodically assessing advances in clinical care. It is essential that these assessment efforts continue and that crucial information be widely disseminated. This will require collaboration with industry, government, and professional groups.

Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. We are at a stage in the epidemic where research advances are coming frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this therapeutic regimen, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

Within the DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation

and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

Footnotes

a It is, however, believed that with greater use of AZT by HIV-positive pregnant women, the number of new cases in newborns can be reduced.

b **(re-add footnote; check for Vancouver numbers).**

c Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.

d The Adolescent Medicine HIV/AIDS Research Network is cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA).

e The accelerated approval regulation permits companies to seek approval of drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

Endnotes

1 *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.

2. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.

3. *AIDS and Behavior: An Integrated Approach.* Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

4. Heiner Grosskurth, Frankc Mosha, James Todd, Exra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

5. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229

6. Personal communication from CDC Division TB Elimination.

~~In the absence of an effective vaccine the development of safe and effective mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV.~~

7. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.

8. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

9. *HIV/AIDS Policy Guidance.* U.S. Agency for International Development. September 1995.

10. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

11. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. *JAMA.* 1995; 274:1380-1382.

12. Colombotos, J., Messeri, P., McConnell, M.B., et al: Physicians, Nurses, and AIDS: Findings From a National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95-129185)

of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers.

2. Future Opportunities for Progress

Despite these advances, there are opportunities for improvement. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[11] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[12] Reference Kittahare (sp?) article.

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and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

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CARE & SERVICES

"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."
President Clinton, May 20, 1996, upon signing the Ryan White CARE Act Amendments of 1996.

I Record of Accomplishment

Since the epidemic of HIV and AIDS began in 1981, more than 500,000 Americans have been diagnosed with AIDS and required care. As the number of Americans living with AIDS increased, the demands on the U.S. health care system increased dramatically. Federal, State, and local governments along with community-based organizations and private clinicians have responded with compassionate, high-quality medical care. Among the sentinel achievements of these efforts are:

- CDC testing and counseling program?
- AETCs?
- Enactment in 1989 of the Housing Opportunities for People with AIDS (HOPWA) program;
- Enactment in 1990 of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act;
-

Since he took office in 1993, President Clinton has, as one of his highest priorities, sought to increase the national commitment to care for people living with HIV or AIDS. Among those actions are:

- Increasing funding for the Ryan White CARE Act by 134 percent;
- More than doubling funding for the AIDS Drug Assistance Program, which helps uninsured and underinsured individuals purchase prescription drugs;
- Increasing funding for Housing Opportunities for People with AIDS by 96 percent;
- Fighting to preserve the Medicaid guarantee of coverage for the nearly 50 percent of people with AIDS and 92 percent of children with AIDS who rely on this program for their health coverage;

- Revising eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits; and,

- Signing the Ryan White CARE Act Amendment of 1996, extending support for care for people living with HIV/AIDS until FY 2000.

In the early years of the epidemic, the American health care system was unprepared to accommodate the health care needs of people living with HIV. To meet their needs, people with HIV/AIDS often were forced to negotiate a fragmented system of care. A relatively small number of clinicians were trained in the care of people with AIDS; public hospitals and other facilities were often overburdened with demands for care; a larger numbers of patients were either uninsured or reliant on public assistance. Care was more often skewed to the acute care needs of people who had been diagnosed with AIDS rather than the needs of individuals who were recently infected with HIV.

In the intervening 15 years, care for people living with HIV and AIDS has greatly improved. However, a disproportionate percentage of people living with HIV/AIDS are either uninsured or rely on public programs for their health care coverage. People living with HIV now finance their health care services in a variety of ways. Nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program; another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care.[1]

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community, that have admirably served those living with HIV. Taken together, these efforts form a valuable, if still incomplete, safety net for some of the most vulnerable people in our Nation.

Medicaid, a jointly financed Federal-State program of health care for the poor and the disabled, is the primary source of care for people living with AIDS and a major source of care for those who are living with HIV. In FY 1996, Federal Medicaid expenditures for people living with AIDS totaled $1.6 billion. The Medicaid statute authorizes Federal matching payments to the states to provide services to eligible individuals. Medicaid provides coverage for:

- Inpatient and outpatient hospital services
- Physician services
- Certain medical/surgical services of dentists

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[1] JL cite. Add Vancouver numbers.

- Laboratory and x-ray services
- Nursing facility services for individuals 21 and older
- Home health care for persons eligible for nursing facility services
- Rural health clinic services
- Federally qualified health center services
- Assurance of necessary transportation services

States may elect to provide a number of other services for which Federal matching funds are available. Some of the most frequently covered optional services are:

- Prescription drugs
- Clinic services
- Optometrist services and eyeglasses
- Dental services
- Prosthetic devices
- Medical transportation services
- Case management services

In addition to Medicaid, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, administered by the Health Resources and Services Administration (HRSA), is a major source of care for people with HIV and AIDS. The CARE Act programs were was established to fill gaps in coverage and to build systems of care to provide access to health care for people living with HIV/AIDS. The CARE Act is comprised of four separate titles:

- Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis. Title II also provides drug reimbursement funding for persons living with HIV/AIDS under the AIDS Drug Assistance Program (ADAP).

- Title IIIb of the CARE Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness.

- Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care.

HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service (IHS). Additionally, the Bureau of Prisons within the Department of Justice provides care for people living with HIV in Federal prisons.

People living with HIV and their families face significant

obstacles to locating affordable housing. Housing assistance for people living with HIV/AIDS is provided by the Department of Housing and Urban Development (HUD) through its Housing Opportunities for Persons with AIDS (HOPWA) and other programs **[would be better to list these other programs]**. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

To further foster community involvement, HUD also has established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. The Community Development Block Grant (CDBG), the HOME affordable housing program, as well as public housing programs are key resources that are available to communities.

II Future Opportunities for Progress

The current challenge is to ensure that persons living with HIV receive the care they need so they may have the opportunity to lead longer, healthier, and more productive lives. AIDS care and service programs must continue to expand access to care for those without insurance coverage, improve prioritization and accountability, and increase the cost-effectiveness of services they provide. As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

Preserving Medicaid. Medicaid is a lifeline of support for Americans living with HIV and AIDS. As the epidemic continues to spread in lower-income communities, the need for Medicaid coverage of people living with HIV/AIDS will increase. The need to maintain the historic Federal-State partnership on Medicaid has never been greater. Proposals in Congress to convert Medicaid into a block grant would endanger access to care for people living with HIV/AIDS. In particular, proposals to eliminate the Federal guarantee of coverage for people living with disabilities would have a dramatic impact on people living with HIV/AIDS. President Clinton has vetoed one such proposal and has promised to veto any future proposals that reach his desk.

Continuing Support for Ryan White CARE Act. The five-year reauthorization of the CARE Act signed by President Clinton on May 20 provides people living with HIV/AIDS with peace of mind that support from the Federal government will be there through FY 2000. Recent increases in funding for the Ryan White CARE Act have brought this vital program to full funding. As the demand for care continues to grow so must the resources for the CARE Act. President Clinton has proposed **[how much?]** for this program in FY 1997; enactment of that request is essential.

Expanding Support for Housing Services. Without stable housing a person living with HIV has diminished access to care and services

and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of people living with HIV and AIDS are or will become homeless during the course of their illness.[1] President Clinton has requested $191 million in FY 1997 for HOPWA; it is imperative that Congress approve that request.

Providing consistent funding for the housing component of the safety net will continue to be a Federal priority. Integrating AIDS housing services into other programs and ensuring a shared responsibility among Federal, State, local governments and community organizations is another important step in assisting communities to build seamless systems of support for our most vulnerable citizens.

Extending the Continuum of Care. One of the most effective approaches to treating people living with HIV is providing access to an integrated continuum of health care services. One of the more powerful methods of recruiting people into primary care is knowledge of HIV serostatus. People who know their HIV status are more likely to seek health care and act to prevent HIV transmission. Counseling and confidential voluntary testing services serve as a gateway to care. Linking HIV-positive people with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others.

Achieving this level of integration requires active collaborative efforts by physicians, nurses, other clinicians, insurance plans, medical schools, and professional organizations in addition to State, local and Federal governments.

[[I think it is very odd to single out prisoners in this way. First, we are doing virtually nothing for them. Second, singling them out raises the question of why we aren't singling out any other groups. I urge deleting it.]]
Prisoners. Another group of people frequently underserved are prisoners. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level, significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons and strengthening linkages between prisons and outside public health Departments. Success at these efforts can serve to improve discharge planning for HIV-positive prisoners at the time of their release from prison.

Coordinating Assistance. Organizations receiving assistance from the Federal government in providing AIDS-related care often require support from several Federal Agencies. For example,

creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance requires separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

As part of its effort to "reinvent government," the Clinton Administration has been working to simplify Federal funding applications to facilitate improved integration of service programs. HRSA and SAMHSA have issued joint announcements **[on what??]]** and HUD and HRSA have issued a joint announcement for the Special Projects of National Significance (SPNS) program. These efforts to improve integration will be continued and expanded.

Improving Quality of Care. Federally-supported programs can and should consistently provide high-quality care. Ensuring consistency in care delivery requires increased training for health care professionals and greater accountability through the use of performance measures for quality care. Achieving these goals requires the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

Evaluating Program Effectiveness. Strong Federal support for safety net programs must be accompanied by improved accountability and priority setting. Evaluating current activities provides valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people living with HIV.

CIVIL RIGHTS

"Every person with HIV or AIDS is someone's son or daughter, brother or sister, parent or grandparent. We cannot allow discrimination of any kind to blind us to what we must do."

President Clinton, May 20, 1996, upon signing the Ryan White CARE Act Amendments of 1996.

Discrimination against people living with HIV or AIDS violates the human rights of individual Americans and undermines our Nation's efforts to prevent and treat HIV infection. The extraordinary stigma that has been attached to HIV disease hampers the ability of people living with HIV/AIDS to live full lives, free of fear. It inhibits our ability to deliver high-quality care to those who need it and leads to behavior that often results in transmission of HIV.

I Record of Accomplishment

During the early years of the AIDS epidemic, protection of the civil rights of people living with HIV/AIDS was sporadic, at best. Individual lawsuits were the first line of action. By the late 1980s, however, the Federal government began to respond more aggressively. Sentinel achievements include:

- Enactment in 1973 of the Rehabilitation Act, which includes Section 504 prohibiting Federal Agencies and recipients of Federal funds from discriminating against people with disabilities;
- Arline decision
- Enactment in 1990 of the Americans with Disabilities Act (ADA), which protects individuals living with HIV/AIDS from discrimination in housing, employment, and public accommodation. Similar protections are extended to those who **[what's the language regarding people perceived to have HIV???]**;
-

Since he took office, President Clinton has directed relevant agencies to make enforcement of the civil rights of people living with HIV/AIDS a priority. Key actions include:

- Vigorously enforcing the ADA by the Justice Department, the Equal Employment Opportunities Commission, and the Department of Health and Human Services. The Federal government has resolved nearly 800 charges alleging discrimination against people with HIV and AIDS obtaining monetary benefits of more than $6.1 million;

- Vigorously enforcing Section 504 of the Rehabilitation Act of 1973 as it pertains to recipients of HHS funds such as hospitals, nursing homes, and social service agencies;

- Forcefully opposing the so-called "Dornan Amendment," which would require the discharge of all military personnel who are living with HIV. President Clinton declared the proposal unconstitutional and directed the Department of Justice not to defend it if challenged in court. The President led a successful effort to repeal the "Dornan Amendment" and continues to oppose its enactment;

- Establishing an AIDS education program for all Federal workers;

- Using the Presidential "bully pulpit" to continually speak out against discrimination against people with HIV/AIDS.

II Future Opportunities for Progress

Enforcing Rights. Efforts to protect the civil rights of people with HIV/AIDS must be ever-vigilant. The Federal government must continue to exhibit strong leadership on this issue through its enforcement of the Americans with Disabilities Act and public condemnation of discriminatory acts or statements. Of particular concern is discrimination in health care facilities. A joint effort by the Department of Health and Human Services and the Department of Justice aimed at nursing homes is a significant step forward.

Protecting Workers. The Federal government is actively working to examine its own existing policies related to the exclusion of people living with HIV from employment. The Director of National AIDS Policy is working with Federal Agencies to examine individual policies to determine whether they comply with Federal guidelines.

Opposing Discriminatory Legislation. The Administration will continue to oppose, in the strongest terms possible, efforts by the Congress to discriminate against people living with HIV/AIDS.

Providing Leadership. Leaders of government have an obligation to use the power of their elected office to speak out against acts or words of discrimination against any group of people. President Clinton has used and will continue to use his position to oppose discrimination against people living with HIV/AIDS.

INTERNATIONAL ACTIVITIES

Insert quote: check WHCA text

AIDS is a global pandemic. **[[add a sentence about 80 percent of cases -- or is it infections -- are in developing countries]]** The World Health Organization (WHO) estimates that worldwide 27.9 million adults and more than 1.5 million children currently are infected with HIV. An estimated 2 million to 3 million individuals become infected with HIV each year and, by the end of this decade, between 30 million and 40 million people will be infected around the world. As a result of AIDS-related deaths, WHO estimates that between 10 million and 15 million children will be orphaned by HIV/AIDS by the year 2000.

This pandemic jeopardizes decades of economic and social advances in many developing nations. In the nations of Africa and Asia, economic advances are threatened and in some cases may be reversed due to HIV/AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.[2] In many countries governments are coping with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and a reduced number of healthy men and women able to serve in the government and the military.

I Record of Achievement

Since it began, HIV/AIDS has been a global concern. The U.S. has worked closely with developed and developing nations to design an international response that is both vigorous and coordinated. Sentinel achievements include:

- Establishment of WHO's GPA in ???.
-
-
- Creation in ????? of the Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS);

The United States is the largest contributor to international efforts to combat the pandemic of HIV/AIDS. The Clinton Administration has worked to increase U.S. involvement in the international response to HIV/AIDS by:

-
-

At present several Federal Agencies are working at slowing the AIDS pandemic (See Appendix D). The Department of State works with other Agencies and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas of focus are: preventing new infections, reducing the personal and social impact of the pandemic, and mobilizing and unifying national and international efforts.

The U.S. Agency for International Development (USAID) also plays a leadership role in the global HIV effort through development assistance, research, and policy formation. USAID focuses its efforts on developing prevention programs based on proven interventions; addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections; and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic.

The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS.

The Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement.

In addition, several Agencies support international AIDS research including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense. The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH and USAID support basic scientific studies on social and behavioral aspects of AIDS in developing countries. The results of these studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

II Future Opportunities for Progress

Continuing International Leadership. The U.S. has established a global leadership role in combatting the epidemic and this leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).[3] The U.S. is a member of the governing body of UNAIDS and helped to draft and signed the 1994 Paris Declaration and the Greater Involvement of People Living with HIV/AIDS Initiative (GIPA).

Disseminating Results. The U.S. also supports efforts to more effectively make use of available resources as well as to

encourage non-traditional donor countries to provide much-needed contributions. Supporting UNAIDS organizations such as UNICEF, WHO, UNDP, the U.S.-Japan Common Agenda and its innovative programmatic efforts, and UNAIDS' goal of working to increase the availability of therapeutics and vaccines to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Strengthening Partnerships. In addition to maintaining our multilateral partnerships, we must strengthen and expand our bilateral programs. We must guard against efforts to reduce assistance to developing countries where more than 90 percent of the world's AIDS cases are found.

Sharing Technology. USAID has gained valuable insights and lessons from experiences from HIV/AIDS programs in other countries and is applying them to U.S. populations. The "Lessons without Borders Project" initiative brings lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas. These efforts will be continued and should be expanded.

Improving Program Coordination. Effectively planning, coordinating, and evaluating the overall U.S. international effort requires organizational efforts. In order to improve this endeavor, the Agencies supporting international activities must develop a mechanism for identifying and coordinating this effort in a systematic and timely way.

Can we say "Translation of Advances into Practice" since not all of this is research.

TRANSLATION OF RESEARCH INTO PRACTICE

Insert Quote

An important element in the fight against HIV/AIDS is ensuring that advances in research, prevention, and care are translated into practice. The increasing **[prevalence?]**presence of HIV necessitates that all health care providers become knowledgeable about assessing risk, promoting prevention, and caring for people with HIV.

An example of the importance of such efforts is the translation of the research finding in AIDS Clinical Trial Group 076, which found that the use of AZT by pregnant women during pregnancy and childbirth and its application to newborns for the first six weeks of life can reduce the risk of perinatal transmission of HIV by two-thirds. Translation of these results required actions by the Centers for Disease Control and Prevention, which prepared guidelines for physicians caring for pregnant women and for consumers; the Health Resources and Services Administration, which provided guidance to grantees on coverage of such services; the Health Care Financing Administration, which provided similar guidance to State Medicaid Directors.

I Record of Achievement

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place. Ensuring dissemination of HIV-related information falls under the missions of several Agencies (See Appendix E). Key examples are:

- The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the public;

- HHS supports and directs the International HIV/AIDS Clinical Conference Call series, which disseminates critical, state-of-the-art clinical care information to primary care providers via live worldwide audio tele-conferencing;

- NIH supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE;

- The toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA;

- The Centers for Disease Control and Prevention disseminates information through the National AIDS Hotline (1-800-342-

AIDS); its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS); and the AIDS Information Clearinghouse;

- The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*;

- The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; and,

- The Health Resources and Services Administration directs a nationwide system of AIDS Education and Training Centers that provide state of the art HIV clinical information to health care providers. HRSA also has developed guidances for its Ryan White CARE Act grantees and funds an AIDS **[huh? hotline?]**warmline that responds to questions from clinicians across the country.

II Future Opportunities for Progress

There are opportunities for improvement in translating advances into practice. They include:

Increasing Education and Training. As we continue to expand our base of knowledge about AIDS care, efforts to educate and train health care professionals in state-of-the-art care for people living with HIV/AIDS must be expanded. An AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.[4] Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.[5] Reference Kittahare (sp?) article.

Disseminating Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government currently supports a number mechanisms for periodically assessing advances in clinical care. It is essential that these assessment efforts continue and that crucial information be widely disseminated. This will require collaboration with industry, government, and professional groups.

Improving Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. In the case of ACTG 076, improved coordination enabled the Federal government to respond quickly and aggressively to the very promising results of

that research.

Within HHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate people and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Disseminating Prevention Models. Improved dissemination efforts also are needed in the area of primary prevention models. Models of effective prevention interventions have been developed, but often this valuable information is not reaching those people developing, implementing, and evaluating prevention programs. The Public Health Service will take the lead in ensuring that information that can be used to stem the tide of new infections reaches those who can make a difference.

Footnotes

1. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

2. *HIV/AIDS Policy Guidance.* U.S. Agency for International Development. September 1995.

3. Until recently, the United Nations' response to HIV/AIDS was carried out primarily by the World Health Organization's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, co-sponsored by six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the global and country levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

4. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. *JAMA.* 1995; 274:1380-1382.

5. Colombotos, J., Messeri, P., McConnell, M.B., et al: Physicians, Nurses, and AIDS: Findings From a National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95-129185)

New version--1

Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a heightened national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National AIDS Strategy that would chart the Administration's long-term direction in responding to the ~~HIV/AIDS~~ national and international ~~pandemic~~ epidemic. The National AIDS Strategy ~~for HIV and AIDS~~ has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector.

The President has identified the following overarching goals for our Nation's efforts against HIV:

- **To provide strong continuing support for research in order to find additional treatments, ~~and~~ & a cure for those currently infected, and a preventive vaccine to protect the uninfected;**

- **To provide ~~solid~~ strong continuing support for effective prevention strategies ~~so as~~ to reduce the number of new infections each year until there are no new infections; ~~and,~~ &**

New version--1

- To ensure that people have access to services that are affordable, of high quality, and responsive to their needs; and, ~~persons living with HIV receive services that are caring, ethical, and in accordance with legal standards and that they are not subject to discrimination.~~

To ensure that people living with HIV are not subject to unlawful discrimination.

This document is a snapshot of where we are as a Nation and where we think we need to go in achieving these overarching goals. It summarizes some of the key achievements of this Administration's scientific and public health professionals and it identifies key areas for further work. In addition, the appendices provide detailed descriptions of programmatic objectives, linking goals to budgets of all Federal government efforts in the five key areas of HIV policy: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges emerge ~~occur~~. The ~~This~~ Strategy serves as a reference point for lengthier dialogues and collaborative efforts between the public and private sectors that will be necessary to implement this strategy.

The development of the ~~a~~ National AIDS Strategy is an historic undertaking. No previous administration has undertaken so broad a planning effort that: (1) involves all Federal Departments and

New version--1

Agencies that engage in HIV-related efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the Nation should place its most concerted efforts.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work.

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the Presidential Advisory Council on HIV/AIDS (PAC), the advocacy community, participants in the White House Conference on HIV and AIDS, attendees at regional briefings around the Nation co-sponsored by ONAP, the National AIDS Fund, Funders Concerned About AIDS and numerous local organizations, service providers on the front lines of the epidemic, and many HIV-positive persons, their families, friends and care givers have been central to identifying areas for

focused attention. The insights provided by the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing the National AIDS Strategy.

Today we are facing great challenges, but we are also facing equally great opportunities. While AIDS is a terrible tragedy that has already affected -- and will continue to affect -- far too many people around the world, we have made tremendous progress in our understanding of this virus, how we can treat it, and how we can prevent transmission of it. I believe that, ultimately, HIV is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National Strategy for HIV and AIDS lays a foundation for the public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

New version--1

I. INTRODUCTION

Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the Centers for Disease Control and Prevention (CDC) in June of 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

As of December 1995, the Centers for Disease Control and Prevention (CDC) reported 513,486 cases of AIDS among persons in the U.S.; 319,849 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all

New version--1

Americans to the 8th. AIDS strikes those in the prime of life during their most economically productive years. It is now the leading cause of death among Americans aged 25 to 44. (See Figure 1.) In 1995 alone, approximately 74,000 new cases of AIDS were reported to the CDC. More than 46,000 AIDS related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 600,000 and 900,000 Americans are currently living with HIV.

As the epidemic in the United States has evolved, the demographics of the epidemic have changed. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users and their partners as well as non-injecting drug users (i.e., crack cocaine and alcohol). Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In

1995, approximately 800 new pediatric AIDS cases were reported. However, it is hoped that with greater use of AZT by HIV-positive mothers during pregnancy and delivery, and administration to their babies after birth, the number of new cases in newborns can be reduced. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has also increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among young people. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been disproportionately affected by the epidemic. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 19 percent of new cases reported in 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases;

New version--1

however, as of December 1995 these groups comprised 52 percent of cumulative AIDS cases.

AIDS in the United States is no longer just an urban problem. It is spreading to non-urban areas, with especially dramatic increases in certain regions of the South and Midwest. In fact, between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South.[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and the U.S. territories. (See Figure 2.)

AIDS is a costly disease. Average lifetime costs of medical care after diagnosis with HIV is $119,000 (re-add footnote; check for Vancouver numbers). This compares with cancer ($25-$42,000) and heart disease ($61,211). In addition, people living with HIV are disproportionately dependent on the public sector for their health care. Nearly 50 percent of people with AIDS are on Medicaid; over 90 percent of children with AIDS are on this program. The Federal government alone spends $1.7 billion (check) on Medicaid and $xxx billion on Social Security benefits for people disabled by AIDS.

New version--1

Internationally, the toll of the epidemic is greater still and threatens to reverse decades of economic and public health progress in developing countries. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV. In addition, WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000.

International - Printer's Copy

The National AIDS Strategy, Appendix D: International Activities
Draft for ONAP Review: 7.22.96

Agency: Department of Defense

Goal: To support leadership in the international community by sharing research methodologies and findings, observing host nation requirements for HIV testing and reporting, and supporting research at international sites with high prevalence or incidence of HIV and AIDS.

Objective: Participate in global surveillance initiatives and maintain current knowledge of host nation HIV screening and reporting requirements.

Action Steps: Determine the prevalence of HIV initiative, infections, and genotypes in geographic areas of military activity.

Coordinate with Department of State.

Descriptions: International efforts including the study of geographic distribution of genotypes at DOD overseas laboratories. Support for basic research on diagnostic tests and vaccines.

FY 95: $1,500,000
FY 96: $1,500,000
FY 97: $1,200,000

Populations Served: Foreign national and active duty U.S. military personnel.

Constituency Involvement: Active duty military and foreign service national of DoD overseas laboratories.

Unmet Need: None.

Agency: Department of Health and Human Services, Office of International Health

Goal: To support U.S. interests globally by serving as a policy and coordinating body for international activities supported by DHHS, a liaison with other U.S. departments and agencies supporting international activities, and a liaison with foreign governments working with U.S.

Objective: Improve coordination among DHHS and other Federally-supported international activities.

Action Steps: Establish and maintain communications with other departments and agencies supporting international activities.

Develop mechanism for tracking DHHS-related international activities.

Descriptions: International activities mapping project.

FY 95: NA - HIV activities integrated into overall budget
FY 96: NA - HIV activities integrated into overall budget
FY 97: NA - HIV activities integrated into overall budget

Populations Served: Program planners and policy makers.

Constituency Involvement: None.

Unmet Need: Increased resources would improve Office's ability to support U.S. interests.

Agency: U.S. Department of State

Goal: To promote more active involvement on HIV/AIDS issues by foreign governments.

Objective: Persuade foreign governments to increase national and global activities to stem the spread of HIV/AIDS and to mitigate its impact.

Action Steps: Overseas posts will communicate the major objectives of the U.S. International Strategy on HIV/AIDS to host country officials.

Description: Initiative to increase commitment of foreign leaders.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involvement: U.S. State Department, foreign governments, NGOs and business groups.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Agency: U.S. Department of State

Goal: To enhance U.S. participation on HIV/AIDS issues internationally.

Objective 1: Address HIV/AIDS in all appropriate international fora.

Action Steps: Ensure that the U.S. International Strategy is promoted at relevant international meetings of the U.N. and other bodies. Convene interagency meetings to discuss the international calendar and to develop cohesive approaches to AIDS issues.

Description: Implementation of the U.S. International Strategy on HIV/AIDS.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involvement: U.S. State Department and other federal agencies.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Objective 2: Assist U.S. agencies in improving responsiveness to a range of HIV/AIDS-related issues.

Action Steps: Address the issue of the spread of AIDS in international peacekeeping and humanitarian missions. Explore possibilities for closer collaboration with multilateral development banks (MDBs) to stem the spread of AIDS.

Description: Improving U.S. responsiveness.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs around the world and populations threatened by HIV/AIDS.

Constituency Involvement: U.S. State Department and MDBs.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Agency: U.S. Department of State

Goal: To enhance awareness of implications of HIV/AIDS worldwide.

Objective 1: Heighten awareness of Congress as to implications of global HIV/AIDS on U.S. foreign policy.

Action Steps: Communicate to Congress the implications of global HIV/AIDS for foreign policy initiatives. Support biomedical research and international prevention efforts as means of reducing potential impact.

Description: Communicate implications of U.S. International Strategy on HIV/AIDS to Congress.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and the U.S. Congress.

Constituency Involved: U.S. State Department.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Objective 2: Heighten awareness within the U.S. foreign service community and other U.S. agencies of the foreign policy implications of global HIV/AIDS.

Action Steps: Distribute International Strategy on HIV/AIDS to embassy personnel.

Hold workshop on the global implications of HIV/AIDS.

Use training sessions and individual briefings of foreign service personnel to discuss HIV/AIDS as a foreign policy concern.

Work with U.S.-based international businesses to gain a better understanding of the economic impact of global HIV/AIDS on U.S. business.

Continue to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting.

Description: Inform and educate U.S. foreign service personnel.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and State Department foreign service personnel.

Constituency Involvement: U.S. State Department.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Agency: U.S. Department of State

Goal: To support U.S. technical agencies.

Objective: Support U.S. technical agencies in fulfilling the international HIV/AIDS objectives as appropriate to their individual agency mandates.

Action Steps: Assist USG agencies in strengthening or establishing international research and training collaborations and in gaining approval for HIV/AIDS vaccine trials and other research efforts.

Description: Support for international research.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS, researchers and USG agencies.

Constituency Involvement: U.S. State Department, USG agencies and researchers.

Unmet Needs: Budget and personnel constraints limit the Department's ability to coordinate actions identified in the International Strategy on HIV/AIDS document.

Agency: Department of the Treasury

Goal: To support developing international health programs, including HIV-related programs.

Objective: Work with the multilateral development banks (MDBs) to provide large-scale assistance for health projects, including HIV-related projects.

Action Steps: Through the Department's oversight authority over the multilateral development banks, assist in the provision of external financing for primary health and AIDS programs in the developing world.

Descriptions: Multilateral development bank provision of direct finance, technical assistance and policy advice, and MDB coordination of bilateral assistance efforts.

FY 95: Not applicable.
FY 96: Not applicable.
FY 97: Not applicable.

Populations Served: Developing countries.

Constituent Involvement: Recipient countries are actively involved in the preparation and implementation of MDB lending and technical assistance programs.

Unmet Need: None.

Agency: Peace Corps

Goal: To prevent transmission of HIV infection for Peace Corps Trainees and Volunteers.

Objective 1: Provide all trainees with comprehensive HIV/AIDS training during the pre-service training period.

Action Steps: Develop training modules, train overseas medical staff, and educate trainees.

Descriptions: HIV/AIDS prevention training for Peace Corps Volunteers/Trainees.

Objective 2: Provide continued HIV education and counseling for Peace Corps Volunteers and Medical Staff.

Action Steps: Train Office of Medical Services (OMS) staff on communication and counseling skills.

Continue to educate volunteers about HIV/AIDS during in-service trainings and conferences.

Develop and distribute health newsletters.

Provide one-on-one counseling for volunteers on an as needed basis.

Disseminate videos, pamphlets, education material on HIV/AIDS prevention.

Follow CDC guidelines on prevention of transmission in a medical setting.

Descriptions: Follow-up HIV training for volunteers and medical staff. Make condoms available and easily accessible for all volunteers.

FY 95: $300,000
FY 96: $100,000
FY 97: $100,000

Populations Served: Peace Corps Volunteers/Trainees and medical staff.

Constituency Involvement: Peace Corps Volunteers/Trainees and Peace Corps Medical Staff.

Unmet Need: Due to budget constraints, Office of Medical Services (OMS) will only be able to provide courses for in-country Medical Staff every other year.

Agency: Peace Corps

Goal: To enhance the understanding of HIV/AIDS and transfer skills for prevention to the communities and countries in which Peace Corps Volunteers serve.

Objectives: Provide quality programming and training on HIV/AIDS prevention as a primary project in six countries.

Provide quality programming and training to ten percent of all Volunteers to work in HIV/AIDS as a secondary activity.

Support on-going education and training of Associate Peace Corps Directors (APCD) in charge of programming at country level.

Liaison with other organizations working in HIV/AIDS both internationally and domestically.

Action Steps: Recruit 50 Volunteers to work in HIV/AIDS as their primary job.

Train 50 new Volunteers and 45 second year Volunteers in HIV/AIDS, language and cross-cultural skills.

Support 100 Volunteers to work in HIV/AIDS as their primary assignment.

Support the development of projects and training curriculum.

Support workshops for APCDs in three regions.

Provide expert consultants for the development of projects and training.

Support attendance at international and national conferences and workshops on HIV/AIDS and share information.

Description: HIV/AIDS prevention activities in developing countries around the world.

FY 95: $4,500,000
FY 96: $5,000,000
FY 97: $5,000,000

Populations Served: Communities in developing countries, women and youth.

Constituency Involvement: Peace Corps designs all programs in

conjunction with the beneficiary population.

Unmet Need: There is higher demand for Peace Corps Volunteers than the agency can meet, and this is particularly true for program areas such as HIV/AIDS.

Agency: U.S. Agency for International Development

Goal: To achieve sustainable reduction in sexually transmitted infections (STIs) and HIV transmission among key populations.

Objective 1: Develop and test new interventions and methods to prevent transmission and mitigate impact of the epidemic.

Action Steps: Support research to identify activities that immediately and directly influence the effectiveness of existing programs.

Undertake activities that enable women to reduce the risk of HIV infection.

Undertake pilot projects and research to mitigate the impact of HIV in severely affected areas.

Undertake activities that support the public health infrastructure and utilization of HIV vaccines.

Description: Development and improvement of women's access to female controlled barrier methods. Improvement of STD/HIV prevention interventions and technologies for STD management. Support of studies that enhance understanding of behaviors and epidemiology, mitigate the impact of HIV/AIDS on communities. Facilitate opportunities for international field trials of promising vaccines.

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involvement: USAID agency employees, developing country representatives, community representatives, PVO/NGO donors, multilateral donors, and bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

Objective 2: Policy reform addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other STIs.

Action Steps: Conduct policy dialogue with decision makers to encourage a high-level multi-sectoral coordinated response to HIV/AIDS.

Address resource issues and long-term sustainability at all levels.

Address the social and cultural impediments to the successful implementation of HIV/AIDS programs.

Develop tools and complete research to serve policy dialogue and reform.

Description: Increase the use of methods aimed at reducing perinatal and parenteral HIV transmission. Coordinate effective donor responses and leveraged funding. Support international and regional multi-sectoral approaches and mobilize the private sector. Support decision-makers addressing difficult social, cultural, and religious issues. Continue to develop and use tools such as simulation modelling to describe the socio-economic impact of the epidemic.

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

Objective 3: Develop and implement HIV/AIDS prevention programs that utilize proven interventions to prevent transmission.

Action Steps: Promote safer sexual behavior through information, education, and communication.

Increase the demand for, access to, and use of condoms.

Control STIs by improving STI diagnosis and treatment services and by education of persons with STIs.

Description: Improvement of social and cultural commitment to HIV/AIDS prevention. Strengthening programs to create a more supportive environment for behavior change, improving the quality of diagnosis and treatment, and increasing access to services including counseling and training for care providers, and facilitating the procurement of therapies.

Population Served: Persons living with AIDS in USAID HIV/AIDS

emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

Objective 4: Enhance capacity of public, private NGO and community based organizations to design, implement and evaluate effective HIV/STI prevention and care programs.

Action Steps: Improve policy reform, research capability, logistics systems, and use of local and regional NGO networks.

Enhance the technical and managerial capability of indigenous NGOs and PVOs to design, implement and evaluate HIV/STI projects in all HIV/AIDS emphasis countries.

Strengthen local and regional networks of NGOs involved in HIV prevention, care and advocacy in at least six countries.

Assess and strengthen host country capacity for HIV/STI prevention research.

Disseminate models of home and community based delivery of HIV/STI care.

Description: Support for USAID'S response to HIV/AIDS in developing countries, the Paris Summit Initiative, and the Greater Involvement of Persons Infected and Affected by HIV/AIDS (GIPA). Provide support for and strengthen linkages between indigenous NGOs and U.S. domestic PVOs, NGOs, and ASOs. Concentrate bilateral and care resources on selected emphasis countries to assure comprehensive programs; strengthen trans-national and regional activities in prevention and research through the "areas of affinity" concept. Continue collaboration with and support for efforts of multi-lateral organizations such as UNAIDS, WHO, UNDP, ENFPA, UNICEF, and the U.S.-Japan Common Agenda for HIV/AIDS prevention.

FY 95: $119,000,000
FY 96: $114,000,000
FY 97: $114,000,000

Population Served: Persons living in USAID's HIV/AIDS emphasis

countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

Unmet Needs: Given the limited resources available for international development assistance, it is not possible for USAID to meet all the needs in this area.

Agency: U. S. Information Agency

Goal: To increase understanding of and support for U.S. Government (USG) policies and programs on HIV/AIDS among foreign publics.

Objective 1: To provide accurate information on USG policy and programs to key foreign audiences.

Action Steps: Disseminate information via multi-language television, radio and texts distributed directly and through overseas posts and reference centers, tours and briefings for foreign journalists and health policy officials, and public affairs campaigns that support specific USG initiatives in foreign countries.

Description: Information on USG policy and programs.

FY 95: $350,000
FY 96: $325,000
FY 97: $325,000

Population Served: Policy makers, academics, journalists, researchers and Non-governmental Organization (NGO) leaders.

Constituency Involvement: USG officials, academics/researchers and NGO leaders.

Unmet Needs: Lack of technology in many underdeveloped countries may prohibit information from reaching key audiences.

Objective 2: To give foreign decision makers a first-hand experience with U.S. policy and programs -- public and private, national and local -- to address the HIV/AIDS pandemic and encourage exchange with their U.S. counterparts.

Action Steps: Sponsor multi-regional, regional and individual International Visitor Programs, focusing specifically on HIV/AIDS issues and as part of programs on substance abuse, civil society, human rights and community health.

Description: International Visitors Program.

FY 95: $240,000
FY 96: $200,000
FY 97: $200,000

Population Served: Health policy makers and NGO leaders.

Constituency Involvement: U.S. NGOs, state, local and federal agencies and academic/research institutions.

Unmet Needs: The program is currently very limited, only allowing for 31 health policy officials and community leaders from 24 countries to visit the United States.

Prevention-Printer's Copy

Agency: Department of Defense

Goal: Preservation of an effective fighting force through prevention of HIV infection.

Objective 1: Prevent HIV infection in service members.

Reduce the number of new active duty HIV infection by 20 percent by 1997 based on a 1995 baseline figure of 204 persons for all services.

Action Steps: Provide basic information on HIV transmission and risk reduction for new recruits, civilian work force members, and officers;

Require education and general military training on methods of transmission and approaches for avoiding transmission, including barrier methods, avoidance of intravenous drug use, and use of universal precautions;

Provide training for personnel, instructors, and peer educators; and

Support train the trainer courses to develop multidisciplinary teams from medical, dental, nursing, and public health corps for promoting HIV and AIDS education.

Objective 2: Ensure safety of the Armed Services Blood Program Office (ASBPO).

Action Steps: Advise service personnel with serologic evidence of HIV infection or repeated ELISA reactivity, but Western Blot negative or indeterminate, to refrain from donating blood.

Employ ASBPO "Look Back Program" to trace contacts of identified positive donors who serconvert after blood donation -- trace and contact blood recipients.

FY 95: Approximately $500,000
FY 96: Approximately $500,000
FY 97: Approximately $500,000

Populations Served: Active duty service members and their eligible family members, health care providers and those at risk of exposure to body fluids, and recipients of ASBPO blood products.

Constituency Involvement: Active duty force, affiliated civilian workforce, and the health care and public health communities.

Unmet Need: None

Agency: Department of Education

Goal: To disseminate information on Department of Education (ED) Programs in coordination with other Federal agencies.

Objective 1: Coordinate with DHHS to provide information and points of contact for existing ED programs.

Action Steps: Coordinate and share information with CDC-sponsored National AIDS Clearinghouse; include information related to school-based comprehensive health programs (ED funded) in the Comprehensive Health Information Database (HHS).

Descriptions: A broad range of programs are supported; for example, including the Foundation For Children With AIDS, Duke University Medical Center, and University of California Disability Statistics Rehabilitation Research and Training Center.

FY 95: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program.

FY 96: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program:

FY 97: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program.

Populations Served: Elementary and secondary students, teachers and parents through health education curricular, pre-service, and in-service training and parental involvement programs.

Constituency Involvement: The majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

Unmet Need: Many groups are unaware that resources are available to assist them. Increased funding would assist in improved information dissemination.

Objective 2: Identify informational needs of schools regarding HIV/AIDS and disseminate information that addresses those needs.

Action Steps: Using existing survey data, identify informational gaps.

Coordinate with the CDC on the School Health Information Planning Program (SHIPP).

Identify public and private agencies and groups that have developed HIV-related materials appropriate for school-based programs.

Catalog and distribute information on these resources.

Establish process to inform schools about resources available to address HIV/AIDS education and prevention.

Provide schools with information on Federal resources.

Prepare publication on the relationship between HIV/AIDS to drug use.

Meet with the National Coordinating Committee and the Interagency Committee on School Health to assist in identifying areas of need and publicizing the availability of resources.

Descriptions: AIDS prevention information dissemination to schools in the context of high risk behaviors arising out of drug and alcohol use.

FY 95: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.
FY 96: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.
FY 97: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.

Populations Served: Elementary and secondary students, teachers and parents through health education curricular, pre-service, and in-service training and parental involvement programs.

Constituency Involvement: The majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

Unmet Need: Many groups are unaware that resources are available to assist them. Increased funding would assist in improved information dissemination.

Agency: Department of Health and Human Services, Agency for Health Care Policy and Research

Goal: To provide national estimates of the cost and use of HIV-related prevention services.

Objective 1: To examine the effects of an in-home computer information and support system on health care costs and quality of life.

Action Steps: Half of three hundred patients with advanced HIV infection are provided with in-home computer system; the other half receive no intervention. Effects of this system are assessed with respect use of prophylactic treatments, early detection of infections, and quality of life.

Descriptions: Demonstrating Computer Support Impact on AIDS Patients

FY 95: $704,655
FY 96: $56,453
FY 97: $0

Populations Served: 300 volunteers with advanced HIV infection.

Constituency Involvement: Persons with HIV

Unmet Need: None.

Objective 2: Evaluate the cost-effectiveness of alternative strategies for preventing HIV-related opportunistic infections.

Action Steps: Embed clinical and cost data from randomized trials and observational cohorts into a comprehensive decision-analytic, cost-effectiveness model.

Descriptions: Cost-Effectiveness of Preventing AIDS Complications.

FY 95: $346,420
FY 96: $21,020
FY 97: $0

Populations Served: Persons with HIV.

Constituency Involvement: N/A

Unmet Need: None.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To more accurately monitor the HIV epidemic and provide data to assess and direct prevention programs by strengthening existing systems and develop new surveillance systems.

Objectives: Implement projects that evaluate and expand the uses of HIV infection and AIDS case surveillance and sero-surveillance data so that these data systems can more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention activities.

Improve understanding of the natural history of HIV infection as well as the risk factors and protective factors for sexual, drug-related, perinatal, and healthcare worker related HIV transmission in order to develop more effective prevention strategies for all affected populations.

Action Steps: Evaluate HIV infection reporting systems (named, anonymous, unique identifier) used nationally for their ability to monitor the epidemic, provide linkages to medical and social services, and to assess their impact on a person's decision to be tested.

Characterize high risk behaviors of persons with evidence of recent HIV infection such as persons with documented HIV seroconversion, high CD4+ counts, or diagnosis of HIV infection in adolescents.

Assess the impact of public health guidelines and recommendations and prevention efforts,

Characterize persons co-infected with TB and HIV.

Evaluate ways to improve the completeness and quality of risk ascertainment on persons reported with HIV and AIDS.

Identify and characterize previously unreported AIDS cases among deaths investigated by local medical examiners to assess the impact of under-diagnosis of AIDS cases on AIDS surveillance among disadvantaged populations that often do not receive adequate health care.

Test the efficiency of new techniques for reporting HIV and AIDS surveillance data from health care providers and laboratories to health departments.

Collect additional data on persons reported through HIV/AIDS surveillance which may be important for the planning and evaluation of prevention and care programs, such as social/economic status, levels of disabilities, drug use history, sex behavior history, utilization of HIV testing and medical care services, and reproductive history in women.

Assess the interrelationship of behaviors, HIV markers and surrogates, and their potential role in surveillance systems.

Assess the interaction of socioeconomic, behavioral, and biologic factors in HIV transmission.

Determine the role of female-specific biological factors that are linked to acquisition and transmission of HIV infection and that influence the course of HIV disease.

Determine factors contributing to the efficiency of sexual transmission of HIV.

Assess the risk of transmission of HIV and TB from HIV-infected health-care worker to patient and vice versa.

Develop systems to monitor the emergence of multidrug-resistant TB in the HIV infected.

Continue to develop improved methods for projecting or modeling the HIV epidemic.

Develop methods to differentiate HIV-specific antibodies generated in participants in HIV vaccine trials from those generated in response to HIV infection.

Develop methods to identify potential cases of HCW-to-patient transmission.

Expand HIV reporting systems to collect information about primary and secondary HIV prevention services needed and received by HIV-positive clients (in collaboration with HRSA).

Work with providers and users of lab services to develop & implement systems which provide assurance that the capacity and quality requirements for HIV testing are met.

Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS.

Develop methods to evaluate the use of HIV infection and AIDS surveillance systems to assess early intervention strategies.

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: $141,046,000
FY 96: $139,668,000
FY 97: $139,778,000

Populations Served: All major racial, ethnic, and risk groups.

Constituency Involvement: There is regular consultation with national, state, and local public health officials and many other relevant organizations such as HIV-related community-based organizations.

Unmet Need: The current system does not provide for adequate surveillance of risk behaviors that contribute to HIV transmission, nor does it provide an accurate means for monitoring HIV incidence.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To increase the public understanding of, involvement in, and support for HIV prevention.

Objectives: Provide leadership in HIV and STD prevention by (1) establishing sustained and active national agenda through the media; (2) promoting credible messages based on science through credible channels; and (3) encouraging and supporting prevention efforts at the local level.

Establish a collaboration of partners composed of national, State, and local organizations to facilitate (1) diffusing social marketing principles applied to HIV and STD prevention at the local level; (2) identifying and promoting mechanisms to exchange technology and information; and (3) developing guidelines for applying social marketing principles to local HIV and STD prevention.

Apply social marketing principles at the local level for the purpose of (1) demonstrating the participatory social marketing process (i.e., skills and resources needed to effectively engage the community); (2) measuring the effects of behavior-based social marketing interventions; and, (3) documenting the lessons learned.

Facilitate the application of prevention marketing principles in CDC-funded community planning efforts by (1) promoting guidelines for consideration of these principles at the local level for prevention interventions and (2) providing interactive technical assistance on social marketing technology principles (or prevention marketing) to public health agencies as well as HIV Prevention Community Planning Groups.

Promote HIV prevention as a relevant issue in business settings.

Provide and promote a network of resources and referrals to assist in implementing the Business Responds to AIDS (BRTA) Comprehensive HIV/AIDS Workplace Program.

Market the comprehensive workplace HIV/AIDS program to business.

Establish and execute a research agenda to formulate and assess strategies and resources to advance the knowledge of effective workplace HIV programs.

Action Steps: Monitor changes in public knowledge about how HIV is and is not transmitted;

Develop methodologies to measure community mobilization or changes in institutional behavior in relation to mass media public information and education programs;

Develop new mass media messages, in collaboration with the public health systems and with international, national, state, and local private sector organizations and agencies;

Expand the relationship between CDC and the entertainment industry to improve messages and role modeling for HIV prevention;

Develop communication interventions with appropriate organizations to ensure that consistent, accurate HIV prevention information is provided to the public;

Develop community coalitions for HIV prevention;

Coordinate and disseminate information messages through the media that explain new scientific findings and policies concurrent with the release of new scientific information;

Develop leadership of health/education officials to effectively deliver HIV prevention messages through partnerships;

Evaluate the role of communications in changing individual knowledge, community norms, and individual behavior through establishment of model programs;

Expand the relationship between CDC and academic experts in mass communications to develop methods for measuring the impact of mass media on individual and community behaviors;

Develop ways of measuring the mobilization of community groups, i.e., changes in community norms, capacity;

Monitor business policies and employee education programs regarding HIV/AIDS;

Implement a BRTA initiative to develop HIV prevention and service programs for the workplace and the community;

Sponsor and participate in national meetings of businesses and religious, civic, medical, social, and voluntary agencies which conduct HIV prevention and service programs.

Descriptions: Many of the activities cited above are carried out at local demonstration sites and in coordination with community planning efforts. In addition, specialized projects and studies also serve to focus attention on these activities, these include projects entitled: National Health Communications, Prevention Collaborative Partners, the CDC National AIDS Clearinghouse, and the CDC National AIDS Hotline, and the Prevention Marketing Initiative.

Also, linkage efforts with business, labor, and community groups have received special attention. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs have focused on

issues such as: HIV/AIDS workplace policies, supervisor and labor leader training, employee education, employee family education, and community service and volunteerism. Partnerships have also been forged among a variety of communities including business, labor, religious, voluntary and the media. And, national and regional minority organizations have also been sought out in forging these important linkages.

FY 95: $45,960,000
FY 96: $45,512,000
FY 97: $45,547,000

Populations Served: All segments of the population including all major racial and ethnic groups, young persons (18-25), persons engaging in behaviors that place them at risk for HIV infection, and business and labor leaders including their employees and families.

Constituency Involvement: Regular consultation with leaders from over 200 prevention collaborative partners composed of national, state, and local organizations and over 50 business and labor partners.

Unmet Need: There is a need for more effective use of social marketing principles in HIV prevention programs, further implementation of strategies to promote adoption of BRTA and LRTA comprehensive programs. There is also an increased need for family education materials, more effective materials to encourage abstinence and other prevention behaviors, and more HIV prevention materials for use by religious communities.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To prevent risk behaviors that can cause HIV infection and related health problems in school age children and college age youth through implementation of comprehensive school health education programs.

Objectives: Increase by 15 percent the proportion of school districts that require age-appropriate HIV education at each grade level, K-12, especially at grades 9-12, preferably as part of comprehensive school health education.

Increase by 15 percent the proportion of colleges and universities that provide HIV education for students and staff, preferably as part of an institution-wide health promotion program.

Decrease by 10 percent at each grade level the proportion of 9th to 12th grade students who report they have engaged in sexual intercourse.

Among 9th to 12th grade students who report they have engaged in sexual intercourse, decrease by 10 percent the proportion who report they have engaged in sexual intercourse during the past 3 months.

Among 9th to 12th grade students who report they have engaged in sexual intercourse during the past 3 months, increase by 10 percent the proportion who report they used a condom at last intercourse.

Decrease by 10 percent the proportion of 9th to 12th grade students who report they have injected illicit drugs.

Action Steps: Monitor state-level policy and program requirements that support effective HIV education within comprehensive school health education (CSHEs);

Monitor district-level policy and program requirements that support effective HIV education within comprehensive school health education programs;

Monitor the prevalence of behaviors that cause HIV infection and related health problems among school and college youth;

Implement and revise as necessary, CDC guidelines for effective school health education to prevent the spread of HIV infection;

Enhance the capacity of state and local educational agencies to develop and implement effective HIV education within CSHEs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an

institution-wide health promotion program;

Ensure the integration of education to prevent HIV infection, other STDs and the use of alcohol and other drugs among youth;

Strengthen the capabilities of state and local departments of education and health to collaboratively help schools, colleges and universities implement effective HIV education programs for youth;

Increase the effectiveness of HIV education for youth served by state and local departments of education and colleges and universities through the efforts of selected national organizations;

Enhance the capacity of state and local agencies to help prevent HIV infection and HIV-related problems among youth through the efforts of training and demonstration centers established for state and local departments of education;

Establish teacher training coordinators in every interested state to help teachers provide effective HIV education within a CSHE;

Identify and disseminate, through training and demonstration centers and through teacher training directors, HIV education programs that have been shown to the be effective in reducing behaviors that cause HIV infection and related health problems;

Synthesize and apply the results of research to increase the effectiveness of HIV prevention education for youth;

Conduct formative evaluations of state and local departments of education policies, curricula, teacher training, and school efforts to prevent behaviors that cause HIV infection and related health problems;

Develop a standardized report for each state to profile the nature of priority health problems and risk behaviors among youth in that state and school efforts to prevent these problems and behaviors;

Conduct evaluations of the effectiveness of existing school-based interventions to reduce behaviors that result in HIV infection and related health problems;

Develop state-of-the-art school-based interventions and evaluate their effectiveness in reducing behaviors that result in HIV and related health problems; and

Conduct and apply meta-evaluations of existing research data about the effectiveness of school-based interventions in reducing health risks behaviors among adolescents.

Descriptions: Funding and technical assistance for state and

local educational agencies is provided through several avenues including national non-governmental organizations, colleges and universities, and teacher training sites. There is also support for youth surveys and projects to reach out-of-school youth.

FY 95: $48,205,000
FY 96: $47,735,000
FY 97: $47,771,000

Populations Served: Young persons engaging in behaviors that place them at risk for acquiring HIV through sexual exposure, including all major racial and ethnic groups. All school- and college-aged youth regardless of school enrollment status.

Constituency Involvement: Consultation with a wide range of constituency groups was established to: (1) improve existing programmatic efforts; (2) improve assistance and resources provided by CDC; and, (3) explore strategies that the Nation might take to improve the health status of young people. These groups include representatives from: (1) every state education agency, District of Columbia, and six territorial education agencies; (2) national nongovernmental health or education organizations, 3) colleges and universities, 4) state public health departments, as well as young people themselves. Meetings included an annual constituency meeting, quarterly training programs, and communication through an electronic bulletin board and network.

Unmet Need: Not all youth are accessible through existing institutional-based efforts, and currently not all states monitor youth health-risk behaviors.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To prevent or reduce behaviors or practices which place individuals at risk of HIV infection, and for HIV positive individuals, place others at risk.

Objectives: At least 90 percent of individuals with known HIV infection will be abstinent or will have used a condom at last sexual intercourse, and at least 50 percent of individuals who have engaged in high-risk sexual behaviors within the past 12 months will be abstinent, in a mutually monogamous relationship, or have used a condom at last sexual intercourse.

At least 75 percent of injecting drug users will have stopped injecting drugs or used sterile or decontaminated injection equipment at last injection.

At least 80 percent of the health care and public safety workplaces will implement programs and procedures for preventing HIV transmission at work sites.

Reduce unintended pregnancies to no more than 40 percent of pregnancies among women with or at risk for HIV infection.

The number of individuals donating blood and found to be infected with HIV at the time of donation will decrease by 50 percent through self-deferral.

Among selected populations of youth in high-risk situations, increase by 10 percent the proportion who report they used a condom at last sexual intercourse.

Action Steps: Collaborate with prevention partners to assess risk behaviors and practices in selected communities;

Identify barriers to implementation of HIV prevention programs at community, state, and national levels;

Collaborate with selected communities in developing and implementing a model behavioral intervention program that comprehensively addresses community needs and uses available community resources and prevention partners in selected sites;

Design, develop, and test effective community-level interventions to change risk behaviors through altering community norms and values to support healthy behaviors;

Expand the community's capacity to plan, implement, and evaluate culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

Enhance the capacity of CDC staff to plan, administer, and

evaluate behavioral change strategies and community-based interventions to provide public health leadership and assist our prevention partners in designing and managing effective strategies for HIV prevention programs;

Enhance the capacity of local health departments and other relevant community agencies to collaboratively provide effective HIV education for youth in high-risk situations;

Establish scientifically-based evaluation components for HIV prevention activities; and

Use evaluation of components to design or refine HIV prevention programs and/or redirect HIV prevention resources.

Descriptions: Several mechanisms are employed for achieving the goals and objectives cited above. These include cooperative agreements with state and local health departments, in addition to direct funding of community-based organizations, national organizations, and national minority organizations. HIV intervention research studies are also supported.

FY 95: $185,625,000
FY 96: $183,814,000
FY 97: $203,958,000

Populations Served: All major racial and ethnic groups in addition to persons engaging in behaviors that place them at risk for acquiring HIV.

Constituency Involvement: A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

Unmet Need: There is currently a lack of behavioral risk surveillance data for program planning and evaluation purposes. There is also a need to develop a more effective application of behavioral science findings to HIV prevention programs. And there is a special need to develop and maintain prevention efforts that target high risk women, youth and gay men of color.

Agency: The Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To increase individual knowledge of serostatus and strengthen systems for successful referral to early intervention services.

Objectives: At least 85 percent of the estimated 800,000 to 1,000,000 HIV-infected individuals will know their HIV serostatus.

At least 90 percent of health care sites receiving public funds and serving at-risk persons will provide appropriate HIV counseling and testing services.

At least 80 percent of known HIV infected individuals, either directly or through referral, will receive primary and secondary prevention services.

Action Steps: Working with governmental and nongovernmental partners, enhance community-level assessments of needed primary and secondary prevention services;

Identify opportunities for common HIV prevention data collection and development of uniform data sets;

Integrate HIV prevention services into standards of care for the diagnosis and treatment of HIV disease;

In collaboration with the FDA, develop, test, and implement rapid HIV testing procedures;

Strengthen the capacity of state, and local health departments to provide partner notification services to private health care providers offering HIV counseling & testing;

Develop alternative methods to provide HIV counseling and testing services;

Work with professional groups, hospitals, and state health departments to ensure that health care workers receive adequate training on primary and secondary HIV prevention (in collaboration with HRSA);

Study the impact of discrimination as a barrier to prevention services;

Assist publicly funded counseling and testing sites establish selection criteria and systems for monitoring the quality of referral laboratories;

Interview persons newly diagnosed with HIV infection to identify missed opportunities for earlier diagnosis and CD4+ testing;

Conduct a study of incident AIDS cases to determine what services HIV-positive clients are receiving over time to identify service gaps (in collaboration with HRSA); and

Provide guidelines and training to HIV counselors to improve the quality of counseling.

Descriptions: Counseling, testing, referral partner notification programs are supported as part of cooperative agreements with state and local health departments.

FY 95: $168,995,000
FY 96: $167,351,000
FY 97: $181,027,000

Populations Served: All major racial and ethnic groups and persons engaging in behaviors that place them at risk for acquiring HIV.

Constituency Involvement: A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

Unmet Needs: There is a need for more effective long-term intervention programs for HIV positive individuals in addition to a lack of resources for supporting comprehensive referral and data monitoring systems. Also, there is a need to determine the best balance between CTRPN programs and other HIV prevention strategies.

Agency: Department of Health and Human Services, Food and Drug Administration

Goal: To reduce transfusion-transmitted HIV infection.

Objective: Ensure supply and safety of the national blood supply.

Action Steps: Establish policies, expedite review of product applications, conduct approval inspections, oversee surveillance, and support enforcement activities.

Descriptions: Encourage high risk donors to exclude themselves; update list of unsuitable donors; quarantine and test blood; investigate incidents to identify, and rectify common errors in blood banks.

FY 95: $17,458,000
FY 96: $17,458,000
FY 97: $17,458,000

Populations Served: All persons who may receive blood or blood products.

Constituency Involvement: The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

Unmet Need: With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

Agency: Department of Health and Human Services, Health Care Financing Administration

Goal: To reduce perinatal transmission among Medicaid-eligible women.

Objectives: Develop and implement a campaign to inform HIV positive women in selected pilot areas about the benefits of AZT in FY 95.

Expand pilot project to one State in all regions in FY 96.

Expand project to include all States in FY 97.

Action Steps: Develop, obtain, and distribute brochures and other materials describing current guidelines for the use of AZT during pregnancy for preventing perinatal transmission, and Medicaid eligibility and coverage to Medicaid eligible women.

Descriptions: Establish a consumer-oriented educational campaign in key states with high HIV prevalence rates among women.

FY 95: $50,000 (Federal share)
FY 96: $60,000 (Federal share)
FY 97: $185,000 (Federal share, subject to availability of funds)

Populations Served: HIV positive women eligible for Medicaid coverage.

Constituency Involvement: Significant consultation with high-risk pregnant women and their advocates.

Unmet Need: The pilot project will not initially include women of unknown or negative HIV serostatus.

Agency: Department of Health and Human Services, Health Resources and Services Administration

Goal: To reduce the perinatal transmission of HIV.

Objective: Enhance provider capacity to provide appropriate services for women at the community level.

Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women.

Enhance providers' abilities to provide AZT for HIV positive pregnant women.

Ensure funding and dissemination of innovative models of care that evaluate all of the major care and service goals listed in this plan: effectively educated providers, increased access to and quality of care, reduction of perinatal transmission of HIV.

Action Steps: Establish the Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission (WIN);

Establish ongoing WIN Steering Committee;

Provide technical assistance to grantees;

Conduct centralized training for all WIN sites with follow-up local training;

Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop local guidelines;

Establish MCHB working group to coordinate HIV risk reduction related efforts across programs;

Distribute counseling and testing guidance, AHCPR consumer brochure and video, and other PHS documents to MCHB community;

Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs); and

Evaluate sites.

Descriptions: Enhance outreach for HIV counseling and testing.

Improve service linkages for women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission.

PHS 076 Implementation Plan.

FY 95: $1,520,000
FY 96: $1,800,000
FY 97: $1,890,000

Populations Served: CARE Act grantees. Adolescent and adult women and their infants, with special attention for pregnant women in addition to MCH and HIV providers.

Constituency Involvement: Health care providers, evaluation researchers, communication experts, and patient advocates. There is also consumer participation in WIN steering committee and projects advisory boards in addition to linkages with other HRSA grantees including those from RWCA and SPNS programs.

Unmet Need: Funds needed to provide more services in order to reach more women and enhance evaluation efforts and improve technical assistance and training.

In particular, it is critical to fund services (e.g., outreach, case finding, case management) that better link women of childbearing age with counseling and testing services and, after testing, with comprehensive medical, social, and support services and long-term followup for themselves and their families. Training non-HIV providers, particularly primary care, family practice, ob/gyn, and MCH providers, to perform women-sensitive counseling and testing, to deliver appropriate primary care for women with HIV, and to provide appropriate referrals for these women is another critical need. Funding is also needed for peer-support programs for these women and their families. While it should be our assumption that all women are at risk for HIV, it is important to recognize that certain groups of women (e.g., substance abusers, partners of substance abusers) are at special risk and need additional services in order to enter and remain in care.

Agency: Department of Health and Human Services, Indian Health Service

Goal: To reduce the number of new infections among federally recognized American Indians and Alaska Natives.

Objective 1: Maintain surveillance of HIV infection in American Indians and Alaska Natives.

Action Steps: Maintain timely and complete case reporting to appropriate local, state and national entities and the Indian Health Service (IHS) AIDS Prevention Activities Office.

Descriptions: Area AIDS Coordinators will be responsible for reporting.

FY 95: $ 912,000
FY 96: $ 912,000
FY 97: $1,800,000

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of prevention activities.

Objective 2: Maintain training and information activities to provide health education and risk reduction messages.

Action Steps: Teach empowerment skills at the individual and community level that will enhance the individual's ability to actualize assimilated knowledge as behavior change.

Descriptions: HIV health education and risk reduction message dissemination.

FY 95: Part of overall IHS budget.
FY 96: Part of overall IHS budget.
FY 97: Part of overall IHS budget.

Populations Served: American Indians and Alaska Natives population, tribal leaders, women, youth, individuals practicing high risk behavior, and IHS/tribal health care workers.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of prevention activities.

Agency: Department of Health and Human Services, National Institutes of Health

Goal: To conduct and support behavioral and social science research to further understanding of the determinants and processes that influence behaviors associated with HIV transmission and to develop and improve HIV prevention intervention strategies, and, to conduct and support natural history and epidemiological research to improve the understanding of the risk factors and mechanisms of HIV transmission and disease progression and to develop prevention strategies to reduce or prevent HIV transmission.

NIH's efforts in these areas can be found in Appendix B: Research.

Agency: Department of Health and Human Services, Office of Population Affairs

Goal: To reduce the number of new HIV infections.

Objective: Provide counseling, education, and HIV testing as needed to Title X program clinics.

Action Steps: Include HIV/AIDS education in all clinic education programs.

Include HIV/AIDS prevention in STD screening programs.

Provide HIV testing or referral for testing to all Title X clients who request testing.

Descriptions: Title X Program

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.
FY 97: NA -- HIV services integrated into overall budget.

Populations Served: The Title X program provides family planning and related reproductive health services to approximately 4.5 million clients annually through a network of 4,500 clinics. Clients are predominantly young women; most are members of low-income families, and 30 percent are adolescents and 33 percent are below age 25.

Constituency Involvement: For non-profit grantees, clients participate on boards of directors. For all grantees, clients participate on committees approving all information and education materials.

Unmet Need: The Title X program reaches an estimated 50 percent of potential clients. Expansion of program would provide a concomitant expansion in HIV/AIDS prevention activities, since these are provided as an integral part of the reproductive health services in Title X programs.

Agency: Department of Health and Human Services, Substance Abuse and Mental Health Services Administration

Goal: To reduce the number of new HIV infections.

Objective: Demonstrate the effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance abuse prevention programs.

Demonstrate the differential effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance prevention programs.

Action Steps: Supplementation of high risk youth grants for alcohol, tobacco and other drugs (ATOD) prevention for the purpose of including HIV/AIDS prevention strategies in their present activities.

Develop program to empower youth with skills, knowledge, and beliefs for HIV prevention.

Demonstrate effective strategies to prevent ATOD use and abuse among high risk youth.

Include developmentally and culturally appropriate HIV/AIDS education and prevention approaches.

Descriptions: High Risk Youth Program.

FY 95: $292,000
FY 96: $0
FY 97: $0*

* In addition, SAMHSA's Knowledge Development Application (KDA) Program includes an AIDS initiative in FY 1997. This initiative includes various approaches, including how best to: educate service providers, address family issues, interrupt HIV transmission, and maximize client retention in substance abuse treatment. The FY 1997 estimate for HIV/AIDS in the President's Budget is $15,000,000.

Populations Served: High risk youth or youth at risk for ATOD, adolescent females, and youth at risk for AOD-related violent behavior.

Constituency Involvement: Families of youth, youth service workers, and the communities that support youth at risk for ATOD abuse.

Unmet Need: Presently this initiative reaches only 25 percent of high risk youth grantees. Supplementing all grantees would provide greater opportunity for services integration and evaluation.

Agency: Department of Housing and Urban Development

Goal: To reduce the number of new infections among residents of public and subsidized housing.

Objective: Provide primary prevention programs to public housing residents at risk for HIV infection. Coordinate meetings of the state and local agencies responsible for the prevention program services.

Action Steps: Forge local partnerships and improve coordination of existing resources.

Descriptions: HIV/AIDS Prevention in Public Housing Demonstration Program.

FY 95: $0 (Activities carried out within existing HUD personnel resources.)
FY 96: $0 (Activities carried out within existing HUD personnel resources.)
FY 97: $0 (Activities carried out within existing HUD personnel resources.)

Populations Served: Children and adults in public housing in five targeted cities.

Constituency Involvement: Input received through local planning groups.

Unmet Need: The initial demonstration program reached sites in five cities. An increase in resources would enable HUD to meet increasing demand for services and permit expansion to include other public and subsidized housing efforts.

Agency: Department of Justice

Goal: To reduce risk of infection of infection to INS detainees who are at risk.

Objective: Educate detainees believed to be at risk regarding HIV/AIDS and thereby reduce the risk of transmission and new infections.

Action Steps: Upon obtaining informed consent, test detainees suspected of or diagnosed with HIV/AIDS or test upon detainee request and provide pre- and post-test counseling to detainees deemed at risk.

Descriptions: Provide limited testing and counseling.

FY 95: Part of overall operating budget.
FY 96: Part of overall operating budget.
FY 97: Part of overall operating budget.

Populations Served: INS Detainees.

Constituent Involvement: None.

Unmet Need: None.

Agency: Department of Justice

Goal: To reduce the risk of employee infection and avoid possible worksite performance problems.

Objective: Educate Bureau of Prisons (BOP) staff, Drug Enforcement Agency (DEA) employees, Federal Bureau of Investigation (FBI) employees, Immigration and Naturalization Service (INS) employees, and U.S. Marshals Service (USMS) regarding HIV/AIDS transmission and thereby reduce the risk of infection. Educate all Justice Department employees about HIV/AIDS in the workplace.

Action Steps: For Bureau of Prison (BOP) staff provide: annual HIV information update and infectious disease training to all staff; produce inmate and staff HIV educational videos; and participate at least quarterly with HRSA in audio conferences on HIV issues.

For DOJ employees in occupations that possess a heightened possibility for exposure to HIV or other bloodborne pathogens, including employees of the DEA, FBI, INS, and USMS provide: general training and field office training; annual bloodborne pathogen training to all personnel as mandated by OSHA (discussion of HIV/AIDS is included in this training); and an annual update on the bloodborne pathogens training as necessary to discuss new information or changes in the use of safety equipment, etc.

For all Department employees, the Justice Management Division (JMD) provides: instructional materials to be used in a one time general training; and technical assistance to other DOJ components.

Descriptions: DOJ staff prevention training programs.

FY 95: Part of overall operating budget.
FY 96: Part of overall operating budget.
FY 97: Part of overall operating budget.

Populations Served: DOJ employees.

Constituency Involvement: None.

Unmet Need: Additional resources for field office training for USMS and FBI.

Agency: Department of Veterans Affairs

Goal: To prevent transmission of HIV infection through education of employees and patients.

Objective 1: Train and maintain cadre of professional staff to conduct HIV transmission and prevention education for patients and conduct pre- and post-test HIV antibody test counseling.

Action Steps: Establish national training program to educate two professional staff from every VA medical center to conduct patient education and pre- and post-test counseling.

Maintain on-going training program on limited basis to address turnover of staff and maintain cadre of counselors/patient educators.

Objective 2: Educate and maintain cadre of knowledgeable staff to teach all staff in VA health-care facilities on prevention and transmission of HIV infection.

Action Steps: Develop a national "train the trainer" education program to educate selected staff from every VA Medical Center on how to organize and conduct staff educational activities on HIV transmission and prevention.

Update training materials/revise strategies to maintain knowledgeable base of trainers for every facility.

Objective 3: Integrate HIV prevention education in addiction treatment programs.

Action Steps: Conduct national training program for professional staff in addiction treatment programs and Vet Centers on how to integrate HIV prevention education for patients in their treatment areas.

Objective 4: Stimulate innovative approaches to HIV/AIDS education at the local level (VA Medical Centers and communities).

Action Steps: Award educational demonstration grants to HIV/AIDS education proposals on competitive basis.

Facilitate system-wide dissemination of completed projects through annual publication and national quarterly newsletters.

Objective 5: Maintain education and information support systems.

Action Steps: Continue AIDS awareness and education programs through national system of regional education centers and individual facility programs.

Through library system, continue purchase of appropriate private and Federal sector videos, publications, posters, and other materials.

Objective 6: Prevent transmission of HIV in health-care setting.

Action Steps: Ensure on-going implementation of CDC recommendations on universal precautions, via policy.

Ensure continuing implementation of OSHA rule on protection of health-care workers against bloodborne pathogens via policy.

Provide national training program on interdisciplinary team training for staff from infection control, employee health, safety in all VAMCs to implement OSHA rule.

Descriptions: Prevention activities including education and universal precautions.

FY 95: $31,000,000 *
FY 96: $31,000,000 *
FY 97: $31,000,000 *

* Figures are based on the estimated resource expenditures for universal precautions and education and are part of the general Medical Care Budget. FY 1996 and FY 1997 estimates are based on the resource levels contained in the President's budget.

Populations Served: Eligible veterans through local medical centers and facilities, local VA health-care and support staff, veteran patients and families, general public.

Constituency Involvement: VA medical centers and health-care facilities, and local communities.

Unmet Need: Advances in treatment through research and/or changes in prevention activities may require re-assessment of funding levels.

Agency: Corporation for National Service

Goal: To offer HIV/AIDS education programs and other services with volunteers from the Learn and Serve America project.

Objective: Support HIV-related Learn and Serve America projects.

Action Steps: Continue programs for youth in elementary school or high school to volunteer in community service activities, such as peer education in HIV/AIDS prevention.

Continue to award higher education grants directly to colleges and universities which provide service opportunities on HIV/AIDS prevention.

Program Description: Examples of higher education programs include Robert Wood Johnson Medical School and the University of San Diego where students provide education on HIV/AIDS to homeless and other high risk populations.

FY 95: Part of overall operating cost.
FY 96: Part of overall operating cost.
FY 97: Part of overall operating cost.

Populations Served: Persons living with HIV and AIDS and others who could benefit from HIV/AIDS education.

Constituency Involved: The Learn and Serve America program and students across the country.

Unmet Needs: Without these programs, students would not have an opportunity to serve their communities in HIV/AIDS related projects.

Agency: Department of Defense

Goal: Preservation of an effective fighting force through prevention of HIV infection.

Objective 1: Prevent HIV infection in service members.

Reduce the number of new active duty HIV infection by 20 percent by 1997 based on a 1995 baseline figure of 204 persons for all services.

Action Steps: Provide basic information on HIV transmission and risk reduction for new recruits, civilian work force members, and officers;

Require education and general military training on methods of transmission and approaches for avoiding transmission, including barrier methods, avoidance of intravenous drug use, and use of universal precautions;

Provide training for personnel, instructors, and peer educators; and

Support train the trainer courses to develop multidisciplinary teams from medical, dental, nursing, and public health corps for promoting HIV and AIDS education.

Objective 2: Ensure safety of the Armed Services Blood Program Office (ASBPO).

Action Steps: Advise service personnel with serologic evidence of HIV infection or repeated ELISA reactivity, but Western Blot negative or indeterminate, to refrain from donating blood.

Employ ASBPO "Look Back Program" to trace contacts of identified positive donors who serconvert after blood donation -- trace and contact blood recipients.

FY 95: Approximately $500,000
FY 96: Approximately $500,000
FY 97: Approximately $500,000

Populations Served: Active duty service members and their eligible family members, health care providers and those at risk of exposure to body fluids, and recipients of ASBPO blood products.

Constituency Involvement: Active duty force, affiliated civilian workforce, and the health care and public health communities.

Unmet Need: None

Agency: Department of Education

Goal: To disseminate information on Department of Education (ED) Programs in coordination with other Federal agencies.

Objective 1: Coordinate with DHHS to provide information and points of contact for existing ED programs.

Action Steps: Coordinate and share information with CDC-sponsored National AIDS Clearinghouse; include information related to school-based comprehensive health programs (ED funded) in the Comprehensive Health Information Database (HHS).

Descriptions: A broad range of programs are supported; for example, including the Foundation For Children With AIDS, Duke University Medical Center, and University of California Disability Statistics Rehabilitation Research and Training Center.

FY 95: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program.

FY 96: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program.

FY 97: Funding for AIDS prevention initiatives is part of the overall grant budget through the comprehensive school health program.

Populations Served: Elementary and secondary students, teachers and parents through health education curricular, pre-service, and in-service training and parental involvement programs.

Constituency Involvement: The majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

Unmet Need: Many groups are unaware that resources are available to assist them. Increased funding would assist in improved information dissemination.

Objective 2: Identify informational needs of schools regarding HIV/AIDS and disseminate information that addresses those needs.

Action Steps: Using existing survey data, identify informational gaps.

Coordinate with the CDC on the School Health Information Planning Program (SHIPP).

Identify public and private agencies and groups that have developed HIV-related materials appropriate for school-based programs.

Catalog and distribute information on these resources.

Establish process to inform schools about resources available to address HIV/AIDS education and prevention.

Provide schools with information on Federal resources.

Prepare publication on the relationship between HIV/AIDS to drug use.

Meet with the National Coordinating Committee and the Interagency Committee on School Health to assist in identifying areas of need and publicizing the availability of resources.

Descriptions: AIDS prevention information dissemination to schools in the context of high risk behaviors arising out of drug and alcohol use.

FY 95: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.
FY 96: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.
FY 97: Funding for initiatives part of overall program plan for Safe and Drug-Free Schools National Programs.

Populations Served: Elementary and secondary students, teachers and parents through health education curricular, pre-service, and in-service training and parental involvement programs.

Constituency Involvement: The majority of ED programs are developed at local level and therefore there is little involvement of constituency groups at the Federal level.

Unmet Need: Many groups are unaware that resources are available to assist them. Increased funding would assist in improved information dissemination.

Agency: Department of Health and Human Services, Agency for Health Care Policy and Research

Goal: To provide national estimates of the cost and use of HIV-related prevention services.

Objective 1: To examine the effects of an in-home computer information and support system on health care costs and quality of life.

Action Steps: Half of three hundred patients with advanced HIV infection are provided with in-home computer system; the other half receive no intervention. Effects of this system are assessed with respect use of prophylactic treatments, early detection of infections, and quality of life.

Descriptions: Demonstrating Computer Support Impact on AIDS Patients

FY 95: $704,655
FY 96: $56,453
FY 97: $0

Populations Served: 300 volunteers with advanced HIV infection.

Constituency Involvement: Persons with HIV

Unmet Need: None.

Objective 2: Evaluate the cost-effectiveness of alternative strategies for preventing HIV-related opportunistic infections.

Action Steps: Embed clinical and cost data from randomized trials and observational cohorts into a comprehensive decision-analytic, cost-effectiveness model.

Descriptions: Cost-Effectiveness of Preventing AIDS Complications.

FY 95: $346,420
FY 96: $21,020
FY 97: $0

Populations Served: Persons with HIV.

Constituency Involvement: N/A

Unmet Need: None.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To more accurately monitor the HIV epidemic and provide data to assess and direct prevention programs by strengthening existing systems and develop new surveillance systems.

Objectives: Implement projects that evaluate and expand the uses of HIV infection and AIDS case surveillance and sero-surveillance data so that these data systems can more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention activities.

Improve understanding of the natural history of HIV infection as well as the risk factors and protective factors for sexual, drug-related, perinatal, and healthcare worker related HIV transmission in order to develop more effective prevention strategies for all affected populations.

Action Steps: Evaluate HIV infection reporting systems (named, anonymous, unique identifier) used nationally for their ability to monitor the epidemic, provide linkages to medical and social services, and to assess their impact on a person's decision to be tested.

Characterize high risk behaviors of persons with evidence of recent HIV infection such as persons with documented HIV seroconversion, high CD4+ counts, or diagnosis of HIV infection in adolescents.

Assess the impact of public health guidelines and recommendations and prevention efforts,

Characterize persons co-infected with TB and HIV.

Evaluate ways to improve the completeness and quality of risk ascertainment on persons reported with HIV and AIDS.

Identify and characterize previously unreported AIDS cases among deaths investigated by local medical examiners to assess the impact of under-diagnosis of AIDS cases on AIDS surveillance among disadvantaged populations that often do not receive adequate health care.

Test the efficiency of new techniques for reporting HIV and AIDS surveillance data from health care providers and laboratories to health departments.

Collect additional data on persons reported through HIV/AIDS surveillance which may be important for the planning and evaluation of prevention and care programs, such as social/economic status, levels of disabilities, drug use history, sex behavior history, utilization of HIV testing and medical care services, and reproductive history in women.

Assess the interrelationship of behaviors, HIV markers and surrogates, and their potential role in surveillance systems.

Assess the interaction of socioeconomic, behavioral, and biologic factors in HIV transmission.

Determine the role of female-specific biological factors that are linked to acquisition and transmission of HIV infection and that influence the course of HIV disease.

Determine factors contributing to the efficiency of sexual transmission of HIV.

Assess the risk of transmission of HIV and TB from HIV-infected health-care worker to patient and vice versa.

Develop systems to monitor the emergence of multidrug-resistant TB in the HIV infected.

Continue to develop improved methods for projecting or modeling the HIV epidemic.

Develop methods to differentiate HIV-specific antibodies generated in participants in HIV vaccine trials from those generated in response to HIV infection.

Develop methods to identify potential cases of HCW-to-patient transmission.

Expand HIV reporting systems to collect information about primary and secondary HIV prevention services needed and received by HIV-positive clients (in collaboration with HRSA).

Work with providers and users of lab services to develop & implement systems which provide assurance that the capacity and quality requirements for HIV testing are met.

Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS.

Develop methods to evaluate the use of HIV infection and AIDS surveillance systems to assess early intervention strategies.

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: $141,046,000
FY 96: $139,668,000
FY 97: $139,778,000

Populations Served: All major racial, ethnic, and risk groups.

Constituency Involvement: There is regular consultation with national, state, and local public health officials and many other relevant organizations such as HIV-related community-based organizations.

Unmet Need: The current system does not provide for adequate surveillance of risk behaviors that contribute to HIV transmission, nor does it provide an accurate means for monitoring HIV incidence.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To increase the public understanding of, involvement in, and support for HIV prevention.

Objectives: Provide leadership in HIV and STD prevention by (1) establishing sustained and active national agenda through the media; (2) promoting credible messages based on science through credible channels; and (3) encouraging and supporting prevention efforts at the local level.

Establish a collaboration of partners composed of national, State, and local organizations to facilitate (1) diffusing social marketing principles applied to HIV and STD prevention at the local level; (2) identifying and promoting mechanisms to exchange technology and information; and (3) developing guidelines for applying social marketing principles to local HIV and STD prevention.

Apply social marketing principles at the local level for the purpose of (1) demonstrating the participatory social marketing process (i.e., skills and resources needed to effectively engage the community); (2) measuring the effects of behavior-based social marketing interventions; and, (3) documenting the lessons learned.

Facilitate the application of prevention marketing principles in CDC-funded community planning efforts by (1) promoting guidelines for consideration of these principles at the local level for prevention interventions and (2) providing interactive technical assistance on social marketing technology principles (or prevention marketing) to public health agencies as well as HIV Prevention Community Planning Groups.

Promote HIV prevention as a relevant issue in business settings.

Provide and promote a network of resources and referrals to assist in implementing the Business Responds to AIDS (BRTA) Comprehensive HIV/AIDS Workplace Program.

Market the comprehensive workplace HIV/AIDS program to business.

Establish and execute a research agenda to formulate and assess strategies and resources to advance the knowledge of effective workplace HIV programs.

Action Steps: Monitor changes in public knowledge about how HIV is and is not transmitted;

Develop methodologies to measure community mobilization or changes in institutional behavior in relation to mass media public information and education programs;

Develop new mass media messages, in collaboration with the public health systems and with international, national, state, and local private sector organizations and agencies;

Expand the relationship between CDC and the entertainment industry to improve messages and role modeling for HIV prevention;

Develop communication interventions with appropriate organizations to ensure that consistent, accurate HIV prevention information is provided to the public;

Develop community coalitions for HIV prevention;

Coordinate and disseminate information messages through the media that explain new scientific findings and policies concurrent with the release of new scientific information;

Develop leadership of health/education officials to effectively deliver HIV prevention messages through partnerships;

Evaluate the role of communications in changing individual knowledge, community norms, and individual behavior through establishment of model programs;

Expand the relationship between CDC and academic experts in mass communications to develop methods for measuring the impact of mass media on individual and community behaviors;

Develop ways of measuring the mobilization of community groups, i.e., changes in community norms, capacity;

Monitor business policies and employee education programs regarding HIV/AIDS;

Implement a BRTA initiative to develop HIV prevention and service programs for the workplace and the community;

Sponsor and participate in national meetings of businesses and religious, civic, medical, social, and voluntary agencies which conduct HIV prevention and service programs.

Descriptions: Many of the activities cited above are carried out at local demonstration sites and in coordination with community planning efforts. In addition, specialized projects and studies also serve to focus attention on these activities, these include projects entitled: National Health Communications, Prevention Collaborative Partners, the CDC National AIDS Clearinghouse, and the CDC National AIDS Hotline, and the Prevention Marketing Initiative.

Also, linkage efforts with business, labor, and community groups have received special attention. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs have focused on

issues such as: HIV/AIDS workplace policies, supervisor and labor leader training, employee education, employee family education, and community service and volunteerism. Partnerships have also been forged among a variety of communities including business, labor, religious, voluntary and the media. And, national and regional minority organizations have also been sought out in forging these important linkages.

FY 95: $45,960,000
FY 96: $45,512,000
FY 97: $45,547,000

Populations Served: All segments of the population including all major racial and ethnic groups, young persons (18-25), persons engaging in behaviors that place them at risk for HIV infection, and business and labor leaders including their employees and families.

Constituency Involvement: Regular consultation with leaders from over 200 prevention collaborative partners composed of national, state, and local organizations and over 50 business and labor partners.

Unmet Need: There is a need for more effective use of social marketing principles in HIV prevention programs, further implementation of strategies to promote adoption of BRTA and LRTA comprehensive programs. There is also an increased need for family education materials, more effective materials to encourage abstinence and other prevention behaviors, and more HIV prevention materials for use by religious communities.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To prevent risk behaviors that can cause HIV infection and related health problems in school age children and college age youth through implementation of comprehensive school health education programs.

Objectives: Increase by 15 percent the proportion of school districts that require age-appropriate HIV education at each grade level, K-12, especially at grades 9-12, preferably as part of comprehensive school health education.

Increase by 15 percent the proportion of colleges and universities that provide HIV education for students and staff, preferably as part of an institution-wide health promotion program.

Decrease by 10 percent at each grade level the proportion of 9th to 12th grade students who report they have engaged in sexual intercourse.

Among 9th to 12th grade students who report they have engaged in sexual intercourse, decrease by 10 percent the proportion who report they have engaged in sexual intercourse during the past 3 months.

Among 9th to 12th grade students who report they have engaged in sexual intercourse during the past 3 months, increase by 10 percent the proportion who report they used a condom at last intercourse.

Decrease by 10 percent the proportion of 9th to 12th grade students who report they have injected illicit drugs.

Action Steps: Monitor state-level policy and program requirements that support effective HIV education within comprehensive school health education (CSHEs);

Monitor district-level policy and program requirements that support effective HIV education within comprehensive school health education programs;

Monitor the prevalence of behaviors that cause HIV infection and related health problems among school and college youth;

Implement and revise as necessary, CDC guidelines for effective school health education to prevent the spread of HIV infection;

Enhance the capacity of state and local educational agencies to develop and implement effective HIV education within CSHEs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an

institution-wide health promotion program;

Ensure the integration of education to prevent HIV infection, other STDs and the use of alcohol and other drugs among youth;

Strengthen the capabilities of state and local departments of education and health to collaboratively help schools, colleges and universities implement effective HIV education programs for youth;

Increase the effectiveness of HIV education for youth served by state and local departments of education and colleges and universities through the efforts of selected national organizations;

Enhance the capacity of state and local agencies to help prevent HIV infection and HIV-related problems among youth through the efforts of training and demonstration centers established for state and local departments of education;

Establish teacher training coordinators in every interested state to help teachers provide effective HIV education within a CSHE;

Identify and disseminate, through training and demonstration centers and through teacher training directors, HIV education programs that have been shown to the be effective in reducing behaviors that cause HIV infection and related health problems;

Synthesize and apply the results of research to increase the effectiveness of HIV prevention education for youth;

Conduct formative evaluations of state and local departments of education policies, curricula, teacher training, and school efforts to prevent behaviors that cause HIV infection and related health problems;

Develop a standardized report for each state to profile the nature of priority health problems and risk behaviors among youth in that state and school efforts to prevent these problems and behaviors;

Conduct evaluations of the effectiveness of existing school-based interventions to reduce behaviors that result in HIV infection and related health problems;

Develop state-of-the-art school-based interventions and evaluate their effectiveness in reducing behaviors that result in HIV and related health problems; and

Conduct and apply meta-evaluations of existing research data about the effectiveness of school-based interventions in reducing health risks behaviors among adolescents.

Descriptions: Funding and technical assistance for state and

local educational agencies is provided through several avenues including national non-governmental organizations, colleges and universities, and teacher training sites. There is also support for youth surveys and projects to reach out-of-school youth.

FY 95: $48,205,000
FY 96: $47,735,000
FY 97: $47,771,000

Populations Served: Young persons engaging in behaviors that place them at risk for acquiring HIV through sexual exposure, including all major racial and ethnic groups. All school- and college-aged youth regardless of school enrollment status.

Constituency Involvement: Consultation with a wide range of constituency groups was established to: (1) improve existing programmatic efforts; (2) improve assistance and resources provided by CDC; and, (3) explore strategies that the Nation might take to improve the health status of young people. These groups include representatives from: (1) every state education agency, District of Columbia, and six territorial education agencies; (2) national nongovernmental health or education organizations, 3) colleges and universities, 4) state public health departments, as well as young people themselves. Meetings included an annual constituency meeting, quarterly training programs, and communication through an electronic bulletin board and network.

Unmet Need: Not all youth are accessible through existing institutional-based efforts, and currently not all states monitor youth health-risk behaviors.

Agency: Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To prevent or reduce behaviors or practices which place individuals at risk of HIV infection, and for HIV positive individuals, place others at risk.

Objectives: At least 90 percent of individuals with known HIV infection will be abstinent or will have used a condom at last sexual intercourse, and at least 50 percent of individuals who have engaged in high-risk sexual behaviors within the past 12 months will be abstinent, in a mutually monogamous relationship, or have used a condom at last sexual intercourse.

At least 75 percent of injecting drug users will have stopped injecting drugs or used sterile or decontaminated injection equipment at last injection.

At least 80 percent of the health care and public safety workplaces will implement programs and procedures for preventing HIV transmission at work sites.

Reduce unintended pregnancies to no more than 40 percent of pregnancies among women with or at risk for HIV infection.

The number of individuals donating blood and found to be infected with HIV at the time of donation will decrease by 50 percent through self-deferral.

Among selected populations of youth in high-risk situations, increase by 10 percent the proportion who report they used a condom at last sexual intercourse.

Action Steps: Collaborate with prevention partners to assess risk behaviors and practices in selected communities;

Identify barriers to implementation of HIV prevention programs at community, state, and national levels;

Collaborate with selected communities in developing and implementing a model behavioral intervention program that comprehensively addresses community needs and uses available community resources and prevention partners in selected sites;

Design, develop, and test effective community-level interventions to change risk behaviors through altering community norms and values to support healthy behaviors;

Expand the community's capacity to plan, implement, and evaluate culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

Enhance the capacity of CDC staff to plan, administer, and

evaluate behavioral change strategies and community-based interventions to provide public health leadership and assist our prevention partners in designing and managing effective strategies for HIV prevention programs;

Enhance the capacity of local health departments and other relevant community agencies to collaboratively provide effective HIV education for youth in high-risk situations;

Establish scientifically-based evaluation components for HIV prevention activities; and

Use evaluation of components to design or refine HIV prevention programs and/or redirect HIV prevention resources.

Descriptions: Several mechanisms are employed for achieving the goals and objectives cited above. These include cooperative agreements with state and local health departments, in addition to direct funding of community-based organizations, national organizations, and national minority organizations. HIV intervention research studies are also supported.

FY 95: $185,625,000
FY 96: $183,814,000
FY 97: $203,958,000

Populations Served: All major racial and ethnic groups in addition to persons engaging in behaviors that place them at risk for acquiring HIV.

Constituency Involvement: A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

Unmet Need: There is currently a lack of behavioral risk surveillance data for program planning and evaluation purposes. There is also a need to develop a more effective application of behavioral science findings to HIV prevention programs. And there is a special need to develop and maintain prevention efforts that target high risk women, youth and gay men of color.

Agency: The Department of Health and Human Services, Centers for Disease Control and Prevention

Goal: To increase individual knowledge of serostatus and strengthen systems for successful referral to early intervention services.

Objectives: At least 85 percent of the estimated 800,000 to 1,000,000 HIV-infected individuals will know their HIV serostatus.

At least 90 percent of health care sites receiving public funds and serving at-risk persons will provide appropriate HIV counseling and testing services.

At least 80 percent of known HIV infected individuals, either directly or through referral, will receive primary and secondary prevention services.

Action Steps: Working with governmental and nongovernmental partners, enhance community-level assessments of needed primary and secondary prevention services;

Identify opportunities for common HIV prevention data collection and development of uniform data sets;

Integrate HIV prevention services into standards of care for the diagnosis and treatment of HIV disease;

In collaboration with the FDA, develop, test, and implement rapid HIV testing procedures;

Strengthen the capacity of state, and local health departments to provide partner notification services to private health care providers offering HIV counseling & testing;

Develop alternative methods to provide HIV counseling and testing services;

Work with professional groups, hospitals, and state health departments to ensure that health care workers receive adequate training on primary and secondary HIV prevention (in collaboration with HRSA);

Study the impact of discrimination as a barrier to prevention services;

Assist publicly funded counseling and testing sites establish selection criteria and systems for monitoring the quality of referral laboratories;

Interview persons newly diagnosed with HIV infection to identify missed opportunities for earlier diagnosis and CD4+ testing;

Conduct a study of incident AIDS cases to determine what services HIV-positive clients are receiving over time to identify service gaps (in collaboration with HRSA); and

Provide guidelines and training to HIV counselors to improve the quality of counseling.

Descriptions: Counseling, testing, referral partner notification programs are supported as part of cooperative agreements with state and local health departments.

FY 95: $168,995,000
FY 96: $167,351,000
FY 97: $181,027,000

Populations Served: All major racial and ethnic groups and persons engaging in behaviors that place them at risk for acquiring HIV.

Constituency Involvement: A major avenue for constituency involvement is the HIV Prevention Community Planning Process. Through this mechanism, state and local health departments form community planning groups to assist in developing HIV prevention plans. In addition, there is regular and extensive consultation with representatives from state and local health departments, community planning groups, and national organizations.

Unmet Needs: There is a need for more effective long-term intervention programs for HIV positive individuals in addition to a lack of resources for supporting comprehensive referral and data monitoring systems. Also, there is a need to determine the best balance between CTRPN programs and other HIV prevention strategies.

Agency: Department of Health and Human Services, Food and Drug Administration

Goal: To reduce transfusion-transmitted HIV infection.

Objective: Ensure supply and safety of the national blood supply.

Action Steps: Establish policies, expedite review of product applications, conduct approval inspections, oversee surveillance, and support enforcement activities.

Descriptions: Encourage high risk donors to exclude themselves; update list of unsuitable donors; quarantine and test blood; investigate incidents to identify, and rectify common errors in blood banks.

FY 95: $17,458,000
FY 96: $17,458,000
FY 97: $17,458,000

Populations Served: All persons who may receive blood or blood products.

Constituency Involvement: The FDA depends on scientific advisory committees to provide independent expert advice to the agency in its evaluation of regulated products. These committees are composed of representatives from academia, research, government, industry, and patient advocates.

Unmet Need: With the passage of Prescription Drug Use Fee Act of 1992, the FDA has been able to expeditiously review HIV/AIDS related therapeutic applications. With the continuation of the provisions in the Act, the FDA will be able to continue expeditious reviews.

Agency: Department of Health and Human Services, Health Care Financing Administration

Goal: To reduce perinatal transmission among Medicaid-eligible women.

Objectives: Develop and implement a campaign to inform HIV positive women in selected pilot areas about the benefits of AZT in FY 95.

Expand pilot project to one State in all regions in FY 96.

Expand project to include all States in FY 97.

Action Steps: Develop, obtain, and distribute brochures and other materials describing current guidelines for the use of AZT during pregnancy for preventing perinatal transmission, and Medicaid eligibility and coverage to Medicaid eligible women.

Descriptions: Establish a consumer-oriented educational campaign in key states with high HIV prevalence rates among women.

FY 95: $50,000 (Federal share)
FY 96: $60,000 (Federal share)
FY 97: $185,000 (Federal share, subject to availability of funds)

Populations Served: HIV positive women eligible for Medicaid coverage.

Constituency Involvement: Significant consultation with high-risk pregnant women and their advocates.

Unmet Need: The pilot project will not initially include women of unknown or negative HIV serostatus.

Agency: Department of Health and Human Services, Health Resources and Services Administration

Goal: To reduce the perinatal transmission of HIV.

Objective: Enhance provider capacity to provide appropriate services for women at the community level.

Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women.

Enhance providers' abilities to provide AZT for HIV positive pregnant women.

Ensure funding and dissemination of innovative models of care that evaluate all of the major care and service goals listed in this plan: effectively educated providers, increased access to and quality of care, reduction of perinatal transmission of HIV.

Action Steps: Establish the Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission (WIN);

Establish ongoing WIN Steering Committee;

Provide technical assistance to grantees;

Conduct centralized training for all WIN sites with follow-up local training;

Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop local guidelines;

Establish MCHB working group to coordinate HIV risk reduction related efforts across programs;

Distribute counseling and testing guidance, AHCPR consumer brochure and video, and other PHS documents to MCHB community;

Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs); and

Evaluate sites.

Descriptions: Enhance outreach for HIV counseling and testing.

Improve service linkages for women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission.

PHS 076 Implementation Plan.

FY 95: $1,520,000
FY 96: $1,800,000
FY 97: $1,890,000

Populations Served: CARE Act grantees. Adolescent and adult women and their infants, with special attention for pregnant women in addition to MCH and HIV providers.

Constituency Involvement: Health care providers, evaluation researchers, communication experts, and patient advocates. There is also consumer participation in WIN steering committee and projects advisory boards in addition to linkages with other HRSA grantees including those from RWCA and SPNS programs.

Unmet Need: Funds needed to provide more services in order to reach more women and enhance evaluation efforts and improve technical assistance and training.

In particular, it is critical to fund services (e.g., outreach, case finding, case management) that better link women of childbearing age with counseling and testing services and, after testing, with comprehensive medical, social, and support services and long-term followup for themselves and their families. Training non-HIV providers, particularly primary care, family practice, ob/gyn, and MCH providers, to perform women-sensitive counseling and testing, to deliver appropriate primary care for women with HIV, and to provide appropriate referrals for these women is another critical need. Funding is also needed for peer-support programs for these women and their families. While it should be our assumption that all women are at risk for HIV, it is important to recognize that certain groups of women (e.g., substance abusers, partners of substance abusers) are at special risk and need additional services in order to enter and remain in care.

Agency: Department of Health and Human Services, Indian Health Service

Goal: To reduce the number of new infections among federally recognized American Indians and Alaska Natives.

Objective 1: Maintain surveillance of HIV infection in American Indians and Alaska Natives.

Action Steps: Maintain timely and complete case reporting to appropriate local, state and national entities and the Indian Health Service (IHS) AIDS Prevention Activities Office.

Descriptions: Area AIDS Coordinators will be responsible for reporting.

FY 95: $ 912,000
FY 96: $ 912,000
FY 97: $1,800,000

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of prevention activities.

Objective 2: Maintain training and information activities to provide health education and risk reduction messages.

Action Steps: Teach empowerment skills at the individual and community level that will enhance the individual's ability to actualize assimilated knowledge as behavior change.

Descriptions: HIV health education and risk reduction message dissemination.

FY 95: Part of overall IHS budget.
FY 96: Part of overall IHS budget.
FY 97: Part of overall IHS budget.

Populations Served: American Indians and Alaska Natives population, tribal leaders, women, youth, individuals practicing high risk behavior, and IHS/tribal health care workers.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: Increased staff and resources would permit expansion of prevention activities.

Agency: Department of Health and Human Services, National Institutes of Health

Goal: To conduct and support behavioral and social science research to further understanding of the determinants and processes that influence behaviors associated with HIV transmission and to develop and improve HIV prevention intervention strategies, and, to conduct and support natural history and epidemiological research to improve the understanding of the risk factors and mechanisms of HIV transmission and disease progression and to develop prevention strategies to reduce or prevent HIV transmission.

NIH's efforts in these areas can be found in Appendix B: Research.

Agency: Department of Health and Human Services, Office of Population Affairs

Goal: To reduce the number of new HIV infections.

Objective: Provide counseling, education, and HIV testing as needed to Title X program clinics.

Action Steps: Include HIV/AIDS education in all clinic education programs.

Include HIV/AIDS prevention in STD screening programs.

Provide HIV testing or referral for testing to all Title X clients who request testing.

Descriptions: Title X Program

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.
FY 97: NA -- HIV services integrated into overall budget.

Populations Served: The Title X program provides family planning and related reproductive health services to approximately 4.5 million clients annually through a network of 4,500 clinics. Clients are predominantly young women; most are members of low-income families, and 30 percent are adolescents and 33 percent are below age 25.

Constituency Involvement: For non-profit grantees, clients participate on boards of directors. For all grantees, clients participate on committees approving all information and education materials.

Unmet Need: The Title X program reaches an estimated 50 percent of potential clients. Expansion of program would provide a concomitant expansion in HIV/AIDS prevention activities, since these are provided as an integral part of the reproductive health services in Title X programs.

Agency: Department of Health and Human Services, Substance Abuse and Mental Health Services Administration

Goal: To reduce the number of new HIV infections.

Objective: Demonstrate the effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance abuse prevention programs.

Demonstrate the differential effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance prevention programs.

Action Steps: Supplementation of high risk youth grants for alcohol, tobacco and other drugs (ATOD) prevention for the purpose of including HIV/AIDS prevention strategies in their present activities.

Develop program to empower youth with skills, knowledge, and beliefs for HIV prevention.

Demonstrate effective strategies to prevent ATOD use and abuse among high risk youth.

Include developmentally and culturally appropriate HIV/AIDS education and prevention approaches.

Descriptions: High Risk Youth Program.

FY 95: $292,000
FY 96: $0
FY 97: $0*

* In addition, SAMHSA's Knowledge Development Application (KDA) Program includes an AIDS initiative in FY 1997. This initiative includes various approaches, including how best to: educate service providers, address family issues, interrupt HIV transmission, and maximize client retention in substance abuse treatment. The FY 1997 estimate for HIV/AIDS in the President's Budget is $15,000,000.

Populations Served: High risk youth or youth at risk for ATOD, adolescent females, and youth at risk for AOD-related violent behavior.

Constituency Involvement: Families of youth, youth service workers, and the communities that support youth at risk for ATOD abuse.

Unmet Need: Presently this initiative reaches only 25 percent of high risk youth grantees. Supplementing all grantees would provide greater opportunity for services integration and evaluation.

Agency: Department of Housing and Urban Development

Goal: To reduce the number of new infections among residents of public and subsidized housing.

Objective: Provide primary prevention programs to public housing residents at risk for HIV infection. Coordinate meetings of the state and local agencies responsible for the prevention program services.

Action Steps: Forge local partnerships and improve coordination of existing resources.

Descriptions: HIV/AIDS Prevention in Public Housing Demonstration Program.

FY 95: $0 (Activities carried out within existing HUD personnel resources.)
FY 96: $0 (Activities carried out within existing HUD personnel resources.)
FY 97: $0 (Activities carried out within existing HUD personnel resources.)

Populations Served: Children and adults in public housing in five targeted cities.

Constituency Involvement: Input received through local planning groups.

Unmet Need: The initial demonstration program reached sites in five cities. An increase in resources would enable HUD to meet increasing demand for services and permit expansion to include other public and subsidized housing efforts.

Agency: Department of Justice

Goal: To reduce risk of infection of infection to INS detainees who are at risk.

Objective: Educate detainees believed to be at risk regarding HIV/AIDS and thereby reduce the risk of transmission and new infections.

Action Steps: Upon obtaining informed consent, test detainees suspected of or diagnosed with HIV/AIDS or test upon detainee request and provide pre- and post-test counseling to detainees deemed at risk.

Descriptions: Provide limited testing and counseling.

FY 95: Part of overall operating budget.
FY 96: Part of overall operating budget.
FY 97: Part of overall operating budget.

Populations Served: INS Detainees.

Constituent Involvement: None.

Unmet Need: None.

Agency: Department of Justice

Goal: To reduce the risk of employee infection and avoid possible worksite performance problems.

Objective: Educate Bureau of Prisons (BOP) staff, Drug Enforcement Agency (DEA) employees, Federal Bureau of Investigation (FBI) employees, Immigration and Naturalization Service (INS) employees, and U.S. Marshals Service (USMS) regarding HIV/AIDS transmission and thereby reduce the risk of infection. Educate all Justice Department employees about HIV/AIDS in the workplace.

Action Steps: For Bureau of Prison (BOP) staff provide: annual HIV information update and infectious disease training to all staff; produce inmate and staff HIV educational videos; and participate at least quarterly with HRSA in audio conferences on HIV issues.

For DOJ employees in occupations that possess a heightened possibility for exposure to HIV or other bloodborne pathogens, including employees of the DEA, FBI, INS, and USMS provide: general training and field office training; annual bloodborne pathogen training to all personnel as mandated by OSHA (discussion of HIV/AIDS is included in this training); and an annual update on the bloodborne pathogens training as necessary to discuss new information or changes in the use of safety equipment, etc.

For all Department employees, the Justice Management Division (JMD) provides: instructional materials to be used in a one time general training; and technical assistance to other DOJ components.

Descriptions: DOJ staff prevention training programs.

FY 95: Part of overall operating budget.
FY 96: Part of overall operating budget.
FY 97: Part of overall operating budget.

Populations Served: DOJ employees.

Constituency Involvement: None.

Unmet Need: Additional resources for field office training for USMS and FBI.

Agency: Department of Veterans Affairs

Goal: To prevent transmission of HIV infection through education of employees and patients.

Objective 1: Train and maintain cadre of professional staff to conduct HIV transmission and prevention education for patients and conduct pre- and post-test HIV antibody test counseling.

Action Steps: Establish national training program to educate two professional staff from every VA medical center to conduct patient education and pre- and post-test counseling.

Maintain on-going training program on limited basis to address turnover of staff and maintain cadre of counselors/patient educators.

Objective 2: Educate and maintain cadre of knowledgeable staff to teach all staff in VA health-care facilities on prevention and transmission of HIV infection.

Action Steps: Develop a national "train the trainer" education program to educate selected staff from every VA Medical Center on how to organize and conduct staff educational activities on HIV transmission and prevention.

Update training materials/revise strategies to maintain knowledgeable base of trainers for every facility.

Objective 3: Integrate HIV prevention education in addiction treatment programs.

Action Steps: Conduct national training program for professional staff in addiction treatment programs and Vet Centers on how to integrate HIV prevention education for patients in their treatment areas.

Objective 4: Stimulate innovative approaches to HIV/AIDS education at the local level (VA Medical Centers and communities).

Action Steps: Award educational demonstration grants to HIV/AIDS education proposals on competitive basis.

Facilitate system-wide dissemination of completed projects through annual publication and national quarterly newsletters.

Objective 5: Maintain education and information support systems.

Action Steps: Continue AIDS awareness and education programs through national system of regional education centers and individual facility programs.

Through library system, continue purchase of appropriate private and Federal sector videos, publications, posters, and other materials.

Objective 6: Prevent transmission of HIV in health-care setting.

Action Steps: Ensure on-going implementation of CDC recommendations on universal precautions, via policy.

Ensure continuing implementation of OSHA rule on protection of health-care workers against bloodborne pathogens via policy.

Provide national training program on interdisciplinary team training for staff from infection control, employee health, safety in all VAMCs to implement OSHA rule.

Descriptions: Prevention activities including education and universal precautions.

FY 95: $31,000,000 *
FY 96: $31,000,000 *
FY 97: $31,000,000 *

* Figures are based on the estimated resource expenditures for universal precautions and education and are part of the general Medical Care Budget. FY 1996 and FY 1997 estimates are based on the resource levels contained in the President's budget.

Populations Served: Eligible veterans through local medical centers and facilities, local VA health-care and support staff, veteran patients and families, general public.

Constituency Involvement: VA medical centers and health-care facilities, and local communities.

Unmet Need: Advances in treatment through research and/or changes in prevention activities may require re-assessment of funding levels.

Agency: Corporation for National Service

Goal: To offer HIV/AIDS education programs and other services with volunteers from the Learn and Serve America project.

Objective: Support HIV-related Learn and Serve America projects.

Action Steps: Continue programs for youth in elementary school or high school to volunteer in community service activities, such as peer education in HIV/AIDS prevention.

Continue to award higher education grants directly to colleges and universities which provide service opportunities on HIV/AIDS prevention.

Program Description: Examples of higher education programs include Robert Wood Johnson Medical School and the University of San Diego where students provide education on HIV/AIDS to homeless and other high risk populations.

FY 95: Part of overall operating cost.
FY 96: Part of overall operating cost.
FY 97: Part of overall operating cost.

Populations Served: Persons living with HIV and AIDS and others who could benefit from HIV/AIDS education.

Constituency Involved: The Learn and Serve America program and students across the country.

Unmet Needs: Without these programs, students would not have an opportunity to serve their communities in HIV/AIDS related projects.