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Acad Emphasis

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Strategy

Area

Agency

Goal

Status

~~W2~~

Sci Issue

Objective

Objective

Description
~~Objective~~

Strategies

Action Steps

@ Narrative

@ 96 v. 97

@ Prevention

W2

Meeting with Judy and Wendy

- Judy - separating + prevention + research.
 - Surveillance
 - [- Science →
 - services/programs
 - [- epidemiological - behavioral →
- informed by the science
 - Science should be informed by prevention providers
 - circular.
 - In research - add epi/behav.

*Compromise: * Translation of Science - Inf. Diss. Wendy will check.

Narrative → see

Behavior - talk to Judy

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Draft for Department and Agency Review: 1.30.96

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NB: Only your agency's part of the Appendices is attached.

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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

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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.

*Seems like
things haven't
happened
before* 3

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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} 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.

Added W² for language.

from Western Hemisphere.

Scope of the HIV/AIDS Pandemic

Unabated, Relentless - U.S. v. the
rest of the world. 076
implications.

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. W/2

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

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cases have been on the rise¹ 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

^{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.

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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.

All

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 Syndrome⁴, the "Coolfont"⁵ and "Charlottesville"⁶ reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States⁷. Recommendations have also been issued from a number of groups, including the National Commission on AIDS⁸ 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-

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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 ^{humane} ~~appropriate~~ care for and ^{Compassionate} ~~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.

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- 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

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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

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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.

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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.

Research, broadly

✓

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

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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 ^{development} effective prevention strategies includes ^{begins with} ~~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.

Out of place - put it in services. This is focus on surveillance.

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 be 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 strategies⁹, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Gaps in Scientific Knowledge

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*Base Rk
efforts on
Research data.*

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.

*talk
to today*

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.~~ *a major approach* 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

*... more info
in this area
could improve
more than
700,000*

Intervention Research. A second major gap is research to improve prevention interventions, i.e., research that concentrates on what factors influence *cause* 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.

*used in developing strategies and Research
about those strategies.*

17

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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 invariably 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

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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 be 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

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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.

Reciprocal [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

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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.

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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.

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.

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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.

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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

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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

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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.

Add personal transmission -
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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

Outside assessment.
Vaccine Report. //W2

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

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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,

We are pursuing both.

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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. W2

~~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. W2

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. W2

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 STDs¹⁹, topical microbicides could provide an easily available and inexpensive protection option for millions of women worldwide. Study

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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 program⁴, 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

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.

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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.]

✓ better mechanism for doing this

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.

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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.

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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.

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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.

1 Basic Research & W2

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

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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

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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

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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.

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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.

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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. 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

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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.

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 strengthen 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.

W² -
language
on what
N/A
does
\$80 million.

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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.

7 Linda Reek,
International
7 WZ

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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 its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; 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.

*Explain
more
on front line
more
challenge*

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

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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.

W2/
language
build
on
this
issue

*Relate to laws
public educ.
stigma.*

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.

lengthen

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

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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.

Revised

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■ **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	

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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	<i>Pneumocystis carinii</i> 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	<i>Mycobacterium tuberculosis</i>
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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23. AHCPR - confirm

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VA Northern California Health Care System (Oakland)

Benjamin Schatz
Gay and Lesbian Medical Association

Overall -- this has a broader mandate than the NIH plan --
(which is appealing to investigators, stimulating research, ...)

Behavioral section --

- In area, was under research, changed to prevention.

■ Goal

Wording was: Conduct and develop behavioral and social science research to develop intervention strategies.

Now: Prevent new infections through behavior interventions. (Language from 1st action step.)

Wording didn't make the clear link to prevention. Symbolic of lack of connection to prevention efforts.

■ Objectives *Prevent*

All of the five objectives were "behavioral research" -- sounded like research was an objective onto itself. Text was pulled from action step and description sections to more specifically convey activities.

Was: 1-5

Now: 2, 1, 4, 3/5a, 5b

#1 had reference to sterile injection equipment and was moved back to #2 so as not to have a reference to 'needles' up front.

1. Enhance understanding of determinants of HIV-related behavior.
2. Develop behavioral and social science research intervention strategies.
- ~~3. Assess innovative dissemination strategies.~~
4. Prevent the negative consequences of HIV Infection.
- 5a. Create and test innovative dissemination strategies.
- 5b. Strengthen the behavioral and social science infrastructure.

■ Budget

Consolidated. There were anomalies. For example, for creating and testing innovative dissemination strategies, FY95 \$1,364, FY96 \$1,444, and FY96 Bypass was \$352. Budget

was collapsed to reflect overall numbers for behavioral research.

To avoid confusion/explanation, folded together. Also, the broader picture was more consistent with other department/agency submissions. This approach was agreed to by Wendy for all the sections.

■ Action Steps and Descriptions

Minor editorial changes; no changes in order.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

080

Epi/Natural History

■ Goal

Wording was: Conduct and support research on the natural history and epidemiology of HIV infection and AIDS in all populations.

Now: Improve understanding of natural history and epidemiology of HIV and AIDS in all populations.

■ Objectives

All of the five objectives were "natural history and epidemiology" -- sounded like research was an objective onto itself. Text was pulled from action step and description sections to more specifically convey activities.

Was: 1-5

Now: 1-5

■ Action Steps and Descriptions

Minor editorial changes; no changes in order.

■ Budget

Consolidated. There were anomalies -- in objective #5, the bypass figure was less than the FY96 &95 figures.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

Pathogenesis

■ Goal

Wording was: Conduct and support research on the etiology and pathogenesis of HIV infection to define the mechanism by which the virus causes disease.

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

■ Objectives

All of the seven objectives were "etiology and pathogenesis" -- again, sounded like research was an objective onto itself. Text was pulled from action step and description sections to more specifically convey activities.

Was: 1-7

Now: 1-7

■ Action Steps and Descriptions

Minor editorial changes; no changes in order.

■ Budget

Consolidated. There were anomalies -- in objectives #1 and 3, the bypass figure was less than the FY96 & 95 figures.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

funding levels not consistent with decreasing objectives

Therapeutics

■ Goal

Wording was: Conduct and support research to develop therapeutics for HIV infection and its sequelae.

Now: Develop and evaluate therapeutics for HIV infection and its sequelae.

■ Objectives

All of the eight objectives were "therapeutics". Text was pulled from action step and description sections to more specifically convey activities.

Was: 1-8

Now: 1-8

■ Action Steps and Descriptions

Editorial changes for length and clarity; no changes in order.

■ Budget

Consolidated. There were anomalies -- in objectives #3 and 7, the bypass figure was less than the FY96 figures. Also, funding levels don't decrease with decreasing objectives.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

Vaccines

■ Goal

Wording was: Conduct and support research to develop vaccines for prevention of HIV transmission and infection.

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

■ Objectives

All of the six objectives were "vaccines". Text was pulled from action step and description sections to more specifically convey activities.

Was: 1-6

Now: 1-6

■ Action Steps and Descriptions

Editorial changes for length and clarity; no changes in order.

■ Budget

Consolidated.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

Information Dissemination

■ In area, was under research, changed to translation of science into practice.

■ Goal

Wording was: Develop and support appropriate programs for the dissemination of research information to health care providers and affected communities.

Now: Develop and support appropriate programs for the dissemination of research information to health care provider.

■ Objectives

The objective "information dissemination".

Was: 1

Now: 1

■ Action Steps and Descriptions

Minor changes.

■ Budget

Consolidated.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

Training

■ Goal

Same wording

■ Objectives

The objectives were "training and infrastructure".

Was: 1-2

Now: 1-2

■ Action Steps and Descriptions

Minor changes.

■ Budget

Consolidated.

■ Populations served

Each said 'all populations' -- requested clarification.

■ Constituency involvement

None noted. Suggested language for comment: Researchers, clinicians, community and patient representatives, NIAID Advisory Council, ARAC, and OAR Advisory Committees. Others?

■ Unmet Need

None was noted. Negotiated with Wendy using difference between Bypass and FY96 President's budget. Suggested language for comment: 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.

c:\work\wp\wp51\wp\admin\nih.c96

Submitted by NIH.

RESEARCH

PREVENTION

Agency: National Institutes of Health

Goal: Conduct and support behavioral and social science research to develop intervention strategies

Objectives: Behavioral Research

Action Steps: Prevent new HIV infections through behavior interventions. 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.

FY 95: 50,710

FY 96: 51,302

68,459 Bypass

Populations Served: All populations

Constituency Involvement: Missing

Unmet Need: Missing

Changed goal

Behavioral Research

is not an funding objective. + support research to this kind

Objective 2

in strategy

this is not an action step to behavioral research

Action step for Obj. #2 in strategy

concerned

Objective: Behavioral Research

Objective #1 in Strategy: 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.

FY 95: 79,959

FY 96: 83,149

Bypass 101,664

Populations Served: All populations

Constituency Involvement: Missing

Unmet Need: Missing

SAME

Consolidated

Objective #4 in Strategy

③
Objective: Behavioral Research

Action Steps: Preventing the negative consequences of HIV infection. 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;

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; and

~~Develop and evaluate programs to prevent HIV-related discrimination~~

FY 95: 27,293

FY 96: 25,264

Bypass \$35,022

Populations Served: All populations

Constituency Involvement: Missing

Unmet Need: Missing

SAME

CONSOLIDATED

✓

④
Objective: Behavioral Research *Objective 3 in Strategy. +5a* *Assess innovative dissemination strategies*

Action Steps: ~~Create and test innovative dissemination strategies.~~ 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;

SAME
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 bidirectional 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.

Calculated
FY 95: 1,364

FY 96: 1,444

235

352

} *way off.*

Populations Served: All populations

Constituency Involvement: *Missing*

Unmet Need: *Missing*

⑤
Objective: Behavioral Research

Objective 5 in Strategy. 4

Action Steps: Strengthen the behavioral and social science infrastructure. 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: 394

280

FY 96: 436

396 Bypass

Populations Served: All populations

Constituency Involvement: Missing

Unmet Need: Missing.

c:\work\wp\wp51\data\nihbehav.cwa

FY 95 - 159,720 (Grey FY 96
FY 96 - 161,595 (How Budget
Bypass - 205,893 (white FY 96
Bypass

	FY 95	96	Bypass
#1	50,710	51,302	68,459
#2	79,959	83,149	101,664
#3	27,293	25,264	35,022
#4	1,364	1,444	352
#5	394	436	396
TOTAL	159,720	161,595	205,893

Consolidated

✓

In Strategy.



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.

> was NIH objective #2

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.

was NIH Objective #1

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.

1 Was NHI Objective #4

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.

> was NIA Objective #3

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.

Duplicate of #3 in this document.

5b
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.

NIH
will prob
MACRO
FY 95: 159,720 Actual
FY 96: 161,595 Estimates
FY 97: President's Budget
Pops. Served: All populations

> was NIH Objective #5

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.

Weekly
will
come
up with this.

= Grey =

FY 96 plan

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

(Dollars in thousands)

Behavioral Research

FY 1994 Actual	FY 1995 Appropriation	FY 1996 Pres. Bud.
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Objective 1	Prevent new HIV infection through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.	\$46,181	\$50,710	\$51,302
Objective 2	Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change.	77,541	79,959	83,149
Objective 3	Preventing the negative consequences of HIV infection. 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.	31,849	27,293	25,264
Objective 4	Create and test innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.	1,353	1,364	1,444
Objective 5	Strengthen the behavioral and social science infrastructure. 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.	395	394	436

TOTAL, Behavioral Research	157,319	159,720	161,595
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Training and Infrastructure

Information Dissemination

Budget

Appendices

=Write=
FY 96 Bypass Budget

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

(Dollars in thousands)

Behavioral Research

	FY 1994 Estimate	FY 1995 Estimate	FY 1996 By-pass
Objective 1 Prevent new HIV infection through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.	\$56,568	\$60,506	\$68,459
Objective 2 Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change.	82,677	84,813	101,664
Objective 3 Preventing the negative consequences of HIV infection. 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.	29,725	30,408	35,022
Objective 4 Create and test innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.	218	235	352
Objective 5 Strengthen the behavioral and social science infrastructure. 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.	259	280	396
TOTAL, Behavioral Research	169,447	176,242	205,893

Area Research

Goal 5 Conduct and support behavioral and social science research to develop intervention strategies

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Prevent new HIV infections through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations	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	50,710	51,302	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Prevent new HIV infections through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations (continued)	Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.					
Behavioral Research	Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change	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.	79,959	83,149	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Preventing the negative consequences of HIV infection. 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	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; 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; and Develop and evaluate programs to prevent HIV-related discrimination.	27,293	25,264	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Create and test innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications	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 bidirectional 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.	1,364	1,444	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Strengthen the behavioral and social science infrastructure. 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	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 <i>practica</i> 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	394	436	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Strengthen the behavioral and social science infrastructure. 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 (continued)	Collect, archive, and disseminate existing data for secondary data analysis.					

B compared to A CW#C

PREVENTION RESEARCH

Agency: National Institutes of Health
~~National Insitutes of Health~~

Goal: Prevent new HIV infections through behavioral interventions.

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

~~Conduct and support behavioral and social science research to develop intervention strategies~~

Objectives: Behavioral Research

~~**Action Steps:** Prevent new HIV infections through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations~~

~~THE FOLLOWING TEXT WAS MOVED~~

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.

~~FY 95: 79,959~~

~~FY 96: 83,149~~

~~Populations Served: All populations~~

~~Constituency Involvement:~~

~~Unmet Need:~~

~~Objective: Behavioral Research~~

~~Action Steps:~~ Preventing the negative consequences of HIV infection. Discover,
~~THE PRECEDING TEXT WAS MOVED~~

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, ~~FY 95: 50,710~~
~~FY 96: 51,302~~

~~Populations Served: All populations~~

~~Constituency Involvement:—~~

~~Unmet Need:—~~

~~Objective: Behavioral Research~~

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.

~~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: and care providers, and~~

~~Develop and evaluate programs to prevent HIV-related discrimination.~~

~~FY 95: 27,293~~

~~FY 96: 25,264~~

~~Populations Served: All populations~~

~~Constituency Involvement:~~

~~Unmet Need:~~

~~Objective: Behavioral Research~~

~~Action Steps:~~ Create and test innovative dissemination strategies.

~~Action Steps:~~ Develop, — 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: — Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bidirectional 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.~~

~~FY 95: 1,364~~

~~FY 96: 1,444~~

~~Populations Served: All populations~~

~~Constituency Involvement: —~~

~~Unmet Need: —~~

Objective: Behavioral Research

Action Steps: Strengthen the behavioral and social science infrastructure.

Action Steps: Develop multidisciplinary and interagency collaborative efforts to enhance the AIDS behavioral research effort; ~~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

FY 96: 161,595

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.

~~394~~

~~FY 96: 436~~

~~Populations Served:~~ All populations

~~Constituency Involvement:~~

~~Unmet Need:~~

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NIH Submission

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: National Institutes of Health

Goal: Develop and support appropriate programs for the dissemination of research information to health care providers and affected communities *put back.*

Objective: ~~Information Dissemination~~

Action Steps: 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 as appropriate

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

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 the Global Programme on AIDS 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.

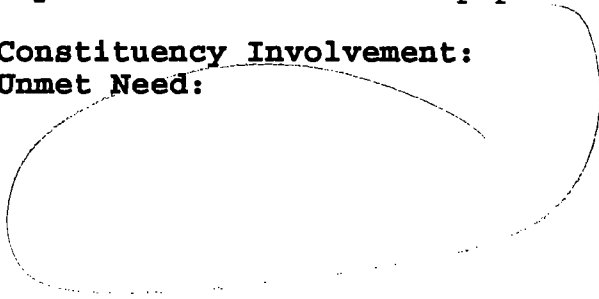
FY 95: 15,400

FY 96: 16,115

Populations Served: All populations

Constituency Involvement:

Unmet Need:



Strategy

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

FY 96: 16,115

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.

A v B

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.

~~Develop and support appropriate programs for the dissemination of research information to health care providers and affected communities~~

Objective: ~~Information Dissemination~~

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.

~~and prevention techniques to domestic as well as international audiences as appropriate~~

~~THE FOLLOWING TEXT WAS MOVED~~

Action Steps: Develop and rapidly disseminate important research findings that have immediate impact on prevention, health care, and treatment of HIV-infected individuals.

~~THE PRECEDING TEXT WAS MOVED~~

~~THE FOLLOWING TEXT WAS MOVED~~

utilizing all NIH, PHS, and public media communications modes.

~~and public media communications modes;~~

~~Provide up-to-date information on eligibility criteria for entry into clinical trials;~~

~~THE PRECEDING TEXT WAS MOVED~~

Descriptions: Provide up-to-date information on eligibility criteria for entry into clinical trials. ~~Develop and rapidly disseminate important research findings that have immediate impact on prevention and on health care and treatment of HIV-infected individuals,~~ 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, ~~and the Global Programme on AIDS 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

FY 96: 16,115

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.

~~Unmet Need:~~

NIH Submission

RESEARCH

Agency: National Institutes of Health

Goal: Provide support for training and infrastructure to carry out HIV and AIDS research

Objective: Training and Infrastructure

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 (about 3 percent of the budget) 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.

FY 95: 33,978
FY 96: 35,486

Populations Served: All populations

Constituency Involvement:

Unmet Need:

Objective: Training and Infrastructure

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, e.g., *M. nemestrina*;

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: 6,858

FY 96: 7,072

Populations Served: All populations

Constituency Involvement:

Unmet Need:

Strategy

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

FY 96: 42,558

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.

1 v. B

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.

~~Provide support for training and infrastructure to carry out HIV and AIDS research~~

~~**Objective:** Training and Infrastructure~~

~~**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; ~~in a range of AIDS-related disciplines to a level comparable (about 3 percent of the budget) 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.

~~FY 95: 33,978~~

~~FY 96: 35,486~~

~~Populations Served: All populations~~

~~Constituency Involvement:~~

~~Unmet Need:~~

~~Objective: Training and Infrastructure~~

~~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 for expansion of breeding facilities to ensure the adequate supply of species of emerging importance, e.g., M. nemestrina;~~

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

FY 96: 42,558

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.

~~FY 95: 6,858~~

~~FY 96: 7,072~~

~~**Populations Served:** All populations~~

~~**Constituency Involvement:**~~

~~**Unmet Need:**~~

RESEARCH

Agency: National Institutes of Health

Goal: ~~Conduct and support research to develop~~ vaccines for prevention of HIV transmission and infection ^{and evaluate}

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

Action Steps: Increase scientific knowledge about host defense mechanisms and protection against HIV infection and disease ^{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. ~~The identification of epitopes for which escape is not possible should receive more attention;~~

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.

~~FY 96: 47,844~~

~~Populations Served: All populations~~

~~Constituency Involvement:~~

~~Unmet Need:~~

② Identify strategies for eliciting protective
Objective: Vaccines 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 ~~(NIATD)~~;

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:

place additional emphasis on strategies in or about to be in clinical trial, practical immunization schedules, and challenge routes and viral isolates that most closely mimic the human experience;

delineate the mechanisms of immune protection; conduct transfer experiments to help dissect immune correlates;

determine the impact of dose on the nature and effectiveness of the immune response;

examine protection from organ-specific as well as systemic infection;

conduct long-term followup of vaccinated animals that become chronically infected to determine the impact of vaccination on disease progression;

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.

FY 95: 24,135

FY 96: 25,465

Populations Served: All populations

Constituency Involvement:

Unmet Need:

③ Evaluate efficacy of vaccine candidates.
Objective: Vaccines

Action Steps: Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is 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.

FY 95: 19,189

FY 96: 19,912

Populations Served: All populations

Constituency Involvement:

Unmet Need:

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

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.

FY 95: 3,174

FY 96: 3,501

Populations Served: All populations

Constituency Involvement:

Unmet Need:

⑤ Identify promising vaccine candidates
Objective: Vaccines 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.

FY 95: 19,398

FY 96: 21,177

Populations Served: All populations

Constituency Involvement:

Unmet Need:

Objective: ^⑥ ~~Vaccines~~ Conduct vaccine efficacy trials.

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: 200

FY 96: 229

Populations Served: All populations

Constituent Involvement:

Unmet Need:

1	45,735	47,844	57,506
2	24,135	25,465	35,473
3	19,189	19,912	24,361
4	3,174	3,501	10,386
5	19,398	21,177	21,424
6	200	229	5,621

118,128

154,771

Δ 36,643