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National Plan Comments-January 1996 [1]

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Date: 30 January 1996

To: CDC
From: ONAP

Re: CDC Review of National Strategy for HIV and AIDS

There are several areas we need your help with, specifically:

Text:

- Confirmation of accuracy for all epidemiological and demographic data.

- Is the national prevention goal theoretically achievable (i.e., reducing infections each year until there are no new infections).

Appendix:

- In Redlined text there are specific questions.

- Is it possible to condense some of the description information under the goal of monitoring the epidemic?

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Date: 30 January 1996

To: SAMSHA
From: ONAP

Re: SAMSHA Review of National Strategy for HIV and AIDS

There are several areas we need your help with, specifically:

Text:

- Information on the extent of AOD-related behaviors -- the text reads: There is substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. It is estimated that xx of the population is affected by alcohol and other drugs in addition to injection drug use.

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Date: 30 January 1996

To: SAMSHA
From: ONAP

Re: SAMSHA Review of National Strategy for HIV and AIDS

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Agency Comment

National Strategy for HIV and AIDS
Draft for Department and Agency Review: 1.30.96

TABLE OF CONTENTS

Letter from the Director of the Office of National AIDS Policy

The national epidemic and international pandemic of HIV and AIDS is a public health crisis of unprecedented proportions, it is the health crisis of this century. The HIV/AIDS epidemic poses a continuing public health crisis that requires solid support for multiple approaches to finding a cure and a vaccine. We must also persevere in our efforts to promote prevention, care, and the ethical treatment of persons with AIDS.

This is the first time a government-wide national plan for the United States has been developed for fighting HIV. It links programs to national objectives. Such a plan was one of the recommendations put forth in 1993 by the National Commission on AIDS. The President, as part of his strong commitment to assuring an efficient coordinated effort, requested that the Office of National AIDS Policy develop a comprehensive plan to guide the federal response to this epidemic.

The Office of National AIDS Policy (ONAP) was created by President Clinton in 1993 to provide greater national focus and direction for the Federal government's response to HIV and AIDS. ONAP is an integral participant in the development of Federal AIDS policies, including annual budget requests and legislative initiatives. As Director of ONAP, I also serve as the head of the U.S. delegation to the United Nations Joint Programme on HIV/AIDS and other international forums.

True government-wide planning requires a commitment from all departments, agencies, and all levels of government to work together toward clearly defined goals. Therefore, this strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF) a request went out for the executive branch agencies to identify their activities, goals, and objectives. With leadership from the President and in partnership with the departments and agencies that are members of the IDTF, we have taken unprecedented steps to prospectively assess and map out future action. As presented here, the national strategy establishes a baseline of current efforts government-wide, links goals to budget objectives, and guides us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. It is intended to be a living document that will require regular updating as goals are reached and replaced with new challenges.

The purpose of this comprehensive national strategy is to set

forth overarching national goals and priorities for 1996 in charting our course for combatting the epidemic of HIV and AIDS. It also includes an accounting of current Federal activities in the areas of prevention, research, services, translation of science into practice, international activities, and civil rights. This document is meant to build on other planning documents such as the legislatively mandated NIH plan and the U.S. International Strategy on HIV/AIDS developed by the U.S. Department of State. I would like to thank and credit the agencies for the time and attention given by their staffs in developing the individual portions of the comprehensive plan.

This epidemic challenges our Nation on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged the people of this country to look at things they would prefer to not confront. There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into this epidemic, persons living with HIV still endure daily prejudice and discrimination based on their HIV status. We are challenged by the inadequacy of a social and health care infrastructure -- a system that is in many places, woefully unprepared to address the needs of the HIV-infected. Moreover, the safety net provided by programs such as Medicare and Medicaid is being threatened by funding changes. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

But despite the difficulties, AIDS has also brought forth the compassion and caring found throughout this Nation. In my many meetings around the country with persons living with HIV I have been inspired by their personal courage. I have been impressed by the compassion and the dedication with which many communities and individuals have risen to the challenge of preventing infections and caring for those who are sick, demonstrating how this Nation can rise to meet the most difficult challenges placed in its path. And those Americans living with HIV, and others who are at risk of infection, their families, and their communities deserve a thoughtful, effective, and aggressive plan to combat this epidemic.

The epidemic of HIV and AIDS threatens the economic progress of many countries around the world. In the United States HIV is now the leading cause of death among Americans aged 25 to 44. Now is when we must move forward and build upon our efforts -- the future of our Nation and of our children and our world depend on it.

This is a time of great challenges and great opportunity. And while AIDS is a terrifying tragedy that has already affected far, far too many people around the world, I believe it is a disease that we can defeat -- just as we have defeated polio, smallpox, many forms of cancer, and other scourges in the history of our planet. We will be able to win our battle with HIV and AIDS with commitment, courage, and leadership.

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 people and governments here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. This national and international pandemic of HIV disease, now well into its second decade, is progressing virtually unabated. It also remains a deadly infection for which there are limited treatments, no vaccine, and no cure.

An Expanding Public Health Threat

As of October 1995, the Centers for Disease Control and Prevention (CDC) reports that 501,310 cases of AIDS have been diagnosed in the U.S. and an estimated 311,381 Americans have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death to the 8th and it is now the leading cause of death among all Americans aged 25 to 44. (See Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS were reported to the CDC and over 44,000 Americans died of AIDS-related causes in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As we have witnessed a relentless increase in infections, the demographics of the epidemic have been shifting. 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 (43%) of all new cases. Among the populations being more heavily affected now are young men between 20 and 24 (%), and women (18%), and heterosexual injecting drug users (24%). And although gay men no longer represent the majority of new cases, this groups represents the majority of persons living with HIV and AIDS. In 1995 alone, more than 14,xxx women were diagnosed with AIDS and women now comprise 21 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned by AIDS by the end of this decade.[1a] As of October 1995, pediatric

cases have been on the rise[1] and in 1994 alone, more than 1,000 new pediatric AIDS cases were reported -- an 8 percent increase in just one year.

Communities of color are more severely and disproportionately affected. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 18 percent of new cases through October 1995, although this group represents only 9 percent of the general population. In 1981 persons of color represented only x percent of AIDS cases, as of October 1995 this group now comprises x percent of new AIDS cases. Moreover, in certain regions of the country gay men of color account for approximately 39 percent of new AIDS cases. Young gay men of color aged 10 to 24 are especially hard hit, representing 53 percent of new AIDS cases nationwide.

The proportion of cases due to the common modes of transmission are also changing. The CDC estimates that in the United States approximately 50 percent of all new cases are now related directly or indirectly to substance abuse, particularly the use of injectable drugs. As a result, the incidence and prevalence of HIV infection in injecting drug users (IDUs) and their sexual partners and their children is rising.

Moreover, AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to rural areas, including dramatic increases in certain regions of the south. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462) were reported from the south, which also accounted for the largest proportionate increase in cases (31%).[2] 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, and each of the American territories. (See Figure 2.)

Internationally, the toll of the epidemic is even greater. The World Health Organization (WHO) estimates that since 1981, 2.4 million cases of AIDS have occurred worldwide. It has estimated

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[1a] It is anticipated that this trend could be reversed with the implementation of the PHS recommendations for the administration of AZT to women during pregnancy and to their infants after birth.

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 at least 25 million people will become infected with HIV, or an average of 10,000 people a day.

The Social Impact

Sadly, prejudice and discrimination are still encountered by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical services, emergency medical treatment, dental services, and medical insurance. They have been discharged from their jobs and evicted from their homes. And unlike other persons with infectious diseases, many persons living with HIV to have been the target of violence, rejected by their families, and suffered discrimination based on their HIV status.

AIDS is a disease that can strike at anytime but most often affects people in the prime of life. It disproportionately kills people during their most productive years. It is the leading cause of death among Americans 25 to 44, the age group that constituted 54% of the civilian labor force in 1992.[3] Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In terms of years of potential life lost, in 1994 AIDS ranked fourth among all leading causes of death. In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children.

Goal of the National Strategy

The purpose of the national strategy is to establish national goals and identify opportunities for progress for 1996 in order to chart our course in combatting the epidemic of HIV and AIDS. To ensure efficient use of Federal, State, local, and private resources, it is imperative to plan and coordinate government-wide efforts.

This is the first time a government-wide national strategy for HIV and AIDS for the United States has been developed. This strategy links programs to national objectives in each federal agency that supports AIDS-related activities. It lays forth the national goals and emphasis areas for HIV/AIDS, documents current Federal activities, and links goals to budget objectives based on current scientific opportunities, public health needs and priorities, and fiscal constraints. It is intended to be a living document that will be updated regularly. By establishing a government-wide baseline, this plan will help guide Federal agencies in refining their goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The national strategy for HIV and AIDS presented here is broader in scope than prior planning efforts. To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome[4], the "Coolfont"[5] and "Charlottesville"[6] reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States[7]. Recommendations have also been issued from a number of groups, including the National Commission on AIDS[8] in addition to significant planning efforts on the part of individual agencies. However, there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also incorporates issues such as housing, health care, and civil rights. This strategy addresses this important need. Moreover, realizing the goals of the strategy will require continued consultation and planning with Federal departments and agencies, and with the infected and affected communities.

Common Goals and Opportunities for Progress

This national strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a group that consists of representatives from executive branch departments and agencies that conduct AIDS-

relevant work, a request went out for the agencies to identify their activities in relation to national goals and objectives. The IDTF member agencies developed their individual portions of the strategy, linking their goals, objectives, to budget levels and identifying areas for progress and collaboration. IDTF members, with their specialized knowledge on a broad range of HIV-related issues, have been crucial in identifying opportunities for progress and areas requiring special attention. In developing these areas for progress the Office of National AIDS Policy has also consulted members of the President's Advisory Council on HIV and AIDS, the activist community, participants in the White House Conference on HIV and AIDS, people on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and caregivers. The insights provided by a number of groups including 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 helpful. Therefore, the expertise and experience of those who work closely with communities, clinicians, researchers, service and research organizations, and infected persons is reflected in these goals and opportunities for progress.

Based on these consultations, the following national goals are established.

- Provide strong support for research in order to find a cure for those currently infected and a preventive vaccine to protect the uninfected.

- Provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections.

- Ensure appropriate care for and ethical treatment of persons with AIDS.

It is these goals that will set the country's sights and remain our guide as we chart our course. In addition, through the above-mentioned consultations, it became clear that there was a consensus regarding the major challenges facing us in 1996, and that these challenges warranted special attention. There was also a common sense that these challenges also represented opportunities for progress -- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected. Based on this counsel, six areas for progress were identified and are listed below.

- Strengthening HIV prevention activities;
- Supporting diversified research approaches;
- Strengthening approaches to substance abuse treatment and prevention;
- Strengthening the health care and services safety net;
- Improving translation of research results into medical practice; and,
- Improving evaluation and priority setting.

Within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of this strategy, there is specific discussion about opportunities for progress that are relevant to that substantive area.

Challenge of the HIV Epidemic

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. But, the challenges we face today are very different than challenges we have faced so far. It is a growing epidemic in which more persons are infected every year, in every geographic area, every ethnic and racial group, and every age range. We now know how it is transmitted, the etiologic agent, and we have a test to diagnose infected persons and protect the blood supply. And thanks to behavioral researchers and the innovative outreach and prevention strategies developed by community groups, we have prevention models that work. The challenge before us now is to build on these successes and develop prevention interventions that reach even more Americans at risk for infection. Thanks to clinical research, significant progress has been made in drug development and clinical care. As a result, people with AIDS now live twice as long as they did a decade ago. And with the results of the NIH-sponsored research we now have the ability to prevent perinatally acquired HIV infection in some newborns by treating women with AZT during pregnancy.

A significant challenge facing the country now is ensuring access to prevention services and medical care for the growing number of people who are currently disenfranchised from the health care system. We need to improve our efforts in providing people with care early in their infection so they can receive quality health care. We also need to train health care professionals so they know the best way to provide that care. Strengthening our prevention efforts has never been more important. Developing prevention messages that are specially targeted to the group or

groups they are intended to reach is critical if we are to reduce the number of new infections. And, from a societal perspective, we still have a long way to go in overcoming fear and discrimination.

Moreover, HIV and AIDS is just one of many infections emerging world-wide that has the potential to devastate communities and nations. It is one of the most lethal epidemics to affect mankind, but it is probably not the last challenge of this kind that we will face. There are likely to be others for which there is no cure, treatment, or vaccine. Our efforts in combatting the pandemic of HIV and AIDS could well benefit us not only in ending this pandemic, but in preventing future ones as well.

Overview of Federal Efforts

Introduction

The scope and nature of the HIV/AIDS epidemic has brought state, local, and Federal involvement into many AIDS-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 Federal activities since the beginning of the epidemic. Currently, these activities include direct support for research, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for state and local governments and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

The national strategy for HIV and AIDS has been organized around the substantive areas that reflect the major components of the Federal effort: prevention, research, care and services, international activities, translation of science into practice, and civil rights. Current agency activities have not been organized around administrative structures, but by substantive areas. In cases where a single agency may have responsibility for more than one component of a substantive area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In many cases there are cross-cutting issues that could fall in several categories, such as internationally-based treatment and prevention efforts. In this case, programs that are specifically targeted towards countries or regions, are included in the international section. Efforts that are part of an overall program that may include domestic and overseas endeavors, are included in their relevant sections, and not the international activities section.

Agency support of HIV/AIDS activities falls into two general categories, where HIV/AIDS activities are a central part of their mission or, not an explicit part of their mission but AIDS-related activities are indirectly supported or receive collateral benefit from agency supported work and/or policies. There are a number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the

Health Resources and Services Administration (HRSA)), while other agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Agencies that support research and provide shared access to highly sophisticated and expensive technology, such as the Department of Energy and its support of sophisticated imaging equipment, can assist a wide range of researchers including those studying HIV. Data are therefore presented in a manner consistent with the level of involvement an agency may have.

This report is organized by the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights. Information and discussion of Federal activities can be found in two places. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has an associated appendix that provides information on individual agency goals, objectives, funding levels, constituency involvement, and unmet needs. Given that agencies and departments may have several areas of responsibility, listings of individual agency activities may be found in more than one appendix.

PREVENTION

The Nation's prevention goal is to provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections. Achieving this goal will require a dedicated alliance between the Federal government, states, local governments, communities, businesses, non-governmental organizations, families, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the prevention task faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.[2] The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 American will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, long period of time where people may not be aware of their HIV status, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted primarily as a result of personal and private individual behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a vast diversity of age, race, HIV status, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

Prevention activities are currently supported by several Federal agencies. (See Appendix A.) Most Federal prevention efforts are funded by the Public Health Service, although other departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These

[2] This section will address primary prevention activities. Other aspects of prevention, such as secondary prevention (i.e. preventing complications of HIV infection), development of topical microbicides, the behavioral components of vaccine research, and international prevention activities will be discussed in the following research, care and services, and international activities sections.

efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the agency with primary Federal HIV-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with states, local governments, and community-based organizations. Other agencies focus on specific aspects of prevention. For example, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages 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.

The efforts of Federal agencies have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both formal research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will prompt behavior change.

Prevention priorities must be guided toward gaining knowledge that will improve our efforts to develop effective prevention programs. We need to improve our understanding of the major modes of transmission, close gaps in scientific knowledge, including identifying effective prevention models and strategies, and work towards eliminating gaps in program areas.

Opportunities for Progress

Modes of Transmission

An important part of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the epidemic of HIV in the United States is being driven by people who engage in injection drug use and their sexual partners, men having sex with men, heterosexual

transmission, and perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to estimate the burden of HIV illness, gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. As previously noted, the CDC is the Federal agency with primary responsibility for monitoring the epidemic. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must collected with the appropriate confidentiality protections.) Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs also require that the CDC reevaluate and reconfigure its data collection efforts; such a change may require reconfiguring of currently collected data to address these needs. As part of the agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies[9], the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Gaps in Scientific Knowledge

Factors that place individuals at risk for acquiring HIV infection are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not **assume** we intuitively know which interventions will work, but instead base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, but when they are it is because the intervention incorporated findings from both experience and relevant research. Behavioral research is a relatively young science and there are currently more questions than answers. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Since behavior change is the primary prevention intervention immediately available for halting the spread of HIV infection, basic behavioral research should be the foundation for prevention programs. Basic behavioral research, similar to basic research in other areas of scientific inquiry, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors. To capitalize on what is already known in addition to improving HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.[10] And although we have some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is much needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying what approaches may be most effective for an individual or a community.[11]

Intervention Research. A second major gap is research to improve prevention interventions, i.e., research that concentrates on modifying behaviors, such as those related to drug use and sexual practices. We know from other behavior-influenced diseases (such as cigarette smoking and hypertension) and practices (such as wearing seatbelts) that basic information about what motivates these behaviors can be incorporated into intervention research to advance approaches to reducing unhealthy behaviors.

In HIV and AIDS, this intervention research can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.[12] Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.[13] A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.[14]

However, despite these successes, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research regarding strategies that facilitate sustained adoption and maintenance of HIV preventive behaviors. Another area for investment is research on cultural barriers and strategies to reach populations resistant to behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism for reducing HIV risk behavior. 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. Enhancing the dialogue between researchers in these two related disciplines will invariable improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research be incorporated into 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. Given the highly innovative nature of these endeavors, the CDC must give 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.

We know from efforts in other countries that HIV related social

marketing efforts can be successful. However, in the United States, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can employed in the design and implementation of prevention interventions. There are good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

Current Gaps in Program Areas

In order to stop new infections, the results of basic behavioral, intervention and social marketing research must serve as the foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, the shifting demographics of the epidemic coupled with restricted resources has resulted in gaps in program areas that limit the Nation's ability to prevent new infections. It is therefore important that prevention planners carefully prioritize their efforts based on local epidemiology.

Community Involvement. For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And 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.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal-local partnership. Through this effort, it is possible to establish joint goals for the prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for good priority setting and decision making.

Substance Abuse Treatment. Injection drug use is one of the major forces driving the epidemic with half of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of this mode of transmission will require efforts on several fronts. First, we need to improve the integration of HIV prevention activities and substance abuse

treatment and prevention programs. As President Clinton has noted, the epidemics of substance abuse and HIV in this country are overlapping and highly interrelated so we must work to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

Another major avenue for controlling the spread of HIV among addicted persons is to enroll them in drug treatment programs. Substance abuse treatment is a form of HIV prevention. At present, there is a continuing need for increased treatment services for persons seeking to control their addictions.

Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. It is estimated that x percent of the population is affected by alcohol and other drugs in addition to injection drug use. It must be part of the Federal response to increase the availability of treatment for a range of addictions.

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, even by as much as 20 times. 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.[15],[16] These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs.

Persons who are HIV positive are at significant risk for developing of *M. tuberculosis* (TB) disease. Studies suggest that the risk of developing TB disease is 7 to 10 percent each **year** for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a **lifetime** for persons not infected with HIV.[17] 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 the person with TB.

It is important that Federal and state efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element. Moreover, the traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National

Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

Harm Reduction.[3] In addition to efforts directed towards enrolling drug users in treatment programs for their addiction(s), harm reduction should be considered by communities when treatment fails or is unavailable. Although harm reduction programs for drug users have not been well accepted in our country, experts feel that it is in this area that we may be able to make a significant impact in stemming the tide of the epidemic.

There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine was that there is no credible evidence that drug use is increased among participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease.[18] There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.

While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, we continue to believe that decisions regarding these approaches should be a community decision based on local epidemiology. We also believe that certain existing statutes restrict potential prevention efforts. The Federal government will work with state and local officials to provide the information they need to take advantage of this intervention.

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[3] Harm reduction efforts support people by reducing their risk of HIV transmission by teaching behaviors that do not transmit HIV. In the case of HIV and substance abuse this can include: needle exchange programs, decriminalization of needle and syringe possession, legalizing syringe purchases without prescription, increasing the availability of clean syringes, providing information on cleaning injection equipment ("cleaning works"), and reducing needle sharing behaviors.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. This includes incorporating a patient's sexual history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to local and Federal governments.

Evaluation. It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement. Incorporating effectiveness measures 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. Achieving this will also require careful examination of what programs should to be continued, what activities need to be initiated and a awareness that a reconfiguration of some program priorities may be required.

RESEARCH

One of the Federal government's goals is to provide strong support for research in order to find a cure for those currently infected and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research. Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the activist community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms, and other parts of the private sector. Realizing this ambitious goal will also require a clear definition of what the Federal government is able to do and an ongoing dialogue between the public and private sectors.

At present, a number of Federal agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports a significant portion of these efforts. The NIH funds research on HIV-related natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, and behavior. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR) funds research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment would not be possible. And the Centers for Disease Control and Prevention (CDC) supports laboratories that have sophisticated methods for identifying virus strains.

Contributions of Research

The Nation has already reaped the benefits of supporting research in general, and HIV-related research specifically. AIDS research has provided advances for treatment of other diseases. For example, HIV-related research has contributed to progress in treating breast cancer. Research revealed that by blocking cytokine receptors, tumor cell growth could be inhibited; this finding led to the development of new treatments for breast cancer. In addition, one of the most promising experimental therapies for advanced breast cancer is high-dose chemotherapy

followed by bone marrow transplantation; this treatment that causes profound immunosuppression and only 1 in 20 women generally survive the transplant. Advances in treating diseases resulting from immunosuppression have come from HIV-targeted research. HIV-related research has also accelerated study of the human immune system which has in turn improved our ability to understand and treat other conditions such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. HIV research involving the blood/brain barrier has led to a better understanding of the mechanisms by which infectious agents spread into the nervous system. This research has valuable implications for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, before the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of other viral diseases and led to development of treatments for many other diseases.

In addition, research investments made before the advent of AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research conducted previously on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses provided valuable information for identifying HIV as the etiologic agent of the emerging epidemic, and advances in molecular biology provided researchers with the tools to understand HIV's structure and develop drugs based on that information.

Due in great part to this Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. AIDS-related conditions that used to mean a quick and often painful death for people living with HIV can be treated and even prevented. An NIH study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Thanks to our investment in prospective epidemiological studies we are beginning to understand the factors that enable long-term non-progressors to live many years after infection virtually disease free. Understanding what happens in these non-progressors may help us develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus.

Combination therapies are also showing great promise in this area. In addition, the Food and Drug Administration, through its accelerated approval program, is now approving drugs faster than ever before and faster than any European nation.

However, despite these advances there is more that needs to be done to reach the national goal of a vaccine and a cure. The epidemic of HIV and AIDS presents an unprecedented challenge. HIV is unique in that it attacks the very immune system that is supposed to protect us from disease -- mankind has never before encountered a virus such as this. Since the beginning of the epidemic, identifying the best approaches to pursue and support has been, and continues to be, a challenging task. Identifying the most promising scientific avenues and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities will require a considered and coordinated effort.

Opportunities for Progress

Coordinated Research Plan and Budget. Developing and implementing the Federal government's AIDS research agenda presents a number of challenges. Within the NIH, the agency with the largest HIV-related research portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. As part of fulfilling the requirements of the law, the OAR develops a yearly NIH plan and budget for AIDS research and receives directly from the President and the Office of Management and Budget (OMB) a single appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgement and provides flexibility for pursuing the most promising research opportunities. It is crucial that the authority granted OAR in the revitalization legislation, including the single appropriation, be supported and maintained. With such a large research enterprise it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

It is also clear that while NIH supports a significant portion of HIV-related research, other agencies and departments also play a

significant role in our search for a cure and a vaccine for HIV. If the government is to effectively support a diversity of promising approaches, these research efforts must also be well-planned, coordinated, and maintain accountability. To achieve this the Director of the Office of National AIDS Policy will coordinate an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge is to develop a coordinated plan and budget specifically for HIV and AIDS research across all departments.

Vaccine Development. Reaching the goal of developing a vaccine will require the joint commitment of government and the private sector. Several challenges currently face the U.S. and the world in continuing the vaccine development effort. The first is to meet the daunting scientific challenge and the second is to create an environment where the private sector can effectively join in partnership with the Federal government. The National AIDS Drug Development Task Force (ADDTF), which included representatives from government, the private sector, and the activist community, identified a range of approaches to accelerating the development of therapeutics for HIV infection. And while the ADDTF focused primarily on the development of HIV-related therapeutics and not vaccines, one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development. Further dialogue involving key players in this areas was deemed as essential in determining and overcoming critical problems and identifying opportunities for development.
Therefore, in order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, President Clinton has asked the Vice President to convene a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents.

At present researchers hold two major views regarding the most promising approaches to vaccine development. Some scientists believe that we need to return to basic science to gather more information to guide us, while others believe that only efficacy trials will provide the answers that really matter and in the face of a global emergency we must empirically test candidate vaccines in people immediately. Both groups have valid arguments.

The issues driving this debate are both scientific and social, with different parts of the world experiencing the epidemic in different ways. Some regions of the world have already experienced the devastating consequences of the epidemic while,

in some regions the epidemic is in its early stages. Some governments have shown a greater interest than others in pursuing vaccine trials as a method of slowing the growth of the epidemic in their countries. Both the social and scientific issues must be considered when planning trials. However, given the state of scientific knowledge, both the 'basic' and 'empirical' avenues can, should, and are being pursued.

It is also vital that this effort be well-coordinated and that all available data are shared and used by scientists as vaccine development moves forward. Therefore, a coordinated vaccine program that ensures support for promising avenues of vaccine research, will be one of the issues addressed in the aforementioned interdepartmental research plan to be developed under the direction of the Director of the Office of AIDS Research.

Topical Microbicides. Many scientists believe that the prevention of sexually transmitted HIV infection, as well as the prevention of major sequelae of STDs in women and infants, will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods that will block HIV transmission.

The barrier methods that are currently available have limitations. Most require consent, if not active participation of the male partner, and therefore cannot be independently used at the discretion of the female partner. Although epidemiological studies have demonstrated that the correct and consistent use of condoms can reduce the risk of acquiring some STDs (including HIV) there are many situations in which personal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method which can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and risky behaviors that occur without partner knowledge.

The development of this important prevention approach will depend on strong support for the basic and clinical research. Topical Microbicides are a promising approach, but will require preliminary support before they reach a stage where the private sector can assume a lead role. Given that worldwide over 80% of HIV infections are acquired heterosexually, and given that the risk of becoming infected or infecting others is substantially increased by the presence of other STDs[19], topical microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

Clinical Effectiveness Research. It is also important that we continue to support the wide spectrum of research needed to find effective treatments by maintaining research to forward our understanding of the virus' life cycle and pathogenesis, natural history and epidemiology, and clinical research including clinical effectiveness research.

Due in part 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 the treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding clinical effectiveness is increasingly unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that the post-marketing efficacy studies, currently mandated through regulation are carried out. Conducting these studies will require the efforts of clinicians who have demonstrated their ability to carry out the long-term follow-up of patients that such clinical effectiveness studies require. It is also essential that these studies, like all studies, include persons representing a diversity of race, ethnicity, gender, age, and drug using behaviors. If these studies are not done we will not know which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for these less effective treatments.

One of the most difficult tasks for clinicians and patients is

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[4] The accelerated approval program permits companies to seek approval of drugs for serious or life-threatening illnesses based on surrogate or laboratory markers, such as CD4+ cell count or viral burden measures. For drugs approved under this program, the sponsoring company is required to conduct follow-up studies that determine whether there is a clinical benefit for the patient. There is currently concern that these subsequent clinical effectiveness studies are not being. However, by law, if the subsequent studies do not prove a clinical benefit, approval may withdrawn by the FDA.

interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients is provided in a timely manner. The Federal government must develop a mechanism for ensuring periodic assessment of the state of the art, ensuring that essential information can be found easily, and disseminating that information widely. This will require collaboration with industry, government, and professional groups. [See Translation of Science into Practice section for further discussion.]

Public-Private Partnerships. A key role for the Federal government is to act in partnership with the private sector and support areas where there is a market failure (i.e., areas where industry is unlikely to pursue research that would be beneficial to the public health. Vaccine development is one such area, but there are others. The Department of Defense has been successful in developing partnerships in this area and this effort should be strengthened. As noted previously, topical microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary support before they reach a stage where the private sector can assume a lead role.

It is also unlikely that the free market will conduct head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research. Similarly, 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. Americans are spending millions of dollars per year on such therapies about which little is known.

It is also 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. For example, the Department of Energy has supported sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource that 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.

Research: An Investment for the Future. And finally, 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 them to a cure and a vaccine. At present, the 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, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to improving lives and the Nation must continue this investment.

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. For many of these persons, maintaining adequate health insurance coverage can be extremely challenging. There are many who exhaust their personal resources and private sector options over the course of their illness and are left to rely on the nation's medical care safety. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans 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. For the remainder, their lives often depend on the Federal health care safety net. (See Appendix C.)

For those that qualify, care and services are provided through a number of Federal agencies, many in cooperation with local organizations and the AIDS community who have admirably served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation. By far the largest sources of care for persons living with HIV are Medicaid and Medicare. For Americans living with HIV, Medicaid is the single largest source of health care financing, providing coverage for nearly 50 percent of adults and more than 90 percent of children living with AIDS.

A second major source of care is provided through Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA); it was established to fill certain gaps in coverage 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 III of the Act provides early intervention services such as

counseling and testing, medical care, and educational services for medically underserved persons with the goal 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. 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.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, 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.

The Health Care Safety Net. We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by $169 billion and turn it into a block grant in effect reverses this Nation's 30 year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.

With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and

Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care. Unfortunately, the majority of Americans do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking an HIV positive person with care also provides an opportunity education so they can adopt behaviors which may reduce their chances of infecting others. This in part means offering addiction treatment to assist persons in stopping risky behaviors. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. As noted in the Prevention Section of this plan, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to local and Federal governments.

Housing Services. Housing is also an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS 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 persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course

of their illness.[20] Persons living with HIV have an increased challenge in finding affordable housing on a limited income and finding appropriate housing with needed levels of support. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS. The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. It is estimated that the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital. The HOPWA program must be protected, but it must also be acknowledged that HOPWA cannot do it alone. Protecting this component of the safety net and providing housing for persons living with HIV will require integrating housing services into other programs and ensuring a shared responsibility between Federal, state, local governments and community organizations.

Prisoners. There are also groups of people, such as prisoners, who fall outside these traditional safety net programs. While 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. Both identifying the HIV positive prisoners and ensuring access to quality care for incarcerated persons is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and access to research opportunities that do not face the non-incarcerated population.

Improving access to appropriate HIV-related care in prisons must be a priority. This effort can be accomplished by improving the knowledge and skill of the health care team in the prison in the management of HIV-related issues. In addition, efforts must be made to improve collaborative efforts to build linkages between prisons and outside public health departments and agencies who have experience in providing care for prisoners. These efforts can also serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.

Program Coordination. For care and services to have the most beneficial impact they must be coordinated and comprehensive.

However, for organizations on the front lines of the epidemic, putting together a comprehensive integrated program requires applying to numerous Federal agencies. For example, creating a program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening and prevention would require separate applications to SAMSHA, HRSA, and CDC. Adding housing assistance and a research component would require additional applications to HUD and the NIH. The Federal government needs to simplify its funding structures so that primary care, prevention, and treatment can be integrated in order to provide cost-effective integrated services to HIV-infected persons and persons at risk for HIV, such as substance abusers and their partners. Through the Interdepartmental Task Force for HIV and AIDS (IDTF), key agencies must identify approaches for facilitating the development of integrated care and prevention programs at the implementation level.

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 on the frontlines of the epidemic. It can assist us in providing better care to persons 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 if we are to help those persons living with HIV.

Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and 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. One Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection. However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal agencies, professional organizations, medical schools, and individual clinicians.

INTERNATIONAL ACTIVITIES

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide. 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.

This pandemic presents a unique set of health, social, economic, and political challenges. It most often affects people aged 25 to 44 -- those who are in the most productive years of life. The period from initial infection to disease onset can be many years, during which time persons many unknowingly spread the infection. The WHO estimates that there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000.[21] 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.[21] 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.

Due to the global nature of the pandemic, its negative impact on both developed and developing countries cannot be overstated. It is clear that if we do not stop the pandemic globally, we will not be able to halt its spread in the United States.

At present several Federal agencies are working on slowing the AIDS epidemic worldwide. (See Appendix D.) The Department of State has worked 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 identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify 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; and 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). For example, DOD is conducting clinical trials of candidate HIV vaccines in Thailand. 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.

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)[5] . Moreover, the U.S. is a member of the governing body of UNAIDS. Supporting UNAIDS demonstrates the continuing commitment of the U.S. to collaborate with other countries in lessening the impact of the epidemic. 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 and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

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[5] Until recently, the United Nation's response to HIV/AIDS was focused primarily in WHO's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, combining the efforts of six U.N. agencies to stregthen coordination and focus support for HIV/AIDS activities at the country and global 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.

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. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, U.S. based non-governmental organizations and indigenous groups.

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. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the agencies supporting international activities on the Interdepartmental Task Force for HIV and AIDS must develop a mechanism for identifying and coordinating this effort.

TRANSLATION OF SCIENCE INTO PRACTICE

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 standard medical practice of clinicians caring for persons living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about caring for persons with HIV. Improving the translation of research advances into daily clinical practice will require an ongoing collaborative effort on the part of the Federal government, individual health care providers, medical schools, professional organizations, international organizations, health centers and hospitals, and other parts of the private sector.

Information dissemination activities fall 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. NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE in addition to a toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS). The Centers for Disease Control and Prevention (CDC) also 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 it *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; an example these materials are clinician guidelines for the evaluation and management of early HIV infection. The Health Resources and Services Administration has also developed guidances for its CARE Act grantees.

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. In the beginning of the epidemic little was known about effective treatments; care was primarily hospital-based and focused on the most severe complications of late-stage HIV disease. Now, with more knowledge about the course of HIV disease available to clinicians, there is an increased focus on prophylaxis for a range of infections in a primarily outpatient setting. Individual agency projects have

been productive in facilitating this change, such as the Comprehensive Guidelines for the Prevention of Opportunistic Infections in HIV-Infected Persons developed collaboratively between the CDC, NIH, and The Infectious Disease Society of America (IDSA). NIH's state-of-the-art conferences have also contributed to improving the translation of research results into clinical practice.

Opportunities for Progress

However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians miss significant HIV-related symptoms during patient examinations.[22] Other research indicates that a disturbing number of clinicians are not aware of or do not use universal precautions in the course of routine patient care.[23] We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study which 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. 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 breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

Coordination of Federal Activities. The most pressing need in the area of information dissemination is to improve coordination among Public Health Service agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a 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. As noted in the prevention section, good models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons on the frontlines of the epidemic. Here again, the Public Health Service must take the lead in ensuring that information which can be used to stem the tide of new infections reaches those who can make a difference.

CIVIL RIGHTS

One of the Nation's common goals is to ensure the ethical treatment of persons with AIDS. Discrimination based on HIV status, is illegal and morally wrong. It 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. As a result they remain unaware of their HIV status and cannot take advantage of care that could help them live longer more productive lives. In addition, opportunities to educate people are lost.

Opportunities for Progress

The Nation has made progress in fighting discrimination. There are now laws in place to protect people against HIV-related discrimination in employment, housing, and public accommodations. 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.

Federal and State laws do exist to protect persons with HIV. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by state law. The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990 (ADA). (Federal agencies are prohibited from discriminating against people with disabilities under the Rehabilitation Act of 1973.) Title I of the ADA prohibits discrimination against qualified disabled individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

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 clinicians who have refused to care for HIV infected patients and employers who have dismissed persons 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 persons living with AIDS.

The Federal government must also actively work to remedy any of its own existing discriminatory policies. In order to identify areas of possible concern, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

■ Budget Tables

(Will be developed after confirmation of individual budget figures.)

■ Acronyms

ACTG	AIDS Clinical Trial Group
ADA	Americans with Disabilities Act of 1990
ADC	AIDS Dementia Complex
AHCPR	Agency for Health Care Policy and Research
AIDS	Acquired Immune Deficiency Syndrome
AOD	Alcohol and other drugs
ATOD	Alcohol, tobacco, and other drugs
BOP	Bureau of Prisons
CARE	Ryan White Comprehensive AIDS Resources Emergency Act
CDC	The Centers for Disease Control and Prevention
CMV	
CNS	Central Nervous System
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
DOJ	Department of Justice
DOL	Department of Labor
EEOC	Equal Employment Opportunity Commission
FDA	Food and Drug Administration
GCRC	General Clinical Research Centers Program
HCFA	Health Care Financing Administration
HIV	Human Immunodeficiency Virus
HOPWA	Housing Opportunities for Persons with AIDS
HRSA	Health Resources and Services Administration
HSV	Herpes Simplex Virus
HUD	Department of Housing and Urban Development
HTLV-1	
ICD	Institute(s), Center(s), Division(s)
IDTF	Interdepartmental Task Force on HIV and AIDS
IHS	Indian Health Service
IOM	Institute of Medicine
MAI	

NCRR	National Center for Research Resources
NGO	Non-governmental Organization
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NREN	National Research and Education Network
OAR	Office of AIDS Research
OI	Opportunistic Infection
OMB	Office of Management and Budget
PCP	*Pneumocystis carinii* pneumonia
PHS	Public Health Service
PLWH	Persons living with HIV
PSA	Public Service Announcement
PVO	Private Voluntary Organization
PWA	Person with AIDS
RFIP	Research Facilities Infrastructure Program (NIH)
RPRC	Regional Primate Research Center (NIH)
RWCA	Ryan White Comprehensive AIDS Resources Emergency (CARE) Act
SAMHSA	Substance Abuse and Mental Health Services Administration
SPF	Specific Pathogen-Free
SSA	Social Security Administration
SSI	Supplemental Security Income
TA	Technical Assistance
TB	*Mycobacterium tuberculosis*
UNAIDS	United Nations Programme on AIDS
USAID	U.S. Agency for International Development
USIA	U.S. Information Agency
WHO	World Health Organization

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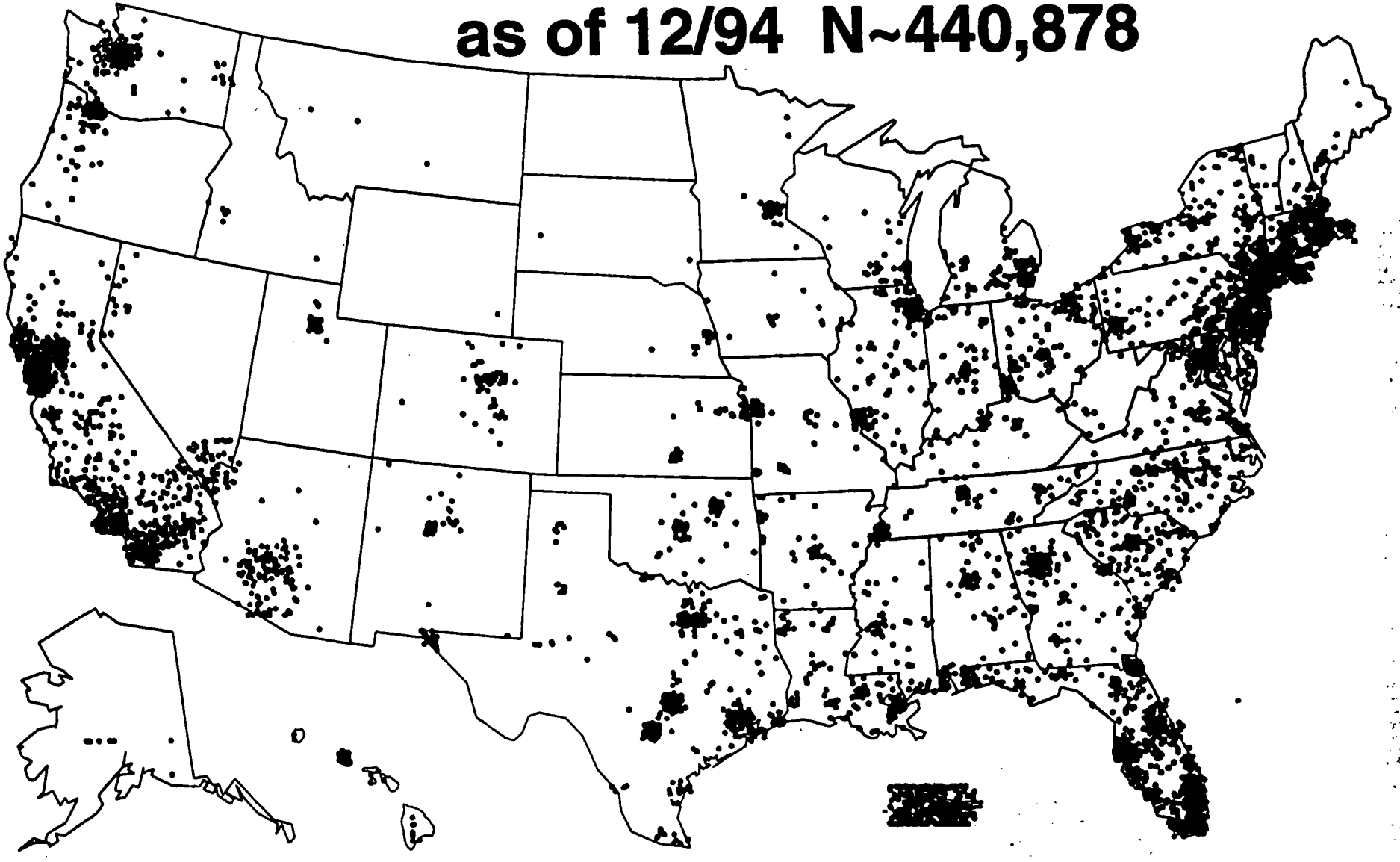
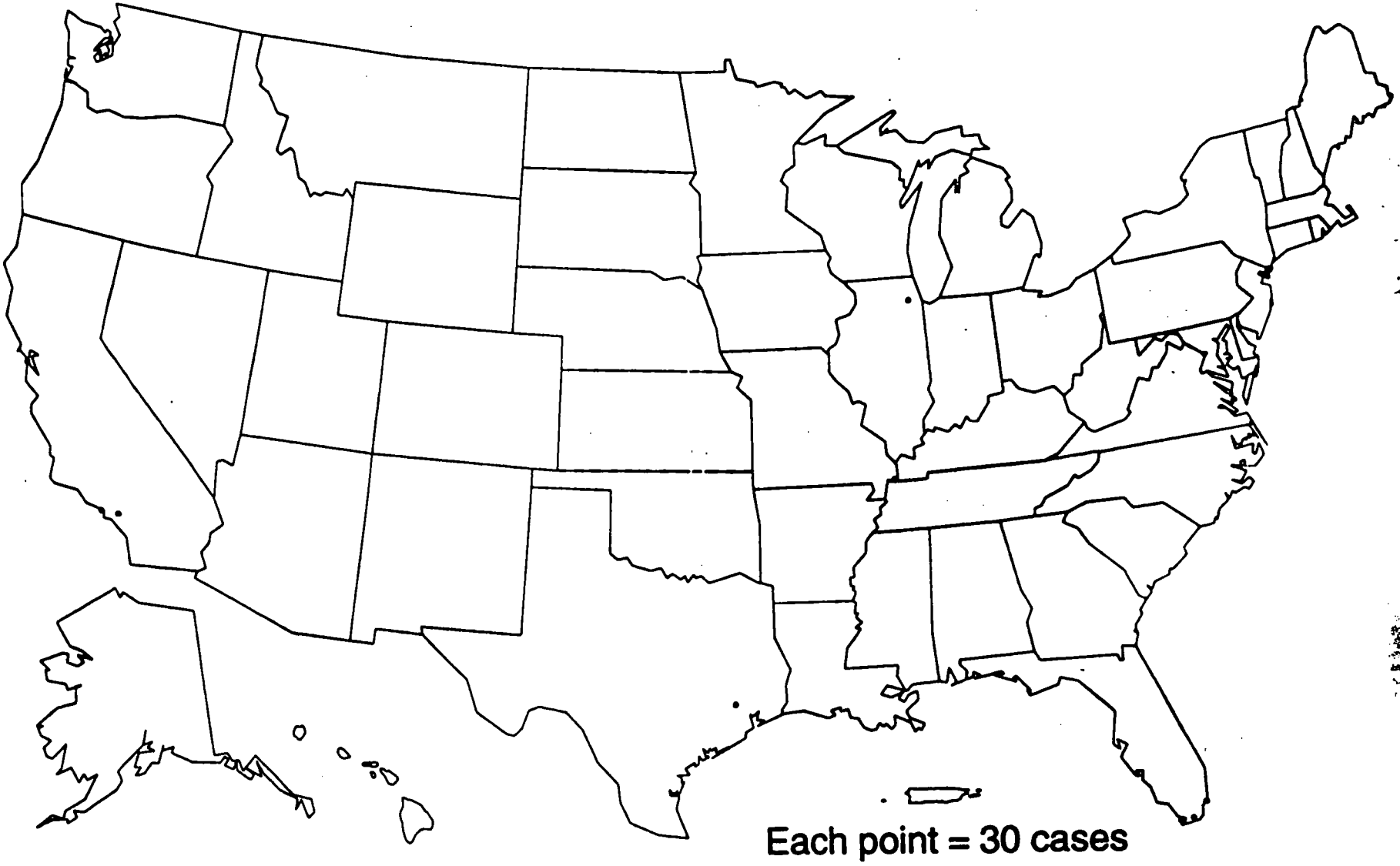
CHART #2

Cumulative U. S. AIDS Cases as of 12/94 N~440,878

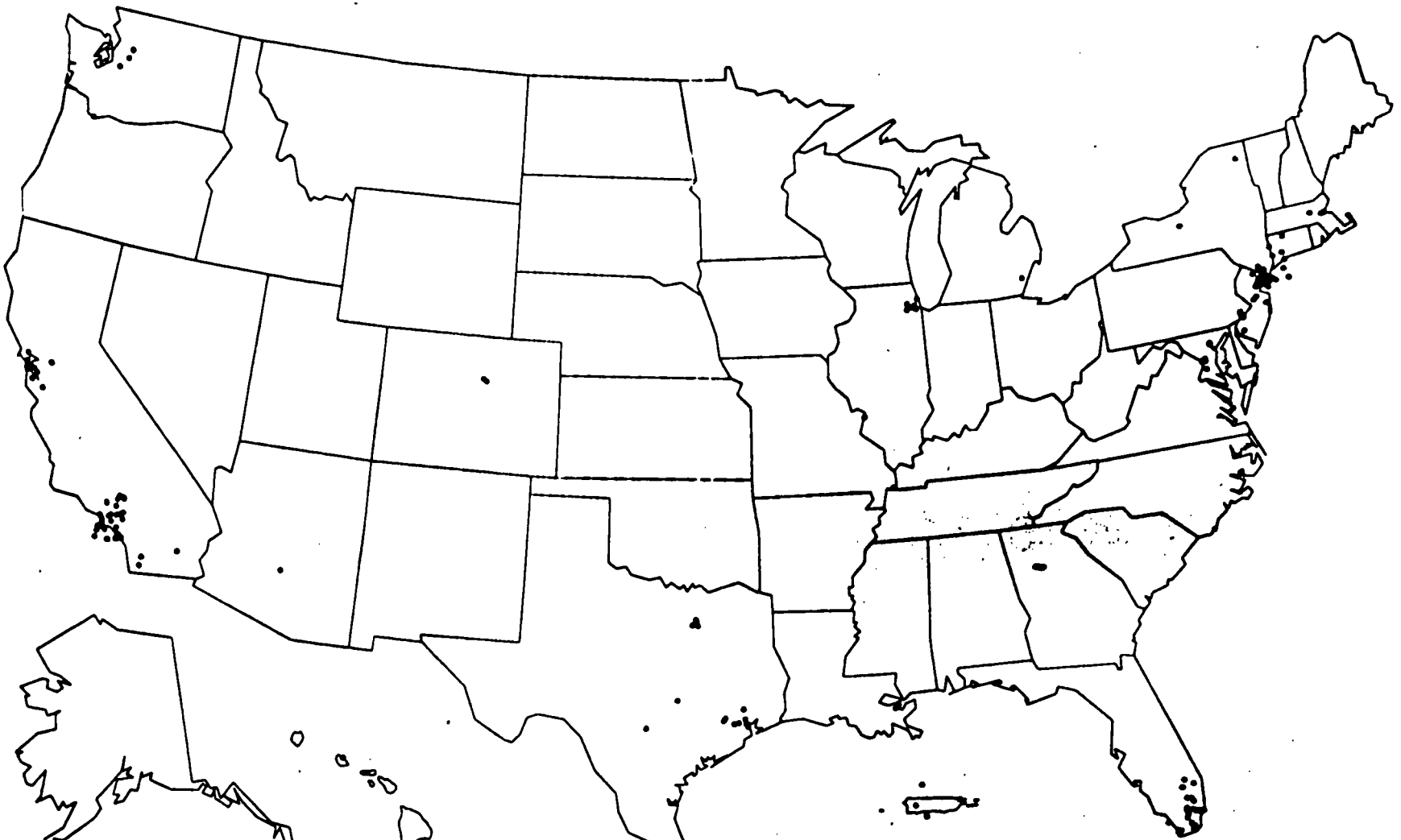


Each point = 30 cases

Cumulative U.S. AIDS Cases as of 2/83 N~1,000



Cumulative U. S. AIDS Cases as of 5/85 N~10,000



Each point = 30 cases

Cumulative U.S. AIDS Cases as of 7/89 N~100,000

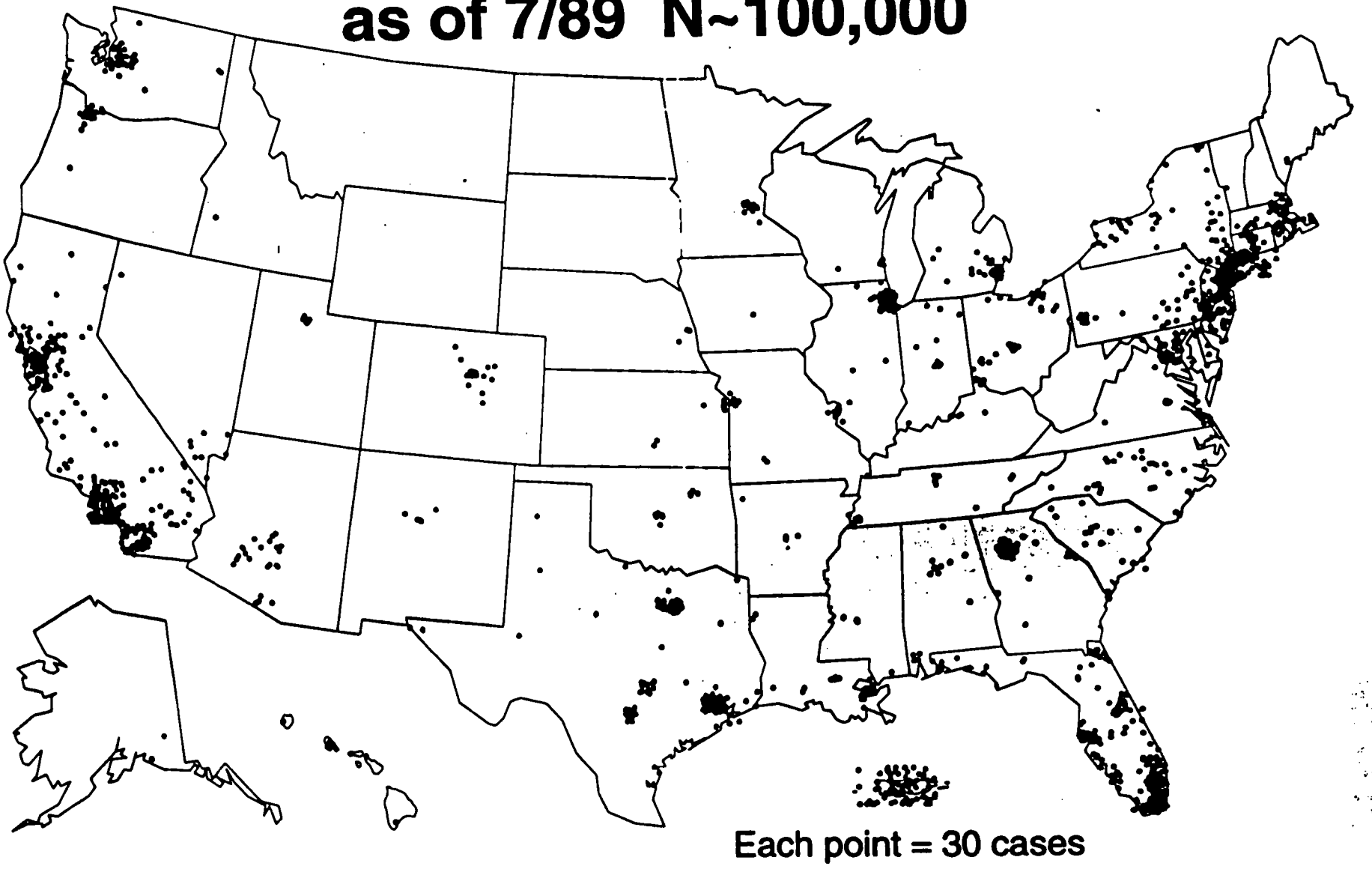
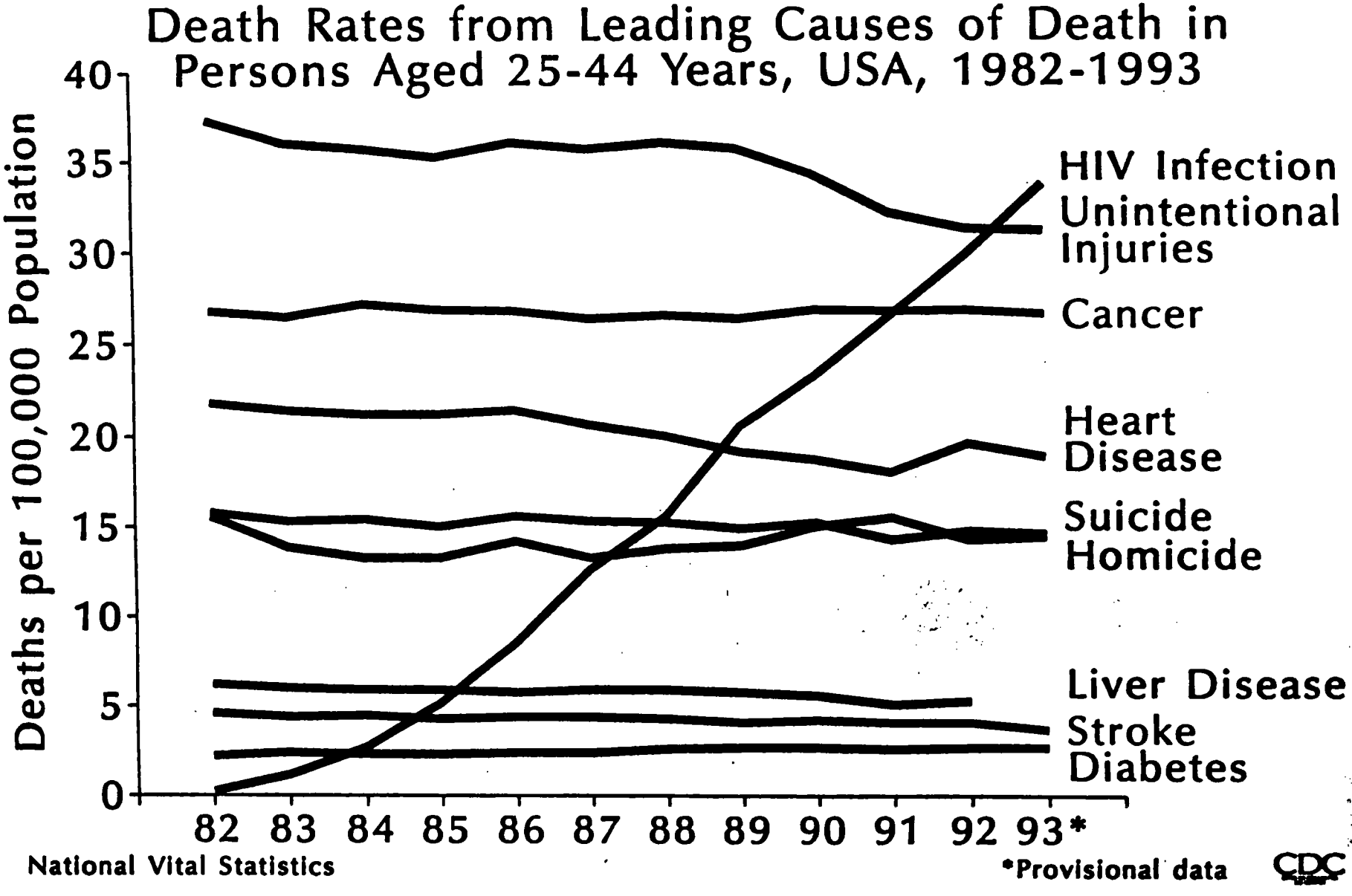


CHART #1


Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982-1993
Deaths per 100,000 Population
40
35
30
25
20
15
10
5
0
82 83 84 85 86 87 88 89 90 91 92 93*
HIV Infection
Unintentional Injuries
Cancer
Heart Disease
Suicide
Homicide
Liver Disease
Stroke
Diabetes
National Vital Statistics
*Provisional data
CDC

CIVIL RIGHTS

Agency: Department of Justice

Goal: Enforce HIV-related civil rights laws and heighten issue awareness.

Objective: Prevent discrimination on the basis of real or perceived HIV status.

Action Steps: Enforce civil rights laws and inform and educate the public.

Descriptions: Litigate HIV-related civil rights cases involving housing discrimination and discrimination in the provision of services.

Provide information via the Americans with Disabilities Act (ADA) hotline and provide technical assistance to state and local governments, Federal agencies and other entities having rights and responsibilities under Titles II and III of the ADA.

Developed and disseminated information about the ADA and its applicability to persons with HIV and AIDS to 500 agencies providing services for this population.

FY 95: Hotline $350,000; other activities part of overall operating budget.

FY 96: Hotline $350,000; other activities part of overall operating budget.

Populations Served: Victims of HIV/AIDS discrimination, Federal, state and local agencies, businesses, and the general populace.

Constituency Involvement: Ongoing communication with AIDS-related disability groups. -- Correct?

Unmet Need: Funds for attorneys for additional litigation. Public education and technical assistance for health care and day care providers about their ADA obligations to persons with HIV.

Liz Savage mailing list for ADA Litigation - sit down + talk

CIVIL RIGHTS

Agency: Department of Justice

Goal: To provide education and training for law enforcement and social services agencies regarding victims of crime.

Objective: To improve trainees' interaction with the populations they serve, especially those who might have been exposed to the HIV virus or those who may be HIV positive.

Action Steps: Provide funds to the National Victims Center (NVC) under a cooperative agreement. (The NVC provides education, and sensitivity training to law enforcement personnel and social service agencies.)

Provide grant funds to the Educational Development Center (EDC) for training regarding hate/bias crimes. (The EDC trains law enforcement and social service agency personnel regarding procedures for identifying and handling hate crimes, including such crimes against those who are HIV positive or living with AIDS).

Descriptions: Provide grants and operate cooperative agreements.

FY 95: $133,900
FY 96: Unknown

Populations Served: Law enforcement and social service agencies are directly served. The crime victims who interact with these agencies benefit indirectly.

Constituent Involvement: NA. Any consultation with victim's rights groups?

Unmet Need: Additional resources to provide more regional training.

Funding to conduct surveys of individual facilities and increase surveys of the juvenile system, and to conduct additional work in the areas of prevention and education.

PREVENTION

Agency: Department of Justice

Goal: Reduce the risk of employee infection and avoid possible worksite performance problems caused by fear and intolerance.

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

Provide technical assistance to other Department of Justice (DOJ) components.

Action Steps: For Bureau of Prison (BOP) staff provide:

annual training and limited testing: > applies to inmates

"annual HIV information update and infectious disease training to all staff;

produce inmate and staff HIV educational videos;

participate at least quarterly with HRSA in audio conferences on HIV issues; and

conduct random HIV testing on inmates upon admission.

Training for people in "external populations" ↓ they do blood borne pathogen training.

For employees of the DEA, FBI, INS, JMD, and USMS provide: training for people who do litigation. Responsible for training non external personnel.

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. Supplement update with periodic memos on use of personal health equipment.??? How is this different from bullet above? the difference is how different annual update on bloodborne Pathogens → plus → if something comes up. DEA

Descriptions: DOJ staff prevention training programs.

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

Populations Served: DOJ employees and BOP inmates.

Constituency Involvement: NA??? Nurses (HIV's do training.
Not applicable or None.

Unmet Need: Funding for counseling and testing of all inmates -- currently approximately 10 percent are tested upon entry? during length of incarceration?. Additional resources for field office training for USMS and FBI.

BOP → about 10% randomly

PREVENTION

Agency: Department of Justice

INS

Goal: Reduce risk of infection to at risk detainees.

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

Action Steps: 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.

Populations Served: Detainees

Constituent Involvement: ??? None / Not applicable

Unmet Need: None. How does this connect with previous goal where 10 % are tested?

Research

~~CARE AND SERVICES~~ DoJ Research Arm } Bureau of Justice Statistics

Agency: Department of Justice

Goal: To estimate the prevalence of HIV/AIDS among the corrections and parole population and to monitor the HIV/AIDS-related policies of the detention and parole systems.

Objective: Data collection and publication of periodic reports.

Action Steps: Conduct surveys of federal, state and local prisons and inmates and publish results in periodic reports.

Descriptions: Survey of HIV/AIDS in Correctional Facilities and publication of survey findings in both the adult and juvenile correctional facilities.

Publication of reports describing findings of multi-year project, "HIV Education in Lockups and Booking Facilities."

1996 Survey of HIV/AIDS in Correctional Facilities.

Census of prison, survey of jail and prison inmates and probationers, and study examining research on prevention programs directed towards at persons whose behavior makes them vulnerable to HIV infection.

Is prevalence data used to allocate resources for care and treatment for inmates? Use to improve services for HIV+ personnel.

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

Populations Served: Department of Justice, corrections administrators, and public.

Constituent Involvement: NA.

Unmet Need: Funding ~~for~~ research into treatment. research into special segregation of inmates, treatment -- does this mean health care? , extent of risk and contact while under supervision. no

Funding to conduct surveys of individual facilities and increase surveys of the juvenile system, and to conduct additional work in the areas of prevention and education.

Care + Services ≠ NIH-defined standards

RESEARCH

Agency: National Institutes of Health

Goal: Enhance understanding of the etiology and pathogenesis of HIV infection.

Objective 1: Support research to further understanding of HIV immunopathogenesis.

Action Steps: Delineate the cellular and molecular mechanisms associated with viral immunopathogenesis.

Descriptions: Delineate the direct and indirect mechanisms underlying HIV-induced depletion and dysfunction of target cells/tissues;

Define the virologic (load and phenotype), immunologic (specific and nonspecific), genetic, and environmental factors that contribute to disease progression and nonprogression;

Delineate the molecular mechanisms by which virus-derived factors regulate HIV replication and pathogenesis, with special emphasis on the use of primary virus isolates and cells;

Delineate the role of immune activation and host factors, including cytokines, in HIV replication and pathogenesis;

Delineate the role of lymphoid organs, including mucosal-associated lymphoid tissue, in HIV pathogenesis;

Further develop and utilize experimental models to examine the pathogenesis of lentiviral infections;

Delineate the role of lymphoid and hematopoietic precursor cells and their microenvironment in immune impairment;

Develop new assay systems for effective measurement of changes in viral load and host immune function that are predictive of disease progression;

Delineate the range of cell types infected by HIV *in vivo* and their potential role as viral reservoirs; and

Establish and expand collaborative programs to facilitate sharing of key patient samples, animal model resources, and laboratory reagents.

Objective 2: Support research to enhance understanding of HIV-related immune dysfunction.

Action Steps: Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression.

Descriptions: Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection;

Determine the impact of early events in the establishment of HIV infection on the clinical course of disease;

Determine the cell or tissue type that serves as the portal of entry of HIV and the impact of STDs and other pathogenic processes that influence HIV transmission;

Determine the effects of viral genotype and load on transmission of cell-free and cell-associated virus;

Determine the roles of specific and nonspecific mucosal immunity and host factors that inhibit/enhance HIV transmission;

Determine the mechanisms of vertical HIV transmission; and

Elucidate unique aspects of HIV transmission and disease progression in underresearched populations.

Objective 3: Support research to enhance understanding of HIV-related malignancies.

Action Steps: Elucidate the etiologic factors and cofactors in the pathogenesis of HIV-related malignancies.

Descriptions: Elucidate the role of HIV infection, immune dysfunction, and interactions with potential cofactors in the development of HIV-associated malignancies;

Identify the characteristics of the host that predispose to development of malignant disease, including genetic, hormonal, growth factor, cytokine, and immunologic characteristics; and

Identify the molecular correlates of HIV-associated malignancies, including but not limited to oncogenes, tumor suppressor genes, tumor promoters and carcinogens, and viral and microbial genes and proteins.

Objective 4: Support research to enhance understanding of HIV-related neuropathogenesis.

Action Steps: Elucidate the pathogenic mechanisms involved

in HIV-associated neurological diseases.

Descriptions: Investigate the contributions of viral infection and virally induced indirect factors (in neuronal and non-neuronal cells) to nervous system impairment;

Delineate how HIV enters and persists in the nervous system and causes functional impairment;

Investigate both biological and environmental factors that may affect nervous system function in the context of HIV disease;

Study the effects of neurotrophins and immunoregulatory and proinflammatory cytokines on both host and viral gene expression;

Delineate the role of OIs and drug treatment in neurologic complications of AIDS, including peripheral neuropathies, hearing and visual loss, and behavioral changes;

Assess neural tissue and organs as virus reservoirs in HIV disease and as sources of specifically neurovirulent/neuroinvasive viral strains; and

Develop neuroimaging tools for correlative structural-functional studies of progressive HIV-associated neurological disorders.

Objective 5: Support research to enhance understanding of HIV-related opportunistic infections.

Action Steps: Elucidate the pathogenesis of HIV-related opportunistic infections.

Descriptions: Investigate the mechanisms of immune function that mediate protection against the OIs;

Develop *in vitro* techniques and animal models, where needed, to propagate the opportunistic micro-organisms and conduct studies designed to provide details of the basic biology and pathogenic mechanisms of these micro-organisms;

Identify and elucidate the genetic and environmental risk factors associated with susceptibility, development, and progression of opportunistic infections;

Develop and validate diagnostic assays for the reliable and rapid identification of HIV-associated opportunistic infections;

Study the effects of OIs on immune dysfunction; and

Elucidate immunologic markers that are correlative with

disease progression for HIV-associated OIs and develop assays to accurately monitor these markers as a function of therapy.

Objective 6: Support research to enhance understanding of HIV-related wasting syndrome.

Action Steps: Elucidate the etiology and pathophysiology of HIV-related wasting, failure to thrive, and growth retardation.

Descriptions: Define alterations in body composition, nutritional status, metabolic patterns, energy balance, and growth and development associated with HIV infection; and

Elucidate the pathogenesis of HIV-associated wasting and impaired growth and development, including the roles of cytokines, malabsorption, anorexia, opportunistic infections, HIV, and other factors.

Objective 7: Support research to enhance understanding of HIV-related organ and tissue disorders.

Action Steps: Elucidate the etiology and pathogenesis of HIV-related organ/tissue-specific disorders, such as HIV-associated renal, gastrointestinal, endocrine, cardiopulmonary, autoimmune, and other diseases

Descriptions: Investigate the etiologic and pathogenic mechanisms of HIV-associated enteropathy, including the role of HIV, opportunistic infections, tumors, and other factors;

Identify host, viral, environmental, and other factors responsible for the pathogenesis and progression of HIV-associated nephropathy;

Elucidate the etiology and pathogenesis of endocrine dysfunction and the role of alteration in the endocrine/immune axis in progression of HIV disease; and

Elucidate the etiology and pathogenesis of HIV-related cardiopulmonary disease and other organ/tissue-specific manifestations, including autoimmune disease.

FY 95: 345,663,000
FY 96: 374,767,000

Pops. Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $46,216 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Provide support for training and infrastructure to carry out HIV-related research.

Objective 1: Meet the training needs of HIV/AIDS researchers.

Action Steps: Provide both domestic and international training in biomedical and behavioral research on HIV.

Descriptions: Increase predoctoral and postdoctoral training, as well as advanced research training, in a range of AIDS-related disciplines to a level comparable to that of other training programs within the NIH;

Sponsor an annual AIDS Fellows Meeting to promote collaboration and information dissemination;

Increase training of scientists and clinical investigators in basic AIDS research to better link basic and clinical pathogenesis research;

Stimulate predoctoral and postdoctoral training in prevention, behavior change, and adherence and compliance to treatment;

Promote training of biomedical and behavioral scientists in the use of high-performance computing systems for HIV-related research;

Expand training and research capacity to deal with the epidemic of tuberculosis (TB), including multiple drug resistance associated with HIV infection;

Increase participation in the Fogarty International Center (FIC)-sponsored international training and research programs and expand these programs by recruiting trainees from additional countries in Asia and Latin America, with the long-term goal of providing AIDS-related training for leading health scientists from all developing countries;

Develop new grant mechanisms to link leading U.S. AIDS research scientists and institutions with leading AIDS research scientists and institutions in foreign countries;

Expand both predoctoral and postdoctoral training in structural biology; and

Expand the NIH AIDS Loan Repayment Program to bring scientists and physicians to the NIH to expand the cadre of trained intramural researchers.

Objective 2: Meet the resource needs of HIV/AIDS researchers.

Action Steps: Establish appropriate infrastructure for the conduct of HIV research domestically and internationally.

Descriptions: Provide additional facilities to study animal models of pediatric AIDS;

Foster animal models to study HIV-related malignancies;

Continue the Research Facilities Infrastructure Program (RFIP) and General Clinical Research Centers (GCRC) Program;

Expand the use of the National Research and Education Network (NREN) for national and international collaboration and data communications;

Provide for expansion of breeding facilities to ensure the adequate supply of species of emerging importance;

Provide NCRR animal model support tied to needs of basic research grants;

Provide for the long-term support of advanced in-country research and research infrastructure in those developing countries participating in efficacy trials of candidate HIV vaccines and other priority intervention research;

Develop and support animal models predictive of human behavior, specifically, models of non-human primate behavior of impaired impulse control and risk-taking;

Provide additional laboratory and biocontainment facilities for primate research;

Increase support for the Internet connections program at health sciences centers and hospitals for research and patient care;

Establish and support repositories of samples obtained from individuals with HIV infection for current and future studies;

Increase support for screening for the development of HIV macaque monkey models;

Develop and support Regional Primate Research Center (RPRC) expertise in molecular immunology, peptide biochemistry, and pharmacology;

Provide for the establishment of specific pathogen-free (SPF) non-human primate programs at all the RPRCs; and

Provide further support for the development of SPF macaque

colonies.

FY 95: 40,836,000
FY 96: 42,558,000

Populations Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $16,145 over the FY 96 figure.

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: National Institutes of Health

Goal: Develop and support programs for the dissemination of research information to health care providers.

Objective: Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences.

Action Steps: Develop and rapidly disseminate important research findings that have immediate impact on prevention, health care, and treatment of HIV-infected individuals, utilizing all NIH, PHS, and public media communications modes.

Descriptions: Provide up-to-date information on eligibility criteria for entry into clinical trials, results of trials, and relevant research findings through the AIDSTRIALS and AIDSDRUGS databases as well as the AIDS Clinical Trials Information Service;

Maintain an interface with the Cancer Information System and PDQ to provide information on clinical trials for AIDS-related malignancies;

Collaborate with other agencies of the PHS and outside organizations to determine the information needs in the biomedical and behavioral research community and identify appropriate mechanisms for dissemination;

Provide online access to the full-text guidelines for state-of-the-art care;

Continue support of community, regional, national, and international conferences and workshops to facilitate the exchange of scientific information;

Provide support for NIH-sponsored annual meetings on pathogenesis, vaccines, and drug development;

Collaborate with public and health sciences libraries to facilitate access to needed information by community groups;

Disseminate results of behavioral research studies to collaborating centers and service providers for use in planning, designing, and implementing preventive intervention strategies;

Continue support for and development of the International Network for AIDS Research and Training;

Explore collaborations with the World Health Organization (WHO), the Pan American Health Organization (PAHO), and international AIDS agencies to obtain and disseminate information about international clinical trials;

Develop and improve user-friendly information systems and services in HIV/AIDS and provide training for them;

Provide the full text of abstracts from meetings, where available, online before scientific meetings;

Collaborate with the WHO, the PAHO, and UNAIDS to develop the Global HIV/AIDS Network, a computerized AIDS information system; and

Working with community groups, develop educational materials to foster the dissemination of information about research and the clinical trials process to primary care providers, community-based HIV/AIDS service organizations, and persons with HIV/AIDS.

FY 95: 15,400,000
FY 96: 16,115,000

Populations Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $2,412 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Develop and evaluate vaccines for prevention of HIV transmission and infection.

Objective 1: Enhance understanding about host defense mechanisms and protection against HIV infection and disease.

Action Steps: Support research on protective immune responses.

Descriptions: Develop nonhuman primate and other animal models for HIV vaccine evaluation; determine immune responses that affect infection and disease course; focus on chronic infection with attenuated virus versus wild-type virus; determine why disease does not occur or is delayed in some models;

Determine the correlates of immune protection against, and immunologically mediated control of HIV;

Study acutely infected individuals, exposed/uninfected humans (and other primates), and rapid/nonprogressors to determine viral and host factors that impact clearance of circulating virus and disease course; ensure that plasma, PBMC, biopsy, autopsy, and other key patient and animal samples, including CNS samples, are accessible to qualified laboratories;

Elucidate the three-dimensional structure of viral epitopes and determine the mechanism of escape from antibody-mediated neutralization and recognition by cytotoxic T cells;

Define conserved viral epitopes that are potentially relevant to protective immune responses; devise strategies to enhance their immunogenicity;

Determine the molecular nature of HIV genetic and antigenic diversity and incorporate the findings into ongoing vaccine development; focus on characterization of HIV at potential efficacy trial sites;

Foster multidisciplinary approaches that bridge basic, animal, and clinical approaches; and

Develop quantitative measures of HIV concentration in bodily fluids to determine whether there is a relationship between HIV concentration and transmission.

Objective 2: Identify strategies for eliciting protective immune responses.

Action Steps: Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models.

Descriptions: Develop further multidisciplinary approaches for the design and development of potential vaccine candidates; expand research on mucosal delivery and stimulation of mucosal immune responses;

Include research on but not limited to: whole-particle designs such as whole-killed HIV and genetically engineered, noninfectious HIV mutants that lack the viral RNA genome or have a defect in a critical protein but contain a full complement of HIV antigenic proteins; live, recombinant viral and bacterial vectors engineered to express one or more HIV proteins; genetically engineered, live-attenuated strains of HIV; synthetic peptide candidates capable of inducing and boosting both cellular and humoral immunity; DNA candidates as HIV vaccines; combination strategies including priming and boosting;

Evaluate vaccine strategies in AIDS animal models;

Encourage development of candidate vaccines suitable for domestic and international use;

Conduct research on adjuvants and novel formulations that have a qualitative or quantitative impact on immunologic responses to vaccine candidates;

Evaluate strategies to decrease or eliminate HIV from sexual fluids; Characterize and evaluate the potential negative side effects of candidate vaccines, including production of enhancing antibodies and neurotoxicity; and

Develop methodologies for comparative *in vitro* measure of immune function.

Objective 3: Evaluate efficacy of vaccine candidates.

Action Steps: Identify appropriate domestic and international populations and develop infrastructure, and develop behavioral research and community education and outreach activities, that are necessary for ensuring adequate performance of Phase III efficacy clinical trials.

Descriptions: Prepare for adequate followup of individuals participating in vaccine clinical trials to determine the longevity of immune response, the correlates of immune protection, long-term safety, the impact of participation on risk-taking behavior, and the possible positive or negative effects of vaccine immunization against disease progression and HIV transmission;

Utilize infrastructures established for the conduct of AIDS vaccine efficacy trials to implement prevention research activities designed to determine the efficacy of other biomedical or behavioral interventions that could prove of benefit in decreasing the incidence of HIV infection in the population; evaluate promising interventions separately and/or as a component of prophylactic vaccine efficacy trials;

Continue appropriate epidemiologic studies that determine the risk profiles and infection rates of various populations in the United States and internationally in order to identify those groups most likely to be the participants in vaccine trials;

Maintain and expand the AIDS Vaccine Clinical Trials Network to include domestic and international sites with access to populations at high risk for acquiring HIV infection and where vaccine or other prevention research activities may be feasible;

Maintain the necessary laboratory and epidemiologic research infrastructure at designated sites for conducting domestic and international vaccine efficacy trials; develop optimal assays to distinguish infection from seroconversion to the vaccine;

Acquire and analyze HIV isolates from recent seroconverters representative of potential efficacy trial populations so that genetic and antigenic information about virus circulating in the population can be obtained;

Conduct behavioral research in populations at high risk for HIV infection, particularly those difficult-to-reach populations that have been historically underrepresented in clinical trials; determine optimal education, risk-reduction intervention, recruitment, adherence, and retention approaches and estimate behavior changes and other factors pertinent to the design and execution of a successful efficacy trial;

Establish linkages with communities or community organizations where efficacy trials might be conducted to optimize education, recruitment, and followup activities and to help address community concerns related to AIDS vaccine efficacy trials;

Link infrastructure development and vaccine research activities in high-risk populations with other prevention and treatment research activities in these populations, including research on TB and STDs;

Conduct research to determine optimal methods of achieving truly informed consent; and

Conduct research to determine possible adverse social, economic, or legal consequences of participation in clinical trials and develop strategies to mitigate potential harm.

Objective 4: Develop a preventive vaccine for newborns and infants.

Action Steps: Identify mechanisms of protective immunity to HIV in newborns and infants and develop a safe and effective immunologic strategy to prevent HIV infection in this population.

Descriptions: Evaluate genetic and antigenic variation in viruses transmitted from mothers to infants and in maternal isolates that are not transmitted;

Accelerate studies of maternal-infant transmission;

Develop and maintain domestic and international infrastructure necessary to enroll mothers and infants in prospective long-term followup vaccine trials;

Determine the immunogenicity of various vaccines and adjuvants in newborns and infants;

Determine which maternal and infant immune responses are associated with nontransmission of HIV;

Identify antibody preparations for use as passive or passive/active HIV prevention;

Establish criteria for advancement of candidates in Phase I, Phase II, and Phase III clinical trials; and

Conduct Phase I, Phase II, and Phase III clinical trials of the most promising candidates that meet established criteria.

Objective 5: Indentify promising vaccine candidates for efficacy trials.

Action Steps: Develop criteria for selection of suitable candidate vaccines, support appropriate infrastructure, and conduct Phase I and Phase II trials.

Descriptions: Utilize vaccine selection committees to carefully evaluate promising candidates; emphasize need for thorough consideration of efficacy in animal models;

Conduct Phase I and Phase II clinical trials that will determine safety and delineate comparative immunologic analysis of candidates for preventive vaccines; expand immunologic measurements to include a broad range of cell-mediated and mucosal immune responses;

Conduct Phase II trials in high-risk individuals of the most promising preventive vaccine candidates or combinations that proved promising in Phase I trials conducted in low-risk individuals and that have genetic or immunologic relatedness to HIV isolates circulating in the proposed trial population;

Support and maintain the AIDS Vaccine Evaluation Groups;

Closely coordinate the evaluation of research findings on prophylactic AIDS vaccines with research on therapeutic AIDS vaccines, e.g., the use of candidate vaccines to ameliorate disease when administration is initiated after establishment of chronic infection;

Acquire and analyze HIV isolates from recent seroconverters representative of Phase I and Phase II trial populations so that genetic and antigenic information about viruses circulating in the population can be obtained; and

Conduct behavioral research pertinent to preparation for Phase III trials.

Objective 6: Conduct vaccine efficacy studies.

Action Steps: Establish criteria for selection of suitable vaccine candidates and conduct Phase III clinical trials when established criteria are met.

Descriptions: Establish criteria with concurrence of an advisory group that has the requisite scientific, public health, government, and community expertise;

Conduct large-scale efficacy trials of novel preventive vaccine candidates that have proven promising, safe, and immunogenic in Phase II trials and that meet established criteria;

Evaluate HIV vaccine candidate efficacy;

Evaluate multiple scientific hypotheses; and

Ensure that trials are conducted with the highest regard for social and ethical concerns of the participants.

FY 95: $111,831,000
FY 96: $118,128,000

Pops. Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $36,643 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Develop and evaluate therapies for HIV infection and its sequelae.

Objective 1: Identify and develop novel anti-HIV therapies.

Action Steps: Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry.

Descriptions: Identify promising targets for anti-HIV therapy and extend knowledge of their mechanisms of action, develop assays for identifying drugs active against those targets, and develop new compounds active at those targets, with an emphasis placed on identifying agents active at novel targets;

Complete preclinical development, in cooperation with industry when appropriate, of promising new compounds and combinations of compounds and novel natural products, including assessment of efficacy, toxicity, teratogenicity, and fertility in animal models;

Continue and accelerate screening of large numbers of natural and synthesized compounds for anti-HIV activity in the AIDS Drug Screen, with a particular emphasis on the detection of agents active against novel targets; develop and screen combinatorial libraries; emphasize central nervous system penetration; develop formulations that would be suitable for infants and children;

Emphasize basic and applied research to advance cross-NIH development of gene therapy; support development of preclinical laboratories to advance gene therapies;

Determine the high-resolution molecular structures for several of the HIV proteins and apply these structures to the rational design of drugs as part of the targeted drug development program; determine generalizable and effective approaches for the use of macromolecular structure in designing drugs to combat HIV infection and AIDS; make resolved structures available in publicly accessible data bases;

Increase understanding of the mechanisms and limitations of drug resistance; study the effect of various agents on HIV replication and viral variation; evaluate early markers of resistance; evaluate the activity of anti-HIV drugs in various cell types (including macrophages) and in various stages of the cell cycle; and

Develop new compounds capable of inhibiting the sexual transmission of HIV, such as topical microbicides (which may inhibit HIV and STDs associated with enhanced HIV transmission), HIV-specific viricides, and systemic agents.

Objective 2: Develop and evaluate anti-retroviral therapies.

Action Steps: Perform clinical trials of agents active against HIV based on an understanding of pathogenesis, emphasizing emphasis on improved design and methodologies, and integrating clinical trials with ongoing natural history studies.

Descriptions: Support and improve clinical trials of potential therapeutic agents and combinations of agents in studies to determine pharmacokinetics and bioavailability and evaluate anti-HIV combinations that are non-cross-resistant, synergistic, and toxicity-sparing and that may delay development of drug-resistant HIV strains; enhance collaboration between and within ICDs to facilitate opportunities for clinical trials;

Increase the understanding of the pathogenesis of HIV disease based on the evaluation of antiretroviral agents in clinical trials;

Implement the development and evaluation of virologic, immunologic, and clinical markers to assess drug activity and determine the prognostic value of these markers in response to therapeutic interventions;

Support research and development of clinical trials methodology and study design so that appropriate pathways are taken rapidly to evaluate the activity, clinical efficacy, and the ultimate acceptability of new agents and approaches that translate into clinical use;

Improve the utilization of GCRCs for the conduct of single and multi-institutional clinical trials;

Develop and validate quality-of-life parameters included in patient assessments of clinical trials;

Support research on the effectiveness of pharmacologic (including compliance with therapies and STD prevention) and non-pharmacologic (including psychosocial) interventions (including nutritional factors and adherence improvement);

Investigate possible interactions between therapies for HIV-related disease and other substances that HIV-infected individuals might use, such as drug abuse treatment medications, oral contraceptives or other prescription drugs, nonprescription drugs, alternative or complementary

therapies, or drugs of abuse;

Coordinate studies to encourage co-enrollment of patients on all trials where appropriate;

Develop a coordinated plan to evaluate long-term therapeutic strategies, e.g., develop plans for long-term followup, enroll patients in sequential randomized trials once they have reached an end point in their initial trial; and

Evaluate new and existing compounds capable of inhibiting the sexual transmission of HIV, such as topical microbicides and HIV-specific viricides; nested studies to evaluate the infectivity of body fluids, such as semen and cervical secretions in trials of antiretroviral therapies.

Objective 3: Develop and evaluate immune-restoring therapies.

Action Steps: Extend our understanding of immunopathogenesis through the development and testing of strategies that enhance and/or restore the deficient immune systems of HIV-infected individuals.

Descriptions: Evaluate therapeutic approaches that test specific hypotheses of HIV immunopathogenesis;

Develop and validate new methods to evaluate immune function in the context of clinical trials;

Continue and accelerate the testing of cytokines and modulators of cytokines either alone or in combination with antiretroviral agents for the purpose of reconstituting the deficient immune systems of HIV-infected individuals;

Develop and evaluate various approaches of active and passive immunotherapy for both HIV infection and its sequelae;

Develop a program of reconstituting the immune systems of HIV-infected individuals by administration of cellular elements in an autologous, syngeneic, or allogeneic fashion, including use of expanded peripheral blood T cells, bone marrow transplantation, thymic transplantation, cord blood, stem cells, and/or xenogeneic transplantation;

Develop new therapeutic strategies based on gene therapy approaches to protect or potentially reconstitute the immune system;

Use structural biologic techniques to determine the structures of various cytokines and cytokine receptors as potential targets for HIV therapies; and

Enhance collaboration among ICDs to facilitate the conduct

of immune-based therapeutic trials and to enhance pathogenesis-related research in HIV-infected individuals.

Objective 4: Develop and evaluate therapies for HIV-related opportunistic infections.

Action Steps: Target the discovery, development, and evaluation of potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection, including those specific to women, children, and drug users.

Descriptions: Support discovery and preclinical programs to develop therapies especially targeting cryptosporidia, microsporidia, JC virus, CMV, HPV, and azole-resistant fungal organisms, with emphasis on bioavailable agents with favorable pharmacokinetics. Develop *in vitro* culture systems for OIs;

Further conduct clinical trials for the prophylaxis and treatment of HIV-associated OIs in HIV-infected individuals, including pregnant women and children and drug users. Evaluate immune-based therapies as adjuncts for treating OIs;

Determine the optimal strategies and combinations of agents to prevent and treat multiple OIs (i.e., multiple opportunistic pathogen prophylaxis studies [MOPPS]), and their effects in combination with antiretroviral agents.

Develop and utilize animal models for preclinical efficacy and safety testing of potential agents for OIs, including mutagenicity and teratogenicity;

Develop clinically useful assays for the rapid diagnosis, treatment response, and sensitivity testing of OIs;

Support training of basic investigators, clinical investigators, and translational investigators for OI research; and

Determine the role and capability of preexisting immunity (both induced and natural) to control OI infections and the ability of HIV-infected individuals to respond to vaccination throughout the course of infection and disease.

Objective 5: Develop and evaluate therapies interventions to block perinatal transmission.

Action Steps: Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child.

Descriptions: Support the rapid translation of basic

research observations to strategies for the interruption of vertical transmission; apply the results of clinical trials to the investigation of pathogenesis and to clinical practice;

Develop strategies and agents to interrupt the vertical transmission of HIV from pregnant women to their offspring; explore the potential of combined strategies; evaluate the safety, toxicity, pharmacokinetics, and antiretroviral activity of anti-HIV agents in pregnant women and newborns;

Expand the obstetrical and pediatric infrastructure for the conduct of perinatal trials through collaborative efforts, both national and international;

Support the long-term followup of all women and children who participate in perinatal trials to evaluate potential distant effects of antiretroviral agents and/or biologicals;

Investigate the role of the placenta in transmission of anti-HIV drugs from mother to fetus;

Develop and improve sensitive and specific diagnostic parameters that are cost-effective to permit early differentiation of HIV-infection status in children born to HIV-infected mothers;

Assess the potential efficacy and feasibility of obstetric interventions to prevent vertical transmissions, such as cesarean deliveries and other aspects of intrapartum care;

Evaluate the risk of vertical transmission of drug-resistant virus; and

Evaluate factors that contribute to or protect against vertical transmission; develop effective strategies that could more easily be afforded globally to help reduce vertical transmission and perhaps decrease transmission via breast milk.

Objective 6: Develop and evaluate therapies for HIV-related malignancies.

Action Steps: Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis.

Descriptions: Identify novel mechanisms and targets (e.g., cytokines, angiogenesis, viral or hormonal cofactors) for treatment and prevention of HIV-associated tumors, including Kaposi's sarcoma, non-Hodgkin's lymphoma, HPV-associated malignancies, and others, and develop new therapeutic strategies on the basis of these findings;

Use structural biologic and biochemical information to rationally design drugs to inhibit specific pathogenic factors of HIV-associated malignancies;

Encourage the development and coordinate the conduct of clinical trials that concurrently evaluate therapeutic strategies directed against the malignancy with anti-retroviral and anti-OI strategies in order to assess the effects of such treatment on the malignancy as well as on the underlying HIV infection, immune function, and clinical course;

Continue and expand screening, discovery, and development of novel therapeutic agents with activity against HIV-associated malignancies;

Develop trials to optimize existing therapies for malignancies in HIV-infected patients;

Encourage collaborative studies to develop mechanisms for early identification of patients at high risk for malignancy and to develop and assess interventional strategies to reduce or prevent the development of malignancies;

Support training of basic investigators, clinical investigators, and translational scientists for research of malignancies in HIV-infected patients;

Improve diagnostic methods for early diagnosis of malignancies and for early detection of recurrent cancer;

Coordinate referral of patients with malignancy end points on other studies to malignancy trials; and

Improve collaboration between various adult and pediatric cooperative groups conducting clinical trials of HIV-associated malignancies and ICDs and industry to accelerate trials completion and approval of active agents.

Objective 7: Develop and evaluate therapies for HIV-related neurologic disease.

Action Steps: Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection.

Descriptions: Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction;

Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop

strategies directed at the prevention and treatment of this complication of HIV infection;

Implement clinical trials addressing nervous system complications of HIV infection and incorporate neurologic assessments into other HIV-related clinical trials;

Develop therapeutic agents that are capable of crossing the blood-brain barrier and are active against HIV infection in relevant cells in the CNS; develop an understanding of mechanisms involved in penetration of the blood-brain barrier;

Better delineate etiologies of peripheral neuropathy in HIV infection, and develop strategies to prevent and treat this complication;

Develop and utilize *in vitro* and animal models of CNS impairment and ADC to further identify agents that can reverse HIV neuropathogenesis; and

Implement assessments and approaches for the diagnosis of HIV-related dementia in clinical studies.

Objective 8: Develop and evaluate therapies for HIV-related complications.

Action Steps: Develop an understanding of HIV-associated complications, including wasting syndrome, growth failure, metabolic disorders, dermatologic disorders, ITP, nephropathy, oral diseases, and other symptoms and serious complications.

Descriptions: Develop and evaluate therapeutic strategies to ameliorate the various sequelae of HIV infection based on an increased understanding of pathogenesis;

Develop and evaluate therapeutic strategies for alleviating the various symptoms of unclear etiology in HIV-infected persons and improving the quality of life; and

Develop and validate quality-of-life parameters for the various sequelae of HIV infection.

FY 95: 473,262,000
FY 96: 495,839,000

Populations Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for

Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $49,566 over the FY 96 figure.

PREVENTION

Agency: National Institutes of Health

Goal: Prevent new HIV infections through behavioral interventions.

Objective 1: Enhance understanding of determinants of HIV-related behavior.

Action Steps: Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change

Descriptions: Support studies to develop models of behavioral, social, cultural, cognitive, and psychological mechanisms and processes that determine the acquisition, maintenance, and change of HIV-related behaviors in individuals and groups in various populations and settings;

Identify processes that exacerbate or minimize adverse consequences of HIV infection for the individual, group, and community;

Support basic behavioral and social research on factors that shape and change social norms concerning HIV-related behavior and their influence on individual behaviors;

Develop and improve methods to obtain and analyze valid and reliable data on HIV-related behaviors; and

Study the process of information diffusion; understanding this process is necessary for effective communication of HIV-related knowledge.

Objective 2: Develop behavioral and social science research intervention strategies.

Action Steps: Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.

Descriptions: Develop and evaluate demographically and culturally appropriate behavioral and social interventions based on the changing epidemiology of HIV in different populations and on the incidence, frequency, and change in high-risk HIV-related behaviors; international comparisons are essential for identifying effective interventions;

Support multidisciplinary research on behavior change strategies that target the sustained adoption and maintenance of HIV preventive behaviors (e.g., increase use of condoms, virucides, spermicides, and sterile injection

drug equipment);

Support research on increasing the effectiveness of drug abuse, mental health, and alcoholism treatment for reducing HIV risk behavior;

Design and test interventions to increase the recruitment, retention, and adherence to protocols for adopting and maintaining low-risk behavior in prevention research, including vaccine studies; and

Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.

Objective 3: Assess innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.

Descriptions: Develop and test innovative dissemination strategies for promoting adoption of successful (empirically tested) behavior change interventions by HIV prevention providers;

Develop, test, and rapidly disseminate research findings that have immediate implications for the conduct of HIV prevention and education programs conducted in the community; explore novel mechanisms to disseminate behavioral and social science research findings and model approaches to the prevention field (e.g., consensus conferences, interactive computer bulletin boards, media strategies, and mechanisms to reach providers and community-based organizations);

Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bi-directional exchange of information and experience to enhance research and prevention efforts; and

Utilize new and innovative techniques (e.g., social marketing) to disseminate research to different populations.

Objective 4: Prevent the negative consequences of HIV Infection.

Action Steps: Discover, develop, and evaluate strategies to prevent or minimize the physical, psychological, cognitive, and social consequences of HIV, including strategies to improve adherence to proven therapies and recruitment, retention, and adherence to clinical trial protocols.

Descriptions: Identify the behavioral, psychological, cognitive, and social consequences of HIV disease for HIV-seropositive individuals, their support systems, and their communities; develop and evaluate innovative behavioral and social approaches to manage these consequences, including health behavior changes, stress management, and improved access and utilization of care;

Discover, implement, and evaluate therapeutic strategies to delay or prevent progression of HIV-associated cognitive dysfunction;

Develop and evaluate interventions to increase recruitment, adherence, and retention in HIV treatment studies and clinical trials; and

Develop and test models of caregiving tailored to the physical, cognitive, and emotional needs of patients with HIV disease, including their significant others, extended family members, and care providers.

Objective 5: Create and test innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications

Descriptions: Develop and test innovative dissemination strategies for promoting adoption of successful (empirically tested) behavior change interventions by HIV prevention providers;

Develop, test, and rapidly disseminate research findings that have immediate implications for the conduct of HIV prevention and education programs conducted in the community; explore novel mechanisms to disseminate behavioral and social science research findings and model approaches to the prevention field (e.g., consensus conferences, interactive computer bulletin boards, media strategies, and mechanisms to reach providers and community-based organizations);

Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bi-directional exchange of information and experience to enhance research and prevention efforts; and

Utilize new and innovative techniques (e.g., social marketing) to disseminate research to different populations.

Objective 5: Strengthen the behavioral and social science infrastructure.

Action Steps: Develop multidisciplinary and interagency collaborative efforts to enhance the AIDS behavioral research effort; enhance the behavioral aspect of research into therapeutics, natural history and epidemiology, and vaccines. Train researchers to conduct basic and applied social science research related to HIV. Provide the state-of-the-art physical facilities and equipment that are necessary to conduct HIV-related behavioral and social science research within relevant settings

Descriptions: Establish multidisciplinary AIDS research consortia to test novel behavioral approaches, replicate psychosocial and behavioral studies, and promote their use in appropriate populations; collaborate with other agencies of the PHS and outside organizations to maximize research resources;

Promote HIV-related research in predoctoral and postdoctoral programs; facilitate the development of *practica* and field placements in HIV treatment, prevention, and research settings; provide research career awards; actively recruit ethnic minorities, women, and those dedicated to community-based programs; expand behavioral and social training and research efforts aimed at limiting infections such as TB and malignancies related to HIV infection;

Ensure adequate representation of social and behavioral scientists on IRGs, OAR Advisory Committees, and OAR staff;

Support and expand computer networking among behavioral and social science researchers; provide additional laboratory and research facilities for human and animal research for behavioral studies; and

Collect, archive, and disseminate existing data for secondary data analysis.

FY 95: 159,720,000
FY 96: 161,595,000

Pops. Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $44,298 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Improve understanding of the natural history and epidemiology of HIV infection and AIDS in all populations.

Objective 1: Collect natural history and epidemiological data to further understanding of HIV transmission and progression.

Action Steps: Develop and assess intervention strategies to assist in the development of treatment and prevention interventions.

Descriptions: Support development and evaluation of improved, acceptable, effective physical and non-irritating chemical barrier methods and conduct research on existing barrier methods to prevent sexual transmission of HIV and STDs;

Develop strategies and conduct studies to evaluate vaccines, drugs, and other interventions such as cesarean sections, vaginal cleansing, and breast-feeding practices that prevent perinatal transmission;

Assess the efficacy of combined strategies that decrease blood-borne transmission of HIV; for example, evaluating existing needle exchange programs, the use of bleach as a disinfectant, and drug abuse prevention and treatment on reducing HIV transmission and seroincidence;

Develop domestic and international cohort-based infrastructures for testing HIV vaccines and other interventions (e.g., microbicides, behavioral) for preventing HIV transmission;

Develop and evaluate interventions related to sexual behavior, including (1) STD treatment and prevention and their effects on HIV transmission, (2) interventions focused on influencing safe sexual behaviors, reproductive decision-making, and contraceptive choices for women, and (3) integration of health care delivery systems such as those that combine reproductive health and STD/HIV prevention and treatment services;

Develop methods of outreach that would engage high-risk populations, enroll them in research to identify factors that contribute to high-risk behavior, and increase and maintain compliance with interventions as well as recruit and retain hard-to-reach populations in studies;

Incorporate interdisciplinary evaluation research designs of HIV prevention strategies to ensure adequacy of findings

regarding outcome, process, and descriptive analysis;

Evaluate the social acceptability, the ease of compliance, and barriers to access and use of interventions (e.g., AZT for perinatal transmission, virucides);

Develop and evaluate improved procedures for screening, monitoring, and inactivating HIV and other retroviruses in the blood supply; and develop and evaluate alternatives to allogeneic blood transfusion, including artificial blood substitutes and hematopoietic growth factors; and

Assess the impact of drug and alcohol abuse on efficacy of behavior modification interventions directed at sexual transmission.

Objective 2: Examine the role of risk factors and mechanisms of HIV transmission to assist in the development of biologically- and behaviorally-based interventions.

Action Steps: Characterize the risk factors and mechanisms of HIV transmission in various populations.

Descriptions: Evaluate HIV transmission in relationship to:

a. viral factors, virus load in the blood and at mucosal sites, characteristics of the HIV virus present (virus subtype and phenotype), and co-infection with other viruses (HTLV and HIV2);

b. host factors such as pregnancy, menstrual cycle, hormonal contraceptives, and HLA type;

c. local factors including intercurrent STDs, oral and anogenital inflammation (ulceration), mucosal immunity, and anatomic factors such as ectopy; and

d. behavioral risk factors, such as oral and anal sex;

Further differentiate the timing and mechanism of perinatal transmission;

Study susceptibility to HIV infection, especially in individuals who are at high risk for repeated exposure to HIV but who remain uninfected, in order to determine factors related to resistance, including mucosal immunity, viral, genetic, and other immunologic factors, endocrinologic factors, and other factors;

Determine the role of breast-feeding in the transmission of HIV from infected mother to child; and

Examine the extent to which drug use (including alcohol and tobacco) and drug-using behaviors affect susceptibility

and/or transmission of HIV.

Objective 3: Enhance understanding of HIV-related disease progression to assist in the development of effective treatment strategies for HIV-infected patients.

Action Steps: Elucidate the progression of HIV-related disease, from early infection through long-term consequences and sequelae, with the goal of understanding, preventing, and treating those factors that may lead to disease

Descriptions: Identify pathogenic mechanisms and cofactors for disease progression and disease-specific outcomes in well-defined subsets of individuals (e.g., high-CD4 long-term survivors, low-CD4 long-term survivors, rapid progressors). Studies should include investigation of behavioral, genetic, virologic, immunologic, and host factors;

In diverse populations, describe the full spectrum of HIV-related disease, including OIs, HIV-related malignancies, wasting, and organ-specific complications; evaluate the impact of sociodemographic variables, gender, age, and route of transmission on HIV disease progression, time to AIDS, and specific outcomes;

Study the natural history of early HIV infection;

Evaluate issues specific to HIV-infected children, including: (1) mechanisms that contribute to impaired growth and neurodevelopment, (2) impact on childhood infectious diseases and the safety and efficacy of immunization, and (3) childhood-specific complications including lymphoid interstitial pneumonitis;

Evaluate the interaction of hormonal factors (including pregnancy, contraceptives, and hormonal replacement therapy) and HIV disease progression;

Maintain longitudinal cohorts and create linkage with clinical studies (e.g., ACTG, CPCRA) to (1) efficiently examine the full spectrum of disease, (2) assess the impact of therapies on the frequency and severity of HIV-related sequelae, disease progression, and survival, and (3) assess and validate laboratory and behavioral markers;

Study the progression of HIV-related disease in adolescents;

Study the factors that predict, protect against, contribute to, or limit the progression of HIV infection in the nervous system including early cognitive impairment, dementia, and neuropathy;

Develop, maintain, and expand national repositories for the collection and banking of blood, other body fluids, and tissue specimens obtained from longitudinal cohort studies and other well-characterized populations of HIV-infected individuals as a resource for studies of HIV-mediated pathogenesis, correlates of immunity to HIV infection, and specific HIV-related outcomes;

Study the nutritional and absorption factors that predict, protect against, contribute to, or limit the progression of HIV-related wasting and weight loss;

Evaluate strategies of care delivery and case management to determine their impact on HIV disease progression and quality of life;

Elucidate the mechanisms of HIV-associated carcinogenesis and improve strategies for early diagnosis and for effectively treating these malignancies;

Study oral lesions in HIV disease and progression; and

Study the long-term natural history of related retroviruses (e.g., HTLV and HIV-2) to elucidate retroviral pathogenesis and resistance mechanisms.

Objective 4: Enhance understanding of susceptibility to HIV infection.

Action Steps: Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease.

Descriptions: Apply cutting-edge laboratory approaches and behavioral strategies to assess susceptibility to infection and transmission and monitor disease progression and response to intervention in population studies;

Facilitate the transfer of novel laboratory and behavioral strategies from basic research to epidemiologic applications;

Promote development and application of laboratory approaches to elucidate mechanisms, cofactors, and timing of maternal-fetal-infant transmission of HIV infection;

Assess new virologic parameters (e.g., viral burden, genotype/phenotype) applicable to body fluids that correlate with infectiousness for evaluating interventions (e.g., spermicides/microbicides, vaccines);

Identify laboratory parameters associated with HIV-related outcomes, such as intermediate end points preceding HIV-

associated infections and malignancies, predictors of long-term survival or rapid progression, and markers of exposure to HIV without infection;

Facilitate, develop, evaluate, and apply assays for assessment of mucosal immunity related to susceptibility to infection and impact of intervention;

Identify, characterize, and evaluate reliable diagnostic markers, including markers in saliva, for the purpose of applying rapid and sensitive diagnostic technologies for detecting HIV infection;

Promote development and assessment of assays to detect HIV infection in vaccinated populations; and

Establish, maintain, and expand national repositories of biologic specimens (e.g., blood, body fluid, and tissue) obtained from well-characterized individuals in longitudinal studies to facilitate rapid evaluation of existing strategies and development of new strategies.

Objective 4: Enhance understanding of HIV disease in populations in which HIV is prevalent, emerging, and/or increasing for the purpose of developing treatments and preventive vaccines.

Action Steps: Perform the epidemiologic studies of HIV infection, related conditions, and risk behaviors in domestic and international populations in which HIV is prevalent, emerging, and/or increasing.

Descriptions: Identify emerging high-risk groups in the United States through seroincidence studies and identification of behavior risk factors in the population. Examples of groups that need particular attention and further evaluation include minorities, women, adolescents, children, young gay men, homeless mentally ill, drug users, and the incarcerated;

Develop infrastructure to define populations in the United States and throughout the world with high incidence and prevalence suitable for vaccine and other intervention trials;

Delineate the epidemiology of behavioral risk factors for HIV in defined population-based studies;

Measure the occurrence of other infectious agents, e.g., other viruses (HTLV-1, HSV-2, hepatitis B and C, etc.), sexually transmitted diseases, and mycobacterium (e.g., MTB, *M. avium*) in populations at risk for HIV;

Coordinate with the CDC, WHO, and other institutions to maintain a comprehensive view of the epidemic with as much

detailed information about subpopulations as possible;

Promote the development of new high-quality biometry programs for AIDS research evaluation, including new methodologies;

Define the scope and role of HIV in the etiology of cancer and determine the impact of HIV-related malignancy on total cancer burden in the population; and

Cooperate with health services agencies to determine why many individuals and groups continue to underutilize health services related to HIV that are already available (e.g., access to care, perceptions regarding efficacy, etc.).

FY 95: 179,014,000
FY 96: 188,822,000

Pops. Served: All populations

Constituency Involvement: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of $48,449 over the FY 96 figure.

PREVENTION

Agency: Office of Population Affairs

Goal: Reduce the number of new 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.

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 2/3 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.

PREVENTION

Agency: Indian Health Service

Goal: 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

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: ???

Objective 2: Maintain training and information activates 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: The changed behavior includes adjustments of beliefs and the formation of AIDS community-based task forces at the local level.

FY 95: 2,321,000
FY 96: 2,321,000

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: ???

CARE AND SERVICES

Agency: Agency for Children and Families

Goal: To meet the crisis needs of infants, children, and youth at risk for HIV.

Objective 1: Stabilize crisis situation and provide needed services.

Action Steps: Provide shelter and immediate services including diagnostic medical services and education and prevention related to HIV/AIDS.

Descriptions: Runaway and Homeless Youth Program.

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

Populations Served: Runaway and homeless youth at risk for HIV.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

Objective 2: Provide foster care and adoption services to abused, neglected, or otherwise needy children including those with HIV/AIDS.

Action Steps: Provide diagnostic and treatment services, counseling for children, parents, extended family, foster and adoptive parents, and others relevant to HIV/AIDS.

Descriptions: Child Welfare Services Program.

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

Populations Served: Children in foster care.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

Objective 3: Provide health and social services for abandoned infants and young children who have been drug-exposed and/or have HIV/AIDS.

Action Steps: Provide foster care, health services, counseling and other social services, and recruitment and interdisciplinary training.

Descriptions: Abandoned Infants Assistance Program.

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

Populations Served: Abandoned infants and young children who have been drug-exposed and/or have HIV/AIDS.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

Objective 4: Provide comprehensive services to children, including those with HIV/AIDS, their parents, and families.

Action Steps: Services to Head Start families may include prevention and education, identification, and intervention related to HIV/AIDS; children with HIV/AIDS are enrolled in the on-going Head Start program.

Descriptions: Head Start Program.

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

Populations Served: Low income pre-schoolers and their families, including pregnant women.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

Objective 5: Provide assistance and services to increase and support the independence, productivity, and integration into the community of persons with developmental disabilities.

Action Steps: Support the twenty-seven of the current 51 grantees operating pediatric HIV/AIDS clinics.

Descriptions: University Affiliated Program

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

Populations Served: Developmentally disabled persons.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

RESEARCH

Agency: Agency for Health Care Policy and Research

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

Objective 1: To provide comprehensive information on unmet needs for service and barriers to accessing services.

To examine effects of different systems of organizing and delivering care on outcomes such as cost, utilization, survival, patient satisfaction, and quality of life.

To examine effects of patient characteristics (including gender, race/ethnicity, substance abuse, mental health, socioeconomic status, insurance coverage) on outcomes such as service utilization, unmet service needs, and costs.

To provide data on service utilization and costs for a representative sample of rural residents with HIV infection.

To examine patterns of transition between different types of provider (e.g., private physician to public clinic) and the relationship of such transitions to changes in clinical status, employment, and insurance coverage.

Action Steps: This study will be the first to obtain a true national random sample of people with HIV infection receiving treatment. Approximately 3200 adult patients in urban and rural areas, and 400 children (age less than 13) will be enrolled. Study will be conducted in collaboration with HRSA, NIMH, NIDR, NIAAA, and NIDA.

Descriptions: HIV Costs and Service Utilization Study (HCSUS)

FY 95: $4,000,000
FY 96: $4,000,000

Populations Served: HIV-infected individuals receiving treatment.

Constituency Involvement: Community Advisory Board, comprising members of infected and affected groups, has been established.

Unmet Need: Insufficient resources for a national probability sample of pediatric HIV-infected patients. Insufficient resources for a sample of HIV-infected adolescents.

Objective 2: To examine health care utilization among participants in the NIH-sponsored Women's Interagency HIV Study (WIHS).

Action Steps: Supplement the WIHS by adding a health services research component.

Collect and analyze utilization data on women with HIV infection (in addition to the detailed clinical data obtained in the core study.)

Descriptions: Women's Interagency HIV Study (WIHS)

FY 95: 55,000
FY 96: 75,000

Populations Served: Women with HIV infection participating in the WIHS.

Constituency Involvement: A broad representation of researchers and patient advocates had input in the development of the WIHS ??.

Unmet Need: None.

Objective 3: To examine factors affecting health care utilization among participants in the NIH-sponsored Multicenter AIDS Cohort Study (MACS).

Action Steps: Supplement the MACS by adding a health services research component.

Collect and analyze utilization data on men with HIV infection (in addition to the detailed clinical data obtained in the core study.)

Descriptions: Multicenter AIDS Cohort Study (MACS)

FY 95: 75,000
FY 96: 0 -- is the study completed?

Populations Served: Homosexual and bisexual men participating in the MACS in four urban areas.

Constituency Involvement: A broad representation of researchers and patient advocates had input in the development of the MACS -- correct?.

Unmet Need: None

Objective 4: To examine health care utilization among participants in the CDC-sponsored HIV Epidemiological Research Study (HERS).

Action Steps: Supplement the HERS by adding a health services research component.

Collect and analyze utilization data on women with HIV infection (in addition to the detailed clinical data obtained in the core study.)

Descriptions: HIV Epidemiological Research Study (HERS)

FY 95: 50,000
FY 96: 50,000

Populations Served: Women with HIV infection participating in the HERS.

Constituency Involvement: A broad representation of researchers and patient advocates had input in the development of the HERS -- correct?.

Unmet Need: None.

Objective 5: To provide longitudinal data on utilization of inpatient, outpatient, home care, pharmaceutical, and other services, and to estimate their associated costs.

To examine the impact of a Medicaid Home and Community-Based waiver on service utilization, costs, functional status, and survival.

To examine any substitutions of formal for informal home care.

Action Steps: Conduct interviews with participants in New Jersey Medicaid Waiver program.

Abstract data from Medicaid claims.

Descriptions: Health Care Costs and Utilization in AIDS Home Care.

FY 95: 394,557
FY 96: 0 -- is study completed?

Populations Served: Medicaid recipients with AIDS in New Jersey.

Constituency Involvement: ????

Unmet Need: None.

Objective 6: To examine types of ambulatory care providers used to treat HIV infection, patterns of transitions between ambulatory provider types, and service utilization and costs for pediatric HIV patients.

Action Steps: Analyze Medicaid claims and eligibility data from New York State Medicaid.

Descriptions: Ambulatory Care for HIV/AIDS, Models and Outcomes.

FY 95: 392,103 (from FY94 funds).
FY 96: 0 -- is study completed?

Populations Served: New York State Medicaid recipients.

Constituency Involvement: ????

Unmet Need: None.

Objective 7: To assess the impact of antiretroviral, antimicrobial, and prophylactic treatment on the natural history of HIV infection, and the effect of pharmaceutical therapies on service utilization, costs, and clinical outcomes.

Action Steps: Develop clinical database linked to Medicaid claims data.

Descriptions: Outcomes of Pharmaceutical Therapy in HIV Disease.

FY 95: 527,287
FY 96: 420,000

Populations Served: HIV-infected population in Maryland.

Constituency Involvement: ????

Unmet Need: None.

Objective 8: To study issues of costs and quality of care, with a focus on women and children, examine trends and variation in adherence to scientifically-based clinical guidelines, and study predictors of variation in treatment, by patient, physician, and practice setting characteristics.

Action Steps: Analyze Medicaid claims and eligibility data, supplemented with AIDS Registry data.

Descriptions: Quality and Costs of Care for HIV Infected Medicaid Patients.

FY 95: 110,704 (from 1994 funds)
FY 96: 0 -- is study completed?

Populations Served: New Jersey Medicaid recipients.

Constituency Involvement: ???

Unmet Need: None.

Objective 9: To develop an econometric framework for the simultaneous study of health care usage and survival, and synthetic estimates of per-person lifetime costs of HIV disease for various groups of HIV-infected individuals.

Action Steps: Formulate statistical models and associated computer software.

Descriptions: Developing Econometric Models to Estimate AIDS Costs.

FY 95: 188,136
FY 96: 80,000

Populations Served: Participants in the AIDS Costs and Service Utilization Survey, with potential extensions to all persons with HIV disease.

Constituency Involvement: ????

Unmet Need: None.

Objective 10: To identify personal and institutional factors that shape physicians' willingness to care for HIV-infected patients.

Action Steps: Conduct the third in a series of interviews with physicians, who are currently in their sixth post-graduate year.

Descriptions: Determinants of Physicians' AIDS-Related Practice Behavior

FY 95: 216,054 (from 1994 funds)
FY 96: 0 -- is study completed?

Populations Served: Physicians who graduated from six New York State medical schools in 1989.

Constituency Involvement: ????

Unmet Need: None.

Objective 11: To compare outcomes of inpatient care for AIDS provided by dedicated AIDS units versus scattered-bed approaches.

Action Steps: Conduct comparative multi-site observational study of 23 hospitals.

Descriptions: Outcomes of Hospital Dedicated AIDS Units

FY 95: 137,538 (from 1994 funds)
FY 96: 0 -- is study completed?

Populations Served: 1500 patients receiving services in study hospitals.

Constituency Involvement: ????

Unmet Need: None.

Objective 12: Obtain and analyze data on inpatient hospital utilization by people with HIV infection.

Action Steps: Assemble database of hospital discharge data from all hospitals in 12 States.

Descriptions: Hospital Cost and Utilization Project

FY 95: 500,000
FY 96: 500,000

Populations Served: Patients with AIDS receiving inpatient care in hospitals in 12 states.

Constituency Involvement: ????

Unmet Need: None.

PREVENTION

Agency: 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: 430,440
FY 96: 390,000

Populations Served: Study volunteers.

Constituency Involvement: No HIV positive persons were included in the design or analysis of the study?

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: 198,541
FY 96: 225,000

Populations Served: Study volunteers.

Constituency Involvement: ????

Unmet Need: None.

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: Agency for Health Care Policy and Research

Goal: To expedite the incorporation of data from research advances into clinical practice.

Objective 1: To provide Federally approved and accurate information concerning current and appropriate treatments for HIV-related conditions.

Action Steps: Through the use of reference specialists, provide appropriate treatment information to callers, drawing on NLM's database of AHCPR guidelines, in addition to NIH, CDC and other Federal agency guidelines and consensus statements.

Descriptions: AIDS Treatment Information Service

FY 95: 41,300
FY 96: 53,326

Populations Served: Primary care practitioners, case managers, allied health professionals, and HIV-positive individuals.

Constituency Involvement: This PHS interagency project incorporates HIV-positive individuals and advocacy groups.

Unmet Need: ???

Objective 2: To provide accurate information to service providers and consumers concerning management of early HIV infection.

Action Steps: A panel of experts reviewed relevant literature and summarized findings into specific clinical practice guidelines, which stress the importance of preventing HIV-related opportunistic infections and the link between prevention and early diagnosis. 1.5 million copies of guidelines have been distributed.

Descriptions: Dissemination of AHCPR's HIV-Related Clinical Guidelines.

FY 95: 30,000 (to AIDS clearinghouse)
FY 96: 30,000 (to AIDS clearinghouse, proposed)

Populations Served: Clinical practitioners and individuals with HIV infection.

Constituency Involvement: Clinicians? HIV positive persons?

Unmet Need: NA

Objective 3: To assess effective and ineffective dissemination strategies employed by community-based HIV education programs.

Action Steps: Examine organizational strategies used by several community-based HIV education agencies.

Descriptions: Effective Strategies of AIDS Programs in San Francisco.

FY 95: 198,883 (from 1994 funds)
FY 96: 0 - is this completed?

Populations Served: Community-based HIV education agencies in San Francisco

Constituency Involvement: ????

Unmet Need: NA

Objective 4: This guide will inform HIV-infected pregnant women about the use of zidovudine (AZT) for the prevention of perinatal HIV infection.

Action Steps: Develop guide which will describe the recommendations of the PHS Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of HIV, based on results of AIDS Clinical Trials Group 076. Provide the information in a format and reading level that consumers can comprehend.

Descriptions: Development of Consumer Guide on Use of Zidovudine for the Prevention of Perinatal HIV Infection (076 Guide).

FY 95: 75,000
FY 96: 0

Populations Served: Pregnant women with HIV infection and women of child-bearing age with HIV infection.

Constituency Involvement: HIV infected individuals and advocacy groups are involved in the development and review of the guide. The guide is cosponsored by multiple Federal and non-Federal agencies.

Unmet Need: NA

INTERNATIONAL ACTIVITIES

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

Goal: Support U.S. interests globally by serving as a policy and coordinating body for international activities supported by HHS, 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 HHS and other Federally-supported international activities.

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

Develop mechanism for tracking HHS-related international activities.

Descriptions: International activities mapping project.

FY 95: NA
FY 96: NA

Populations Served: Program planners and policy makers.

Constituency Involvement: ????

Unmet Need: Staff to initiate and complete project.

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the rate of HIV transmission among high-risk substance abusers and their sexual partners.

Objective 1: To provide a range of high quality mental health services to people affected by or living with HIV/AIDS; change risk behaviors and prevent further HIV transmission; evaluate the effectiveness and efficiency of the different approaches or models used for organizing and providing those services, and determine the outcome of those services on the quality of life of the individuals served.

Action Steps: Increase compliance with medical treatment and enhance access to existing services;

Disseminate information about successful service models;

Develop and rigorously evaluate models for replication and integration into HIV/AIDS delivery systems; and

Increase productive work capacity as result of receiving services.

Descriptions: HIV/AIDS Mental Health Services Demonstration Program.

FY 95: $1,500,000 ($1,400,000 NIH and $1,500,000 HRSA)
FY 96: $1,500,000 ($1,400,000 NIH and $1,500,000 HRSA)

Please clarify accounting -- do the 1.4 and 1.5 million go on NIH's and HRSA's accounts?

Populations Served: People living with or affected by HIV/AIDS including injection drug users, sex partners of injection drug users, sex workers, gay or bisexual men, and racial and ethnic minority populations.

Constituency Involvement: Health professionals, consumers, and community service providers.

Unmet Need: This collaborative effort has successfully enhanced the services rendered by providing comprehensive services to the populations served. However, additional financial resources could include other agencies, i.e. HUD, AHCPR in providing the client population with a spectrum of services relating to diverse needs.

Objective 2: To demonstrate the efficacy of outreach as an intervention for facilitating access to substance abuse treatment for high risk and hard to reach substance abusers.

To demonstrate that comprehensive HIV outreach interventions affect behavior changes in diverse populations.

Action Steps: Identify chronic, hardcore, drug users and their sex and/or needle-sharing partners;

Facilitate entry into substance abuse treatment;

Provide a range of services including medical and diagnostic services for HIV, STDs, and TB;

Employ information-sharing, skills and other prophylactic means to affect behavior change; and

Evaluate program effectiveness.

Descriptions: HIV/AIDS Community Outreach Program.

FY 95: $7,500,000
FY 96: $7,500,000

Populations Served: Chronic, hard core substance abusers and their sex and/or needle-sharing partners, including those individuals who have severe drug problems, frequently inject heroin and/or cocaine and/or are poly drug users. There is also emphasis within various racial and ethnic groups, women, residents of public housing projects, and homeless individuals.

Constituency Involvement: Health professionals, consumers, and community service providers.

Unmet Need: Additional resources for medical treatment of HIV/AIDS, STDs, TB and other medical services would provide greater access to care through integration of substance abuse and medical care services.

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the transmission of HIV through improved training of clinicians. -- Correct?

Objective 1: Enhance mental health professionals' prevention and treatment efforts by training mental health care providers and other health care workers.

Action Steps: Assess neuropsychiatric/psychosocial aspects of HIV/AIDS to prevent the spread of HIV infection;

Establish linkages with health care providers;

Include alcohol and other drug (AOD) related HIV prevention in all training curriculums;

Train mental health professionals who serve people with serious mental illness;

Provide training about pre and post HIV antibody counseling and testing, physiological aspects of HIV/AIDS, in addition to culturally sensitive, linguistically and gender appropriate interventions and methodologies;

Address managed care and training issues; and

Evaluate the effectiveness of training techniques.

Descriptions: AIDS Health Care Worker Training.

FY 95: $2,930,000
FY 96: $2,930,000

Populations Served: HIV/AIDS mental health care providers whose client population may include gay and bisexual men, women, racial and ethnic minority groups, injecting drug users and their sex partners, sex workers, children, adolescents, and the sex partners of people with HIV/AIDS.

Constituency Involvement: Health professionals, consumers, and community service providers.

Unmet Need: Additional financial resources and increased collaboration with other Federal agencies would broaden the scope of the training to include all health professionals.

Objective 2: Provide training programs for health care professionals, modifying curricula and strengthening training opportunities in comprehensive care for people with or at risk for substance abuse, mental illness and infectious diseases including HIV and TB.

Action Steps: Train health care professionals to provide comprehensive services and care; and

Enhance curricula by including training for diverse populations with multiple risk factors and illnesses.

Descriptions: AIDS Training Grants.

FY 95: $2,800,000
FY 96: $0

Populations Served: People with or at risk for substance abuse, mental illness and/or transmission of HIV.

Constituency Involvement: Health professionals and consumers.

Unmet Need: Additional resources would strengthen the training opportunities for health care professionals and enhance services rendered for people with or at risk for substance abuse, mental illness, HIV, and other STDs.

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

Goal: Improve the integration of substance treatment and primary medical care.

Objective: To demonstrate the effectiveness of fostering greater services integration by linking substance abuse treatment, primary medical care, mental health services, and HIV/AIDS, STD and TB services.

Action Steps: Develop and foster linkages among service providers; and

Evaluate the efficiency and effectiveness of linked, integrated services.

Descriptions: The Linkage Initiative.

FY 95: $7,700,000
FY 96: $0 (Funds are subsumed under the new Consolidated Demonstration Program.)

Are these funds still earmarked? Or must this program recompete?

Populations Served: Injecting drug users and other high risk substance abusers and their sexual partners.

Constituency Involvement: ??

Unmet Need: This collaborative effort serves as catalyst for linking AOD treatment, mental health and primary care services, and services for HIV/AIDS, STDs and TB. Additional resources could join this effort with other agencies to enhance the services rendered.

PREVENTION

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the number of new HIV infections.

Objective 1: Reduce the number of new infections by 25 percent among clients served by grantees?.

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; and

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

Descriptions: High Risk Youth Demonstration ? Program.

FY 95: $1,000,000
FY 96: $3,000,000

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.

Objective 2: Apply a community-designed, community-focused approach to the prevention of HIV/AIDS in a culturally appropriate manner, specifically targeting communities of high seroprevalence.

Reduce ATOD use.

Action Steps: Supplementation of all community partnerships and

community coalitions providing communities with the opportunity to design targeted HIV/AIDS messages emphasizing the direct relationship between the use of ATOD and HIV/AIDS; and

Solicit neighboring communities in program implementation.

Descriptions: Demonstration sites and community training in the use of HIV/AIDS curriculum.

FY 95: $0
FY 96: $5,000,000

Populations Served: American communities. (More information regarding which communities.)

Constituency Involvement: All community members.

Unmet Need: Supplementing all community coalition grantees and partnerships would provide greater opportunity for services integration and evaluation.

Objective 3: Improve prevention training skills of FDP grantees.

What is FDP?

Action Steps: Supplement all FDP grantees for the purpose of improving teaching skills related to integration ATOD and HIV/AIDS prevention; and

Improve training regarding professional/client interaction.

Descriptions: Supplementation of FDP grantees.

FY 95: $0
FY 96: $650,000

Populations Served: All Americans -- secondary to the impact this program will have on all health professionals. (More information regarding location.)

Constituency Involvement: Health professional institutions, consumers, and community service providers.

Unmet Need: Additional resources could provide further education and training and thereby reach more health professionals.

CARE AND SERVICES

Agency: Health Resources and Services Administration

Goal: Increase the number of competent primary care providers willing to care for HIV positive persons.

Objective: To increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and manage individuals with HIV infection.

Action Steps: Support didactic and clinical training activities for primary health care providers in collaboration with Federal, state, and local HIV care programs;

Disseminate state-of-the art HIV information to providers; and

Develop and coordinate distribution of HIV provider materials.

Descriptions: A significant source of training takes place under the guidance of AIDS Education and Training Centers. In addition there are quarterly interactive conference calls with experts and providers, the National HIV Telephone Consultation Service (Warmline), phone consultation services, newsletters, bulletins, and provider guides for HIV priority areas (i.e., guidance for clinicians regarding the use of AZT for the prevention of perinatal transmission).

FY 95: $16,300,000
FY 96: $16,300,000 ?

Populations Served: Health care providers and people living with HIV disease.

Constituency Involvement: Faculty, staff, advisory committees, training panels, persons living with AIDS, and academic faculty.

Unmet Need: Not enough adequately trained health care providers to meet patients demand, and, inadequate resources to meet provider training needs.

CARE AND SERVICES

Agency: Health Resources and Services Administration

Goal: Reduce barriers to obtaining dental care for HIV positive persons.

Objective: Increase the number of dental practitioners who provide care to HIV positive patients.

Assist dental schools in meeting uncompensated costs associated in providing oral health care to HIV positive patients.

Action Steps: Provide reimbursement to dental schools of uncompensated costs incurred in treating patients with HIV.

Descriptions: The AIDS Dental Reimbursement Program is designed to reimburse accredited dental schools and post doctoral dental programs for the documented uncompensated costs incurred from providing oral health treatments to HIV positive patients.

FY 95: 6,937,000
FY 96: 6,937,000

Populations Served: Children and adults living with HIV.

Constituency Involvement: American Association of Dental Schools, American Association of Hospital Dentists, and American Dental Association. Consumers?

Unmet Need: Uncompensated costs that dental schools and hospitals incur are much more than the dollars available under the AIDS Dental Reimbursement Program.

CARE AND SERVICES

Agency: Health Resources and Services Administration

Goal: Increase access to care and improve quality of life for persons living with HIV and AIDS.

Objectives: Through the Ryan White Comprehensive AIDS Resources Emergency (Care) Act (RWCA), improve accessibility and quality of care for all persons living with HIV.

Develop comprehensive and participatory planning processes at the state and local levels to guide funding allocation decisions.

Increase patient access to clinical research.

Establish quality guidelines and evaluate program effectiveness.

Action Steps: Support comprehensive outpatient, ambulatory health and support services, case management, and inpatient case management services that prevent unnecessary hospitalization or expedite discharge (RWCA Title I);

Support consortia to improve the quality and availability of health care, including home and community-based services, continuation of health insurance, purchase of AIDS drugs, direct provision of care for individuals and families living with HIV and AIDS (RWCA Title II);

Develop a minimum drug formulary for federally-assisted AIDS Drug Assistance Programs (ADAP --RWCA Title II);

Support outpatient early intervention services for low-income medically underserved people in existing primary health care systems (RWCA Title III);

Support comprehensive care services for affected women, infants children, and youth in a comprehensive community-based, family-centered system of care (RWCA Title IV);

Support initial development of care systems linked to research for children, youth and women in 7 new communities;

Enhance linkages between care providers and sites where research is conducted;

Provide leadership, training, and technical assistance;

Convene youth and family leadership conferences and distribute findings;

Develop, distribute, and train providers on quality indicator and quality assurance guidelines for the clinical management of HIV disease;

Develop guidances for grantees in developing local strategies for changes in the standard-of-care; and

Evaluate program effectiveness.

Descriptions: Many individual grantees and service organizations provide RWCA-supported services. In addition to these broad-based efforts there is support for an Adolescent Research and Clinical Network, and a cooperative agreement with Institute of Family-Centered Care to provide training and technical assistance to youth and families.

FY 95: RWCA Title I:
RWCA Title II:
RWCA Title III:
RWCA Title IV:

FY 96: RWCA Title I:
RWCA Title II:
RWCA Title III:
RWCA Title IV:

Populations Served: HIV positive individuals and their family members, low income persons with HIV/AIDS, pregnant women living with HIV/AIDS, neonates and children born to HIV positive women. In addition, RWCA grantees and planning councils receive technical assistance in conducting and evaluating their programs.

Constituency Involvement: The input and guidance of affected communities is gathered through a variety of avenues. RWCA planning councils, with the input of broad-based local representation, guide local prioritization of RWCA funds.

The development of evaluation measures is a participatory process whereby local groups assist in the development of self-assessment tools. Local participants have early and ongoing involvement in all phases of data collection design, planning, and implementation.

In addition, national groups such as the Pediatric AIDS Foundation and the National Positive Youth Alliance provide valuable assistance and input.

Unmet Need: Funds for existing projects are inadequate to meet rapidly growing caseloads and increased demand for care and training. Meeting these will require expanding programs in general and especially for adolescents to provide needed services such as mental health, substance abuse, and family case management services. For the RWCA Title IV, funds were available for only one third of grant applicants in FY 1995.

Moreover, 24 states lack comprehensive care systems for children, youth, women; funding of approximately $1.8 million would support new planning and initial development projects in these states.

There is also a lack of adequate funding for technical assistance and a need for increased of collaboration with other Federal agencies. **PLEASE EXPAND ON THIS.**

CARE AND SERVICES

Agency: Health Resources and Services Administration

Goal: Develop and evaluate innovative models of comprehensive managed care for persons living with HIV.

Objective 1: Develop models of comprehensive managed care networks that enroll a broad spectrum of primary care and psychosocial providers within the HIV continuum of care, and that provide patients and their families access to services.

Action Steps: Develop innovative models and disseminate results of evaluation.

Descriptions: Special Projects of National Significance (SPNS).

FY 95: 2,092,302
FY 96: 4,000,000

Populations Served: Persons living with HIV and their families.

Constituency Involvement: Primary care providers, community-based organizations, state and local health officials, Ryan White planning bodies, and persons living with HIV.

Unmet Need: There is a need for more effective linkages among community providers and financially stable medical sites.

Objective 2: Ensure that services provided under SPNS program are fully evaluated for both utilization and impacts.

Increase the evaluation capacity within community-based providers' organizations.

Action Steps: Increase emphasis on evaluation;

Increase the representation of evaluation researchers on review groups; and

Provide technical support for evaluation activities.

Descriptions: Evaluation of Special Projects of National Significance

FY 95: 2,000,000
FY 96: 4,000,000 Are these SEPARATE funds for the SPNS evaluation?

Populations Served: SPNS grantees.

Constituency Involvement: Health care providers, evaluation researchers, and patient advocates.

Unmet Need: There is a need to develop more effective linkages between providers and evaluation researchers.

PREVENTION

Agency: Health Resources and Services Administration

Goal: 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.

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 guidances, AHCPR consumer brochure and video, and other PHS documents to MCHB community; 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

Populations Served: Adolescent and adult women and their infants, with special attention for pregnant women.

MCH and HIV providers including: outreach, counseling and testing, perinatal and HIV care.

Constituency Involvement: Consumer participation in WIN steering committee and projects' advisory board. Linkage 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.

Please elaborate on what services...

PREVENTION

Agency: Health Care Financing Administration

Goal: Reduce perinatal transmission among Medicaid-eligible women.

Objective 1: Enable Medicaid-eligible pregnant women to make informed decisions regarding receiving AZT.

> **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 in RI, DE, SC, and NJ.

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

FY 95: Federal resources to be determined.
FY 96: Federal resources to be determined.

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 include women of unknown or negative HIV serostatus. This project should be extended nationwide.

CARE AND SERVICES

Agency: Health Care Financing Administration

Goal: Provide quality home health care for HIV positive Medicaid and Medicare beneficiaries.

Objective: Provide quality standards for appropriate home health care services and treatment of HIV disease.

Action Steps: Identify current home health care practices through literature review and survey of best practices.

Descriptions: Develop and implement quality standards for appropriate home health care for HIV positive beneficiaries in partnership with private sector organizations and PHS agencies;

Develop directives in implementation of developed guidelines.

FY 95: Federal resources to be determined.
FY 96: Federal resources to be determined.

Populations Served: HIV positive Medicaid and Medicare beneficiaries receiving home health care.

Constituency Involvement: Significant constituent consultation throughout course of project development. Other groups?

Unmet Need: Implementation of directives dependent on nature and resources of each project partner. A little more detail needed.

CARE AND SERVICES

Agency: Health Care Financing Administration

Goal: Provide primary health care to Medicaid-eligible HIV positive persons.

Objective: Provide quality primary health to Medicaid-eligible HIV positive persons.

Action Steps: Assess state compliance with Medicaid program standards. Review and evaluate waiver applications. Encourage compliance with changes in the standard-of-care.

Description: Medicaid primary health care services.

FY 95: 1,640,000,000 (Federal share)
FY 96: 1,800,000,000 (Federal share)

Populations Served: HIV positive Medicaid-eligible persons.

Constituency Involvement: More information

Unmet Need: NA

PREVENTION

Agency: The Centers for Disease Control and Prevention

Goal: 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 serosurveillance 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 --- [relevance to goal?];

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: 141,076,000
FY 96: 140,917,000

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. Were Community-based organizations included?

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.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives: Provide leadership in HIV and STD prevention by (1) establishing a national agenda through the media -- does this mean communicating a national agenda or message 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. 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: $45,970,000
FY 96: $46,869,000

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 & labor leaders, 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.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:
What are the baseline figures for the targets listed below?

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 a comprehensive school health education program.

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 programs (CSHEPs);

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 students;

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 CSHEPs;

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 college 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 and colleges and universities;

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

Identify and disseminate, through training and demonstration centers and through teacher training coordinators, 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 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: $48,215,000
FY 96: $48,162,000

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 and 18 local 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.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:
What is the baseline for the below-listed targets? How will they be measured?

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: $185,666,000
FY 96: $209,764,000

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.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:
What is the baseline for the below-listed targets?

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 & 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: $169,035,000
FY 96: $179,006,000

> **At the CP level these figures are listed as one pot of money -- please clarify.**

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.

Department of Housing & Urban Development

National HIV/AIDS Plan

Area: Housing/support

Goal: Promote development of housing and related service support for persons living with HIV as part of comprehensive strategies

<table>
<tr><td>Objective: Provide states and localities with resources to provide housing and related services under long-term comprehensive strategies for meeting needs of persons living with HIV</td><td rowspan="3">Populations Served: Low-income persons living with HIV and their families

Constituency Involvement: Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates and persons living with HIV.</td></tr>
<tr><td>Action Steps: Competitively-awarded and formula grants to provide broad range of housing and services to prevent homelessness</td></tr>
<tr><td>Resources
FY 1995: $186 million
FY 1996 (proposed): $186 million</td></tr>
<tr><td colspan="2">Description: Housing Opportunities for Persons with AIDS (HOPWA) Program and other HUD resources (see other objectives)</td></tr>
<tr><td colspan="2">Unmet Needs: The HOPWA program can be estimated to serve about 50,000 persons living with HIV and their families. This includes about 35,000 units of housing assistance, mostly in the form of short-term payments and rental assistance. Additionally, members of the household and persons who only receive supportive services will benefit from the program. HHS estimates that approximately 300,000 persons are receiving HIV related services.</td></tr>
</table>

National HIV/AIDS Plan

Area: Housing/prevention

Goal: Reduce the number of new infections among residents of public and subsidized housing

<table>
<tr><td>Objective: Provide primary prevention programs to public housing residents at risk of HIV infection</td><td rowspan="3">Populations Served: Children and adults in public housing in five targeted cities

Constituency Involvement: Funneled through local planning groups
Examples of groups?</td></tr>
<tr><td>Action Steps: Forge local partnerships and improve coordination of existing resources</td></tr>
<tr><td>Resources
FY 1995: $-0- (demo underway within existing resources)
FY 1996 (proposed):-0-</td></tr>
<tr><td colspan="2">Description: HIV/AIDS Prevention in Public Housing Demonstration</td></tr>
<tr><td colspan="2">Unmet Needs: The initial demonstration program reached sites in five cities; the program should be broadened to include all other public and subsidized housing efforts.</td></tr>
</table>

National HIV/AIDS Plan

Area: Housing/planning and continuum of care

Goal: Provide support and encourage the development of local continuum of care programs that provide a comprehensive range of housing and related services for persons living with HIV

<table>
<tr><td>Objective: provide states, localities with resources to devise long-term comprehensive strategies for meeting needs of persons living with HIV</td><td rowspan="3">Populations Served: PWAs and their families

Constituency Involvement: Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates and persons living with HIV.</td></tr>
<tr><td>Action Steps: Authorize the use of competitive and formula grants to provide broad range of housing and program development and strategic planning to address housing needs</td></tr>
<tr><td>Resources
FY 1995: $ 0
FY 1996 (proposed): 0</td></tr>
<tr><td colspan="2">Description: Housing Opportunities for Persons with AIDS (HOPWA) Program</td></tr>
<tr><td colspan="2">Unmet Needs: Activities are authorized and recipient communities may choose to expend program funds to support housing and program development and strategic planning. Additional incentives could be devised to encourage comprehensive planning.</td></tr>
</table>

National HIV/AIDS Plan

Area: Housing/disability programs

Goal: Increase permanent housing supply for persons with disabilities including person living with AIDS

Objective: Increase supply of permanent units for PWAs	Populations Served: Disabled persons 18 years and over
Action Steps: Encourage HIV housing/ program sponsors to apply for funds for project for PWAs	
Resources FY 1995: $376 million FY 1996 (proposed): unknown	Constituency Involvement: Through the Consolidated Planning process Examples of groups?
Description: **Section 811 Supportive Housing Program for Persons with Disabilities**	
Unmet Needs: Program can serve PWAs in project which may include persons with other disabilities	

National HIV/AIDS Plan

Area: Housing/rental assistance

Goal: Increase number of scattered site housing subsidies for persons living with HIV who are homeless or at risk of homelessness to support independent living

<table>
<tr><td>Objective: Provide set-aside of 3,000 units of rental assistance vouchers</td><td rowspan="3">Populations Served: Homeless persons or families with AIDS

Constituency Involvement: Local partnership between eligible jurisdictions with housing agencies</td></tr>
<tr><td>Action Steps: Make formula grants to eligible jurisdictions</td></tr>
<tr><td>Resources
FY 1995: $103 million (over 5 years)
FY 1996 (proposed): $0</td></tr>
<tr><td colspan="2">Description: Section 8 Rental Assistance for Persons living with HIV/AIDS who are homeless or at risk of homelessness</td></tr>
<tr><td colspan="2">Unmet Needs: Permanent independent living is the most requested form of housing assistance.</td></tr>
</table>

National HIV/AIDS Plan

Area: Housing/services

Goal: Increase supply of housing with related supportive services for homeless persons living with HIV

<table>
<tr><td>Objective: Ensure the availability of supportive services for homeless persons with disabilities, including persons living with HIV</td><td rowspan="3">Populations Served: Homeless persons and families

Constituency Involvement: Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates and persons living with HIV.</td></tr>
<tr><td>Action Steps: Authorize supported housing options through comprehensive homeless assistance programs</td></tr>
<tr><td>Resources
FY 1995: $150 million (Shelter Plus Care)
FY 1996 (proposed): Discretionary within homeless assistance grants ($1.2 billion)</td></tr>
<tr><td colspan="2">Description: Shelter Plus Care Program</td></tr>
<tr><td colspan="2">Unmet Needs: Resources that meet the related services needs of homeless persons are important to assisting them maintain their housing and respond to factors which contributed to their homelessness</td></tr>
</table>

Are all of these funds for HIV-related services?

National HIV/AIDS Plan

Area: Housing/supportive housing

Goal: Increase supply of supportive housing available for homeless persons living with HIV.

<table>
<tr><td>Objective: Ensure the availability of supportive housing options for homeless persons living with HIV</td><td rowspan="3">Populations Served: Homeless persons and families

Constituency Involvement: Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates and persons living with HIV.</td></tr>
<tr><td>Action Steps: Authorize supported housing options through comprehensive homeless assistance programs</td></tr>
<tr><td>Resources
FY 1995: $600 million (Supportive Housing Program)
FY 1996 (proposed): Discretionary within homeless assistance grants ($1.2 billion)</td></tr>
<tr><td colspan="2">Description: Supportive Housing Program</td></tr>
<tr><td colspan="2">Unmet Needs: Resources that meet the related services needs of homeless persons are important to assisting them maintain their housing and respond to factors which contributed to their homelessness.</td></tr>
</table>

Are all of these funds for HIV positive persons?

National HIV/AIDS Plan

Area: Housing/Single Room Occupancy housing

Goal: Increase supply of single room occupancy housing available for homeless persons living with HIV.

<table>
<tr><td>Objective: Ensure the availability of single room occupancy housing options for homeless persons living with HIV</td><td rowspan="3">Populations Served: Homeless persons

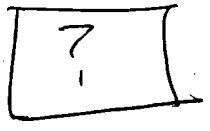
Constituency Involvement: Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates and persons living with HIV.</td></tr>
<tr><td>Action Steps: Authorize supported housing options through comprehensive homeless assistance programs</td></tr>
<tr><td>Resources
FY 1995: $150 million (Section 8 Single Room Occupancy Mod Rehab Program)
FY 1996 (proposed): Discretionary within homeless assistance grants ($1.2 billion)</td></tr>
<tr><td colspan="2">Description: Section 8 Single Room Occupancy Moderate Rehabilitation Program</td></tr>
<tr><td colspan="2">Unmet Needs: SRO units that are supported by additional resources that meet the related services needs of homeless persons are important to assisting them maintain their housing and respond to factors which contributed to their homelessness.</td></tr>
</table>

Are all of these funds for HIV positive persons?

National HIV/AIDS Plan

Area: Housing/technical assistance

Goal: Increase the capacity of AIDS housing and service providers to develop, operate and evaluate housing programs for persons living with HIV.

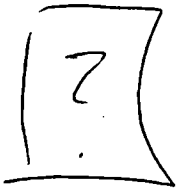
Objective: Ensure the availability of technical assistance and other support for nonprofit providers	Populations Served: Homeless persons Constituency Involvement: 
Action Steps: Authorize TA activities in HUD programs for AIDS related nonprofit providers and grantees	
Resources FY 1995: $0 million FY 1996 (proposed): Discretionary within homeless assistance grants ($1.2 billion) and HOPWA funding ($186 million)	
Description: **Technical assistance or other support for the development of program capacity**	
Unmet Needs: Broaden and deepen the ability of AIDS housing and service providers and AIDS program grantees to expand the range of housing options, ensure quality and responsive programs and undertake evaluation of efforts. Additional needs will be made on programs as the epidemic increases the number of persons living with HIV.	

National HIV/AIDS Plan

Area: Housing/training

Goal: Increase the awareness of staff in public and private organizations to the general and unique needs of persons living with HIV.

<table>
<tr><td>Objective: Increase awareness on HIV among agency and other staff</td><td rowspan="3">Populations Served: Public and private staff and persons at risk of HIV infection

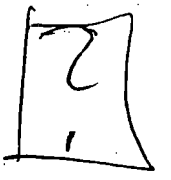
Constituency Involvement:
  </td></tr>
<tr><td>Action Steps: Authorize training activities in HUD programs for HUD staff, AIDS related nonprofit providers and grantees</td></tr>
<tr><td>Resources
FY 1995: $0 million (within training funding)
FY 1996 (proposed): Discretionary within homeless assistance grants ($1.2 billion) and HOPWA funding ($186 million)</td></tr>
<tr><td colspan="2">Description: Training or other support for awareness on HIV</td></tr>
<tr><td colspan="2">Unmet Needs: Misinformation, prejudice and nonresponsiveness continue in the operation of public and private housing programs and the general awareness of individuals in preventing the spread of HIV.</td></tr>
</table>

National HIV/AIDS Plan

Area: Housing/advocacy

Goal: Increase the awareness and responsiveness of HUD programs that may target or incidentally assist persons living with HIV.

<table>
<tr><td>Objective: Ensure that the needs of persons living with HIV are addressed in HUD programs</td><td rowspan="3">Populations Served: Homeless persons, nonprofit organizations, government agencies, HUD staff

Constituency Involvement:
  </td></tr>
<tr><td>Action Steps: Designate an office with direct responsibility for programs and advocacy on AIDS issues</td></tr>
<tr><td>Resources
FY 1995: $0 million (within current efforts)
FY 1996 (proposed): $0 million (within current efforts)</td></tr>
<tr><td colspan="2">Description: Office on HIV/AIDS Housing</td></tr>
<tr><td colspan="2">Unmet Needs: Maintain office functions that promote understanding of AIDS and the needs of persons living with HIV as well as support for programs that support these clients.</td></tr>
</table>