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Message from the Director of the Office of National AIDS Policy

The epidemic of HIV and AIDS constitutes a public health crisis of unprecedented proportions. In 1993, the Office of National AIDS Policy (ONAP) was created by President Clinton to provide a national focus and direction for the government's response to HIV and AIDS. More recently, President Clinton asked ONAP to develop a comprehensive National Strategy that would chart the Administration's direction in responding to the HIV/AIDS national and international pandemic. This was as a result of the President's commitment to the development of efficient and collaborative policy and program efforts.

The development of a National Strategy for HIV and AIDS is an historic undertaking. While dependable support for research on new therapeutics, a cure and a vaccine for HIV/AIDS must be solicited, secured, sustained and on-going, we must simultaneously, and diligently, persevere in our efforts to prevent transmission of HIV, provide adequate health care for affected persons, and ensure the compassionate treatment of persons with AIDS.

No previous administration has undertaken so broad a planning effort that: (1) involves all Federal departments and agencies that engage in HIV-related efforts; (2) reaches out to communities and the private sector; and, (3) identifies areas where the

Nation should concentrate its crisis solving efforts.

Combating HIV disease will require nothing less than the best innovative and collaborative efforts of state, local and federal governments, the private sector, infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the plan's development of the Strategy. IDTF is a group consisting of representatives from executive branch departments and agencies that conduct HIV-relevant work. The appendices that follow the main text are a crucial and integral part of the plan as they contain information, from respectively participating agencies, that link goals and objectives to budget levels.

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the President's Advisory Council (PAC) on HIV and AIDS, the advocacy community, participants in the White House Conference on HIV and AIDS, service providers on the front lines of the epidemic, and many HIV-infected persons, their families, friends and care givers have been central to identifying areas for focused

positive

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

It was our intention to have the plan encompass where we are now in our crusade against HIV and AIDS, as well as where we believe we need to go. Since governance through collaboration is a hallmark of President Clinton's Administration, the National Strategy on HIV and AIDS will serve as a reference point for more lengthy dialogue and improvement in collaborative efforts between the public and private sectors (e.g., AIDS service organizations, the business community, Academia, health care providers and insurers). Community

It is important to remember that our efforts would not have been possible without leadership and direction at the highest levels of government. While the challenges of HIV/AIDS that are facing us cannot be solved by government or the private sector acting alone, more than ever in the history of this epidemic, we need innovative ideas, careful planning, and the strength of public-private partnerships to bring our strategy to fruition.

The HIV/AIDS epidemic challenges us on many fronts. The most common transmission routes of HIV and AIDS are sexual activity and drug use, each of which is a reality that many Americans find difficult to acknowledge, discuss and confront. Despite any individual and collective sensitivity to either reality, our leadership and citizenry has, nonetheless, little alternative but to confront these issues

directly for the sake of long life through good health for ourselves, our children and future generations.

Fear is an integral component of our confrontation - fear of contracting the disease, as well as the unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is threatened with fundamental programmatic changes and reductions in funding. 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.

Despite the many difficulties, AIDS has also brought forth an outpouring of compassion and caring. In my many meetings around the country with persons living with HIV, I have been inspired by numerous examples of great personal courage. I have been impressed by the dedication with which many communities and individuals have overcome obstacles in preventing infections and caring for those who are sick. By example, it demonstrates that, as a Nation, we, too, can collectively rise to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are at-risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease.

Today we are facing great challenges, but

we are also facing equally great opportunities. While AIDS is a terrible tragedy that has already affected far too many people around the world, I believe it is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National Strategy for HIV and AIDS lays a foundation for the public-private partnerships that are essential to our success. Together, with steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

I. INTRODUCTION

Preface

The Need for a National Strategy for HIV and AIDS

The National Strategy for HIV and AIDS has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, state and local governments, and the private sector.

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. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and solutions. Our National Strategy must incorporate innovative ideas, careful

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planning, and the strength of public-private partnerships.

The Strategy as a Catalyst for Change

(1) The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS. The main text of the document addresses goals and opportunities to assist planners in developing implementation plans; the associated appendices are a compendium of current Federal activities and serve as an informational foundation for these planning efforts.

(2) The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. However, the objectives that are identified in the document are the same as the country's core objectives for combating the HIV epidemic; and, the opportunities for progress are the same as those that are within our grasp. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS and private sector organizations. Successfully capitalizing on these opportunities for progress will require both public and private support.

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Executive Summary

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Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. [Awaiting revised language from NIH.] While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the CDC in June of 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

As of October 1995, the Centers for Disease Control and Prevention (CDC) reported 501,310 cases of AIDS among persons in the U.S.; 311,381 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS and more than 45,000 AIDS-related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each

year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has evolved, 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 of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users. Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1994, more than 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1994 alone, more than 1,000 new pediatric AIDS cases were reported. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among people under the age of 21. Under current trends, between 27 and 54 young people in the United States under the age of 21 are infected by HIV each day, or more than two young people every hour. Moreover, a significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are

prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been more severely and disproportionately affected by the epidemic. 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 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of October 1995 these groups comprised 51 percent of cumulative AIDS cases. Gay men of color in certain regions of the country account for approximately 39 percent of new AIDS cases.

AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to non-urban areas, including dramatic increases in certain regions of the South and Midwest. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462) were reported from the South.¹ While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 states, the District of Columbia, Puerto Rico, and each of the American Territories. (See Figure 2.)

Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has

estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

The Social Impact

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been discharged from their jobs and evicted from their homes. Unlike other persons with infectious diseases, many persons living with HIV have been the target of violence, rejected by their families, and suffered discrimination because of their HIV status.

~~[Awaiting revised language from NIH.]~~

AIDS is a disease that ~~can be acquired at any time but~~ most often affects people in the prime of life. ~~[Awaiting revised language from NIH.]~~ It disproportionately kills people during their most productive years. That it is the leading cause of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.² 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 1994, HIV infection was the fourth leading cause of potential life lost before age 65.

AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime

medical care after diagnosis for an HIV-infected person costs more than care for patients with cancer or heart disease, specifically: \$61,211 for heart disease³, \$25,000 to 84,000 for cancer⁴, and \$119,000 for HIV/AIDS⁵. Overall HHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS. In FY 1995 HHS is slated to spend: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$ 6.0 billion for AIDS. [DHHS -- update figures.] ✓

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. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 million children will be orphaned by the year 2000. The human toll has been staggering and is likely to continue.

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The Evolving Challenge of the HIV/AIDS Epidemic

The four decades prior to the report of the first AIDS case in the early 1980s encompassed a period of unprecedented success in controlling infectious diseases. The emergence of HIV, and the subsequent epidemic of HIV and AIDS, has posed an evolving series of unique scientific, economic, and social challenges, both domestic and international. Today the challenges we face with the epidemic are very different from challenges we faced previously.

In the early years of the epidemic, significant scientific resources were dedicated towards understanding how the disease was transmitted and identifying its underlying cause. Thanks to this work, we now know the risk factors, the etiologic agent, and we have a test to ascertain the serostatus of infected persons and can, therefore, protect the blood supply.

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV-related immunology and pathogenesis, and, developing therapies for the primary infection and associated opportunistic infections. New and more powerful therapies that offer new hope for treatment and prevention have been developed. Scientists now believe that a vaccine is possible. Current day discoveries also create new challenges for the future. We now face new scientific challenges in developing a vaccine and the new generation of therapeutics for primary and opportunistic infections. HIV

Since the beginning of the epidemic, behavioral research designed to understand the behavioral, social, cognitive, and biological factors that place individuals at risk for acquiring HIV infection has provided ^{important} insights. Practical experience has also taught us that prevention efforts can be effective. However, behavioral research remains a relatively young science and there are currently more questions than answers. The challenge before us now lies in expanding the scientific underpinnings that will allow us to design more effective prevention programs that will reach even more Americans at risk for infection.

? Progress that entails the development of therapies and prevention programs has also spawned new problems for the health care delivery system. As a result of improved therapies, people with AIDS now live twice as long as they did a decade ago. [Awaiting additional language from NIH.] Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy. The recent approval of a new class of therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier ~~on~~ in their infection so they can receive the new treatments and we need, as well, to ensure that health care professionals are well-trained and know the best way to provide that care.

Ensuring access to prevention services and medical care for the growing number of people who need, or will need, health care is an enormous task. There are societal and

economic changes that are influencing the ways in which the country addresses the issues of health care access and cost. There is a trend towards decentralizing the role of the Federal government in health care and placing more responsibility at the state and local levels, coupled with a movement to managed care systems. These changes will influence efforts to strengthen prevention efforts and ensure health care and services for people with HIV/AIDS.

Internationally, the spread of HIV threatens to undermine the economic progress and political stability of many developing nations. In the early years of the epidemic, the Special Programme on AIDS, which later became the Global Programme on AIDS, was set up during a period of time marked by global fear and ignorance. There was a great deal of uncertainty and hope that the HIV outbreak could be brought quickly under control through a vaccine. There were many questions, including: "What were the best ways of preventing new infections?" "Would HIV spread to all parts of the world or would some countries be spared?"

Today, as the Joint United Nations Programme on HIV/AIDS is born, time has answered many of these questions. Of all the lessons that we have learned, the greatest one is that there is no quick or simple solution to the AIDS epidemic, medical or otherwise. We have moved beyond the medical model and one bullet approach to solving the worldwide pandemic. It is in this context that we need to focus on broader, socio-economic factors such as poverty and access to health care service.

From a societal perspective, while we have

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made tremendous progress in overcoming fear and discrimination, we still have a long way to go. There are no grounds for discriminating against persons with HIV infection and yet the fear that emanates from a false perception of risk has affected their treatment in the workplace and in housing. Discrimination has thwarted access to health care, health insurance, housing, employment, and even funeral services, despite the progress that has been made in ensuring that the protections provided under the law are extended to all HIV-infected persons.

Goal of the National Strategy

The goal of the National Strategy for HIV and AIDS is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, state and local governments, and the private sector. To attain the goal we will need innovative ideas, careful planning, and the strength of public-private partnerships to make these plans a reality. The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

Development of the Strategy

The National Strategy for HIV and AIDS presented here is broader in scope than any prior planning efforts. To date, planning has been focused primarily in the Public Health Service (PHS)⁶, Department of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome⁷, the "Coolfont"⁸ and "Charlottesville"⁹ reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States¹⁰. Recommendations have also been issued by a number of groups, including the National Commission on AIDS¹¹ and the Presidential Advisory Council for HIV and AIDS. There have also been significant planning efforts on the part of individual agencies. However, until now there has not been a national plan that provides for a government-wide coordinated

effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

Effective planning requires a genuine commitment from participants to work together toward clearly defined goals. Therefore, the strategy for HIV and AIDS has been developed by the Federal Departments and Agencies that support HIV-related activities and along with the counsel of HIV-infected persons and their advocates, the private sector, and the Presidential Advisory Council on HIV and AIDS.

Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a formal request went out for the executive branch agencies to identify their activities, goals, and objectives. This pertinent data has been compiled uniformly and is contained within the appendices of the strategy. IDTF members, with their specialized knowledge of a broad range of HIV-related issues, have been crucial in identifying areas requiring special attention.

There has also been a reliance on groups outside of government -- the same groups that have been ~~will~~ continue to be essential partners in developing solutions and capitalizing on the opportunities for progress that lay before us now. The recommendations provided by the President's Advisory Council (PAC) on HIV and AIDS have been invaluable. The insight and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for

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

As presented here, the Strategy establishes a baseline of current efforts government-wide, links goals to budget objectives, and guides the refinement of our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

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Common Objectives and Opportunities for Progress

Based on the consultations, the following national objectives are established:

- To provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- 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; and,
- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

So a summary
It is these objectives that will set the country's sights and remain our guide as we chart our course.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent 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, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

Implementation

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First, it is important to realize that this document is a snapshot of where we are and where we think we need to go. The Strategy serves as a reference point for the lengthier dialogues and a foundation for future collaborative planning efforts between the public (i.e., Federal, State, and local governments), and private (i.e., ~~AIDS~~ *PWAs* service organizations, the advocacy and activist community, businesses, pharmaceutical and biotechnology companies, academia, health care providers, and insurers, etc.) sectors that will be absolutely essential.

timeframes
Each issue raised in the Strategy is ~~unique~~ *and* will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a handful of people, while others will require extensive thoughtful effort on the part of many players in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities. Each issue embodies its own distinctive set of obstacles and opportunities that will require individualized approaches and time frames for resolution.

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The Strategy and the implementation efforts that follow represent many firsts. It is the first time a planning effort for HIV-related activities has been attempted *on a* government-wide scale. For the first *time* there has been a formal mechanism developed for bringing together decision makers from Departments and Agencies with HIV-related programs and responsibilities -- the Interdepartmental Task Force for HIV and AIDS. It is the first time a planning initiative of this magnitude emphasizing the importance of public-private collaboration has been envisioned for HIV-related issues and it is likely to take some trial and error to make it work. *timeframes*

Organization of the Strategy

The National Strategy is organized into 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 three locations within the document. 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 a corresponding appendix that provides information on individual agency goals, objectives, funding levels, constituency involvement, and unmet needs. And third, funding tables can be found in Appendix G.

Current agency activities have not been arranged around administrative structures, but by area. In cases where a single agency may have responsibility for more than one area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In some cases there are cross-cutting issues that could fall into several categories, such as internationally-based treatment and prevention efforts. In this case, programs that are specifically targeted towards countries, geographic regions of the world are included in the international section.

The type of information provided in the appendices varies depending upon the type of efforts Departments and Agencies sponsor. Support for HIV/AIDS activities falls into two general categories: in the first, HIV/AIDS activities are an essential part of the mission; in the second category, HIV-related activities are not an explicit part of the mission but are indirectly supported or receive collateral benefit from agency supported work and/or policies. There are a number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA)), while

other agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Data are presented, therefore, in a manner consistent with an agency's level of involvement.

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Depts + Agencies?
or Agency

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

Department of Labor -- confirm.

For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.

Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.

Journal of the American Medical Association, July 28, 1993.

The Public Health Service Agencies within DHHS with responsibility for a range of activities and programs associated with the HIV epidemic are: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMSHA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Food and Drug Administration (FDA), and the Indian Health Service (IHS). Information regarding these agencies can be found in the Appendices.

7. Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome (AIDS), Public Health Reports 100:453-455, September-October, 1985.

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AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993.

Here are two more sections ... Population + Research . . .

Overview of Federal Efforts

Introduction

The scope and nature of the HIV/AIDS epidemic has brought ~~state~~, local, and Federal involvement into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in ~~Federal~~ activities since the beginning of the epidemic. In 1985 the Federal government spent \$212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached \$6,848 million. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Care Act, ~~the Ricky Ray bill~~, and the NIH Reauthorization of 1993. ~~Not passed~~

Currently, Federally sponsored 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, academic institutions, private foundations, health care institutions and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

PREVENTION

The Nation's prevention goal is to develop effective prevention strategies that will 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 task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.⁷ 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, the long period of time when people may not be aware they are infected, 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 diversity of age, race, 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 Department of Health and Human Services (HHS), although other departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These 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

⁷ 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.

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. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers Program.

The efforts of Federal agencies as well as research conducted at universities and private organizations, 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 ensure lasting behavior change.

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

Opportunities for Progress

Modes of Transmission

An important part of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use and their sexual partners, young and minority men having sex with men, heterosexual transmission, and perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people

were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to 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. Seroprevalence surveys provide information on the level of HIV infections on selected "sentinel" populations. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. 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. (These data must be collected with the appropriate confidentiality protections.) 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 necessitate reconfiguring 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 strategies¹², the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Prevention Research⁸

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

⁸ Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.

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 incorporates findings from both experience and relevant research. Behavioral research is a relatively young science and there are currently more questions than answers. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

Basic Behavioral Research. Information provided by the conduct of basic behavioral research should serve as the foundation for prevention programs. Basic behavioral research, similar to basic research in other areas of scientific inquiry, seeks to explain the determinants and causes underlying biological, behavioral, and social processes. HIV-related risk-taking behavior is often complex and influenced by a host of individual and environmental factors.

To capitalize on what is known and improve 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.¹³ 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.¹⁴ [Awaiting revised language from NIH.]

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

In HIV and AIDS, this intervention research can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has

identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.¹⁵ Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.¹⁶ 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.¹⁷

However, despite this evidence of success, 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 on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in 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.

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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 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. [Awaiting additional language from NIH.]

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, 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.

Prevention Programs

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 Prevention and Treatment. Injection drug use is one of the major forces driving the epidemic with one third of all new cases are directly or indirectly related to this mode of transmission. Limiting the impact of substance abuse on the epidemic will require efforts on several fronts. First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated so we must continue to 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. In addition, it is estimated that x percent of the population is affected by alcohol abuse and other non-injectable drugs. Part of the Federal response to this problem

should be increased the availability of treatment for a range of alcohol and drug addictions.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for those in need of such services. This would include services that accept pregnant women or women with children, indigent members of the community and adolescents.

Work on this issue has begun and will continue. The CDC has convened a meeting of state and local people involved in both public health and drug prevention to develop an action plan that integrates HIV prevention and substance abuse prevention. This meeting was an important initial step and highlighted the need for continued dialogue among various groups (i.e., public health officials, law enforcement, community representatives, clinicians, etc.) to address the issues related to preventing HIV transmission among drug users.

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.^{18, 19} 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.²⁰ In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

It is important that Federal and state efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV prevention element, and, that HIV prevention programs incorporate STD prevention and treatment efforts. Moreover, the traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the

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epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

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

Incorporating a patient's sexual and drug using 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 is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

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 State, 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 be continued, what activities need to be initiated, and awareness that a reconfiguration of some program priorities may be required.

Dr. Williams

11/16/94

RESEARCH

One of the Federal government's goals is to provide strong support for research in order to find treatments and 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 advocacy 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. It will also require 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. 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 health services 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. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The agency also supports facilities employing sophisticated methods for identifying viral variants.

Contributions of Research

[Awaiting revised language from NIH.] The Nation has already reaped some of 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.

Advances in treating conditions resulting from immunosuppression have come from HIV-targeted research. One of the most promising

experimental therapies for advanced breast cancer is high-dose chemotherapy followed by bone marrow transplantation, but the treatment that causes profound immunosuppression; AIDS-related research has provided valuable insights regarding the management of these patients.

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.

Research involving the blood/brain barrier has led to a better understanding of the mechanisms by which infectious agents spread into the nervous system. These findings provide valuable clues for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of more viral diseases and led to development of treatments for many other diseases.

Research investments made before the advent of the AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research previously conducted on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses yielded invaluable 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 Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. Clinicians now have a growing array of medication to treat and in some cases prevent a variety of HIV-associated opportunistic infections. An NIH-sponsored study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Data from federally-sponsored prospective epidemiological studies are helping scientists understand the factors that enable long-term non-progressors to live many years after infection without presenting clinical signs of progression to AIDS. [Awaiting revised language from NIH.] Understanding what happens in these non-progressors may help researchers develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus. [Combination therapies are also showing great promise in this area and in preventing perinatal transmission.] 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, many complex biomedical and behavioral challenges remain. 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

Coordinating Federal Research. Developing and implementing the Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing this massive Federal effort requires coordination efforts at two levels -- one within NIH and the second among the Departments and Agencies supporting HIV research.

Within the NIH, the agency with the largest 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~~ ^{consolidated} 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.

(^{Consolidated} 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 support a broad spectrum of research related to HIV and AIDS. Multiple Federal departments and agencies have responded with research initiatives that bring to bear their unique capabilities and strengths. For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the

Office of National AIDS Policy coordinated an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge it was to develop a coordinated plan and budget specifically for HIV and AIDS research across all agencies departments. [Awaiting additional language from NIH.]

The first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

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

On the scientific level, researchers presently hold two major views regarding the most promising approaches to vaccine development. Some scientists maintain that there is not sufficient information about the virus to warrant efficacy trials and there is a need to gather more basic science information to guide us. Others assert that only clinical efficacy trials in humans will provide the answers that will lead to the development of a successful candidate. This group believes that if a safe candidate is available, it is not necessary to resolve all of the scientific questions before proceeding, and, that in the face of a global emergency testing in people should begin immediately. Both groups have valid arguments.

The issues driving this debate are scientific and social, and stem from the contrasting ways different parts of the world are experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. [Awaiting revised language from NIH.] Both the social and scientific issues must be considered when planning trials. Given the state of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Both approaches face significant obstacles and it is clear that the developing a vaccine cannot be accomplished by the government or

the private sector working apart -- a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue. [Awaiting revised language from NIH.]

In addition to effective collaboration with private sector partners, it is also vital that the Federal effort be well-coordinated. The Federal linkages that were strengthened during the development of the Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS should be utilized in furthering coordination. [Awaiting additional language from NIH.]

Microbicides. Many scientists believe that the prevention of sexually transmitted HIV infection will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections. [Awaiting revised language from NIH.] Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs²¹. Microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

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 will reduce the risk of acquiring HIV and other STDs there are many situations in which interpersonal, 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. [Awaiting revised language from NIH.]

The development of this important prevention option will depend on strong support for basic and clinical research. Microbicides are a promising approach, but will require preliminary Federal support before they reach a stage where the pharmaceutical or biotechnology industries can assume a lead role. Discussions among Federal agencies, the private sector, and advocacy groups have been ongoing and should continue in order to identify areas for worthwhile collaboration and hasten the pace of development. the PAC suggestion of a conference? [Awaiting revised language from NIH.]

Examining the Impact of HIV on Youth. HIV-related research has made great strides on many fronts, however, adolescents have not received the full benefit of research discoveries. To date, HIV research efforts have primarily focused two specific populations: infants and adults.

But scientific information exists to indicate that HIV may behave differently in infected adolescents and that there are adolescent-specific health-care needs that must be addressed. Adolescent treatment approaches may vary from those used for adult or infants. Because little definitive research has been conducted to date with HIV-positive adolescents, the specific impact of puberty on the course of HIV infection has not yet been determined. Behavioral trends that play a key factor in treatment and prevention have also not been sufficiently studied.

Adolescents must become a bigger part of the research process. The NIH and the Food and Drug Administration should examine options for lowering barriers to participation and continue to encourage sponsors to enroll adolescents, when feasible and appropriate, in HIV/AIDS clinical trials.

There is also need for adolescent-relevant information on the part of clinicians and researchers. The Public Health Service should continue to develop in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program⁹, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding clinical effectiveness are increasingly unavailable. For example, we do not know the optimal stage in the course of HIV

⁹ The accelerated approval regulation permits companies to seek approval of drugs for serious or life-threatening diseases when the drug provides meaningful therapeutic benefit over existing therapies. Under these procedures, the FDA may approve drugs based on surrogate endpoints, such as CD4+ cell counts that reasonably predict that a drug provides clinical benefit. The company is then required to confirm this clinical benefit through additional human studies to be completed after marketing approval. The accelerated approval regulation provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

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.

If these studies are not done there will be little data describing 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 treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that post-marketing effectiveness studies, currently mandated through regulation are carried out. In order for the results to be relevant to as many persons as possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, the NIH, and the advocacy community. ~~[Awaiting revised language from~~

Public-Private Partnerships. As has been noted previously, 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 the conduct of vaccine trials and this effort should be strengthened. As noted previously, microbicides (i.e., chemical barrier methods for preventing HIV transmission) are a promising approach, but will require preliminary Federal support before they reach a stage where the private sector can assume a lead role. ~~[Awaiting additional language from NIH.]~~

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is 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 in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted;

these are important efforts that should continue. [Awaiting additional language from NIH.]

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. [Awaiting additional language from NIH.]

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 to a cure, better therapies, 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. [Awaiting additional language from NIH.]

CARE & SERVICES

objections?

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. [For many 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 net.] 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.

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Background

and 90% live

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.

For those ^{who} ~~that~~ qualify, care and services are provided through a number of Federal agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably served those living with HIV. Taken together, these efforts form a valuable if 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.]

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After M'aid

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

for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service/DHHS which provides health care for HIV-infected Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV positive persons in Federal prisons.

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. The HOPWA program has, in partnership with local initiatives, assisted communities to better coordinate local and private efforts, fill gaps in local systems of care, and create model programs. Additionally, HUD has initiated a "Continuum of Care" approach to building local systems to address homelessness (many persons with AIDS are at risk for being homeless); the effort has resulted in significant leveraging of additional dollars (private dollars?) to address this critical problem.

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. The cornerstone of care for people living with AIDS in the U.S. is Medicaid. Nearly 50 percent of all Americans living with AIDS -- including 92 percent of children with AIDS -- rely on Medicaid for their sole source of health coverage. Medicaid provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. These services extend the length and the quality of life for people living with HIV and AIDS. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at \$1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

Maintenance of the Federal guarantee of Medicaid coverage for eligible individuals is essential to the continued ability of the Nation to respond to the health care needs of people living with HIV/AIDS. Of particular importance is the maintenance of a Federal definition of disability. The 30-year State partnership in Medicaid also must be maintained while the program is made more

flexible for state innovations.

With a strong Medicaid program in place, it continues to be vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work yet they are not poor enough or disabled enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

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 who may be at risk for HIV infection 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 for education about behaviors which may reduce their chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, 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 state, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.²²

Persons living with HIV face significant obstacles locating

affordable housing. 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.

Cost effective
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.

assistance
Housing is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS. To foster community involvement, HUD has established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as Public Housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

Providing consistent funding for the housing component of the safety net with programs such as community-oriented programs HOPWA must be a Federal priority. Moreover, integrating housing services into other programs and ensuring a shared responsibility between Federal, state, local governments and community organizations is another important step in assisting communities build seamless systems of support for our most vulnerable citizens. Efforts are underway to improve inter-departmental coordination and should continue.

Prisoners. There are also groups of people, such as prisoners, who are not served by these traditional safety net programs. 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. Identifying the HIV positive prisoners and ensuring them 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 less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health departments and agencies, *and* improving discharge planning. These efforts can 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 should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal agencies. For example, creating a community program that integrates primary care with substance abuse treatment and prevention, ~~and~~ sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

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

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.

Quality of Care. 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.

A 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, states, professional organizations, professional and medical schools, and individual clinicians.

*Look @ daily
Journals.*

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 and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe. *2000*

Advances
The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.²³ In many countries, governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

~~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.~~ *Why?*

At present several Federal agencies are working at slowing the AIDS epidemic internationally. (See Appendix D.) The Department of State has worked with other departments, agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify national and international efforts. The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several agencies support research overseas, including the National Institutes of Health, the

Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. [Awaiting additional language from NIH.] 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).¹⁰ Moreover, the U.S. is a member of the governing body of UNAIDS.

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 increase the availability of therapeutics (and vaccines when developed) to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

Sharing Technology and Bringing Lessons Home. (Include footnote to this project for those who are not familiar with its content). 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

Lesson without Borders Project
bring the lessons back home
bring the lessons back home

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

culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, ^{and} U.S. based non-governmental organizations and indigenous groups.

US indig groups? actions?

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

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} must develop a mechanism for identifying and coordinating this effort.

1022

TRANSLATION OF RESEARCH INTO PRACTICE

1^o Can also broaden definition,
prev?

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 assessing risk, promoting prevention, and 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. DHHS supports and directs the International HIV/AIDS Clinical Conference Call series which disseminates critical, state-of-the-art clinical care information to primary care providers via live world-wide audio tele-conferencing. NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. [Awaiting additional language from NIH.] The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

15 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~~ 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, funds an AIDS warmline which responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers which provide state of the art HIV clinical information to health care providers.

Opportunities for Progress

new knowledge
incorporated into standard practice for → clinicians,
service providers & human
population

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. However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians may miss significant HIV-related symptoms during patient examinations.²⁴ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.²⁵

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~~ ^{and action by a number of federal agencies} 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.

State of the Art Guidelines. One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. ~~[Awaiting additional language from NIH.]~~ It is essential that practical information for practicing clinicians and their patients ^{be} 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.

Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy has the lead responsibility for coordinating the HIV-related activities of the Public Health Service. 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 continued high level of cooperation and coordination among Public Health Service agencies. ~~[Awaiting revised language from NIH.]~~ ^{ignore}

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 developing, implementing, and evaluating prevention programs. 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.

that

CIVIL RIGHTS

One of the Nation's common goals is to ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards. Discrimination based on HIV status *is* illegal and morally wrong.

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, consequently do not take advantage of care that could help them live longer, healthier lives. In addition, opportunities to educate people are lost. Discrimination can also wrongfully deny persons access to housing, employment, and health care.

The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. 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.

Opportunities for Progress

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

Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. The

Director of the Office of National AIDS Policy is working with Federal agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

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

Missing -

> NIH Substantive comments?

> FDA - 1 page on
folic acid enrichment.

~~CHAP raised conc~~
~~accuracy - assume this~~
addresses that

What is ASL?

IHS

OIH

OPA



Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

APR 10 1996

NOTE TO JEFF LEVY

SUBJECT: Comments on the Draft National Strategy for HIV/AIDS

This follows the meeting last Wednesday with you, Jane Sanville and representatives from the Department's Staff Divisions wherein we discussed your preliminary draft National Strategy for HIV/AIDS. The consensus at the meeting was that the preliminary draft document in its present form should not be considered a draft strategy or plan for HIV/AIDS. Specifically our major concerns are that discussion of specific objectives in the draft be viewed as a compendium of current program activities underway in the Federal government and that the narrative portion of the draft be the starting point from which an actual national strategy could evolve.

Specifically, the following broad concerns need to be considered in formulating a national strategy for HIV/AIDS:

- o Involvement of State and local entities and the private sector (business, health, education/academic, research) interests to insure that the strategy is representative of national views and responsibilities. This is essential in insuring a strategy that encompasses more than just Federal government participation. *PP letter, Goal (add resolution section)*
- o The strategy should be built upon previous plans and activities to address HIV/AIDS, both in the Federal (including Congressional) and non-Federal sectors. Progress in combatting the disease as a result of previous efforts should be cited. *(Expand past planning, A title)*
- o The development of a strategy to address HIV/AIDS should be crafted within a defined context of the current scope of the disease. The challenge should be articulated in terms of: the changing nature of HIV/AIDS and why its effects are different today than 10 years ago, and 5 years ago; the demography of the disease and the populations it is now affecting as

Disjoint old strategy/plan

*ARs
- Virus
- Test
- Experience
- How to manage cases*

Page 2 - Mr. Levy

~~compared to past years; new research discoveries that have taken place in recent years and months that are changing the direction of HIV/AIDS treatment and prevention; other, societal changes that are influencing and impacting the ways we address issues of health care, access and cost in our nation (for example: the move to decentralize the role of the Federal government and place more responsibilities at State levels, shrinking Federal, State and local resources, the movement to managed care systems); and the impact these changes may have on our continued efforts to insure care and services for people with HIV/AIDS and to strengthen prevention efforts.~~

- o As a basis for developing the strategy, working groups comprised of Federal and non-Federal participants should identify and delineate met and unmet needs and craft a strategy that moves the nation toward a comprehensive solution. *MTF mechanism, different ^{problems} groups need different approaches.*

Attached are technical comments from various reviewers within the Department. We look forward to reviewing the revised document.

EGP

Eric P. Goosby, M.D.

Attachments

*Jeff's snapshot in time
language.*

Who?

3

Draft National Strategy for HIV and AIDS

Comments

Overall

- o The document should contain a **Preface** that describes: why this plan was developed (the need for it at this time), for whom is it intended (who is the audience?); what is its purpose/intended use; who (what individuals or organizations) participated in preparing it and reviewing it. These are important points to address at the beginning of the document in order to provide a context for the plan and the actions it recommends.

notes in

Note: We would recommend that part of the developmental process for a "national" plan include a method for insuring non-Federal review by a variety of known experts in the specific areas addressed in order to achieve consensus on the importance of issues and the best manner in which to resolve them.

- o The "Letter" from the National Director of ONAP should be revised into a **Message from the National Director of ONAP** of no more than one and one half pages that clearly articulates the urgency of the HIV/AIDS crisis, calls for a unified national approach to addressing it, provides an overview of the urgent priorities that lead to developing this plan, and ends with a statement of vision in how this plan can be instrumental in combatting this disease.

notes in

- o Additionally, the document should contain an **Executive Summary** to highlight the goals and associated areas for progress, and to summarize the key recommendations of this plan. This Executive Summary would be very useful in synthesizing the key issues presented in the more voluminous plan.

Put in place holder

- o We suggest that a professional editor review the whole document to provide consistency of terms and to standardize the language so that the document flows as if written by one entity.
- o The document needs to be double checked for accuracy of all data, budget figures, and cost figures, presented throughout.

Discussion of Issues

- o Page 5. In discussions of the Scope of the disease and the public health threat, some historical perspective is called for in order to illustrate the growing problem HIV/AIDS continues to present after 15 years.
- o Page 7 - Discussions of "The Social Impact" of this disease should be strengthened. Specifically this section needs to be expanded to include specific indications of the impact in areas of cost to the Nation in terms of lost lives/productivity and cost issues associated with treatment and care for those infected with HIV disease.
- o Page 9. The list of three goals does not match the order of the ensuing "areas for progress" on page 10. A specific goal for substance abuse should be included in the list of goals.
- o Page 10. The "Challenge of the HIV Epidemic," needs to be updated. Statements such as "... we now know how it (HIV) is transmitted ..." and "... we have a test to diagnose infected persons and to protect the blood supply," contain information that is over a decade old and widely known. (The HIV antibody test has been in use since 1984.)

The discussion here should embrace the challenge of the epidemic as different than that which was experienced a decade ago. This is best seen in the changing nature of HIV and AIDS: more young women are becoming infected, minority populations are at especially high risk, the geographic diversity of this disease has widened, therefore its impact on the country has increased. (What are the current and future implications of this for the country?) How do we move to address the needs presented by this ever expanding, more diverse disease in an environment of critically shrinking Federal, State and local resources caused in part by changing cultural attitudes that define government as small not big, decentralized and limited in its authority to provide reimbursement for health care, treatment and services for needy populations, such as people with HIV/AIDS?

- o Page 12, "Overview of Federal Efforts." This section should include some reference to the level of past efforts to combat HIV/AIDS (including in general amounts the money that has been spent on Federal programs over the past 15 years.) This section should also include Congressional legislative efforts (Ryan White CARE Act, Americans with Disabilities Act, etc.) to assist people with HIV and AIDS and their families. 2

In this section, discussions of how this "report" is organized should be moved to the front of the document, perhaps as part of a preface section that we recommend should be included (see first page of comments.)

- o Page 14 - 22, "Prevention." The Prevention section lacks a clearly stated concept of targeting high-risk populations. Identifying HIV positive patients in these high-risk populations and bringing them into a continuum of care and support services is essential for maximizing our ability to effectively impact on the spread of the HIV epidemic. The role of protease inhibitor combination drug therapy on primary prevention is not addressed and needs to be.
- o Page 16, third paragraph. The role of surveillance as a link to epidemiologic data in order to target high risk populations is eluded to but not discussed in the context of program activity (there is a need to address how to do this, who should do it, etc.)
- o Page 18, second paragraph - a sentence needs to be added to state that more research is needed in recidivism and strategies to minimize. Study didn't mention but is
- o Page 19, "Community Involvement," second paragraph. A point needs to be made with regard to the lack of accountability in the allocation decisions. The States make the final allocation decision, the Planning Councils' recommendation are only recommendations.
- o Page 21, fourth paragraph, first line: "While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection ..." This statement does not represent DHHS or Administration policy. REMOVED

- o Page 29, "Public-Private Partnerships." The Office of HIV/AIDS Policy in DHHS assists the ASH in coordinating the development of standards of care across the public health operating divisions in the Department (NIH, CDC, HRSA, SAMHSA, and AHCPR.) This includes acting in a liaison capacity with the private sector, the pharmaceutical industry and HMOs. Ø
- o Page 32, "Opportunities for Progress." A central challenge to provision of care and services for HIV/AIDS patients and their families is the current public debate regarding the redefinition of the Federal role in providing reimbursement and the growing support for these responsibilities to be remanded to the States. Important questions need to be examined such as: will the programs continue? What are the implications for people with HIV/AIDS and their families? Are there current studies on what the impact of this will be on affected individuals, families, States and the country as a whole? Ø

Another challenge is the concurrent move to managed care and the implications this will have for HIV/AIDS patients, particularly as Federal reimbursement/support systems shrink and health care becomes more defined as profit based. While the answers are as yet not fully known, these questions or similar concerns should be raised in any discussion of provision of care and services to people with HIV/AIDS.

*transfer
Klein
language*

- o Page 32, add - Other sources of primary care supported by the Federal government are: Department of Defense (DoD) which cares for 1,094 HIV/AIDS positive patients; Department of Veterans Affairs which cares for 17,000 HIV/AIDS patients in VA hospitals and clinics; and the Indian Health Service/DHHS which provides health care for 1,000 known HIV infected Native Americans and Alaska Natives (NA/AN) and 300 NA/AN people with AIDS. Additionally, the Department of Justice's Bureau of Prisons provides care for HIV/AIDS infected persons in the Federal prisons (page 34).
- o Page 33, 4th. paragraph, Add - " Linking an HIV positive person with care also provides an opportunity to impact on primary prevention. Infectivity appears to be directly proportional to decreasing viral load. Decreasing viral load appears to result in decreasing infectivity. Do we know this?
3

The role of nucleosides and the new protease inhibitor combination drug therapy is yet to be defined, but is very promising."

- o Page 35, add - "The DHHS needs to coordinate across agencies to maximize coordination attempts at the local level."
- o Page 37, add - "The Office of HIV/AIDS (OHAP) DHHS has established joint projects with the Ministry of Health in Canada on palliative care and rehabilitation of HIV infected people."
- o Page 39, second paragraph, information dissemination, add - "At DHHS, in a joint collaborative effort, ~~OHAP and HRSA~~ support and direct the International HIV/AIDS Clinical Conference Call series which disseminates critical, state-of-the-art information on treatment for HIV/AIDS patients to primary care providers via live world-wide audio teleconferencing."

OHAP is also coordinating implementation of the protease inhibitor combination drug therapy in DHHS health programs. Additionally, OHAP is the lead organization for the development of standards of care associated with this new therapeutic intervention.

- o Page 40, "Coordination of Federal Activities," first paragraph. A statement should be inserted that clarifies that OHAP is the lead office for coordinating the HIV/AIDS activities in the public health operating divisions of the DHHS.

11/1 Research

PRASCO language

*check c
Luthana*



MAR 5 1996

TO: Claudia Cooley
Executive Secretary

FROM: *pb* Peter B. Edelman

SUBJECT: Draft *National Strategy for HIV and AIDS*

Because of the abbreviated time frame for reviewing this lengthy document and detailed appendix, many HHS agencies have not had sufficient opportunity to review the scientific and technical accuracy of the report, substantive areas covered (including some that are not without controversy such as needle and syringe exchange programs), and the research and program priorities that have been identified for the Nation as a whole and individual agencies. At this point, we understand that some general concerns have already been raised about the content and structure of this report and that additional time is required to address these issues. We share this concern and would appreciate receiving copies of the agencies' comments.

Although we do not have specific comments at this time, we did note a conspicuous disparity in the individual agencies' submissions regarding their HIV/AIDS program activities (Appendix). Agencies should be asked to provide additional detail or descriptive information about their program activities and priorities. Additionally, in the discussion of needle exchange programs on page 21, the first sentence of the last paragraph seems inconsistent with the Administration's current position. To further clarify the last sentence of this paragraph, there may need to be some mention of the current restriction on the use of Federal funds in supporting needle exchange programs. In short, this report is expected to make an important contribution to national HIV/AIDS policy making and thus merits careful and thoughtful agency review.

cc: Glen Harelson



FEB 23 1996

NOTE TO PATSY FLEMING

SUBJECT: Comments on National Strategies for HIV/AIDS

This is to congratulate you and your office on the development of this important document. I have comments below which I hope will be helpful:

- | | |
|--------------------------------|--|
| page 9, bullet 3: | should read HIV/AIDS rather than AIDS |
| page 10, paragraph 2, line 3: | strike "very different" and replace with "increasingly more complex" |
| page 10, paragraph 3, line 5: | strike "receive quality health care" and replace with "benefit from scientific advances capable of prolonging and increasing quality of their lives." |
| page 11, paragraph 2, line 6: | strike the word "treatment" (as it stands, it implies that there is no treatment for AIDS.) |
| page 12, paragraph 1, line 13: | add "academic institutions, private foundations, health care institutions" after "State and local governments" and before "and community based organizations." |
| page 15, paragraph 1, line 19: | add at end of paragraph this sentence: "HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers Program. |
| page 20, paragraph 3: | In addition to alcohol, cocaine use linked with sex-for-drugs is an important factor. |
| page 20, paragraph 5: | This would be a good place to stress the importance of maintenance of traditional (directly observed therapy) public health approaches to TB surveillance, prevention, and treatment. |

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- page 31, paragraph 1:** **Insert after the first sentence: “Many Americans are uninsured by either public or private means. Additionally, poverty, racism, homophobia, geography, and other barriers create access problems beyond those related to lack of insurance. These barriers to access are exacerbated in the context of HIV/AIDS. For individuals with health insurance, maintaining adequate coverage....” Strike “For many of these persons, maintaining...”**
- page 31, paragraph 4, line 5:** **strike “ to fill certain gaps in coverage for people living with HIV/AIDS.” and replace with “fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS.”**
- page 31, paragraph 4, line 11:** **IIIb not III**
- page 32, paragraph 1:** **add as a final sentence: “HRSA also supports professional education so that there will be an adequate supply of providers knowledgeable in HIV/AIDS treatment.”**
- page 33, paragraph 2:** **rather than “counseling and testing” you might consider using the broader term “primary prevention.”**
- page 35, paragraph 3:** **strike “medical schools”, add “professional schools”**
- page 37, paragraph 1:** **the importance of activities supporting treatment of STDs, particularly genital ulcer disease, in prevention of transmission of HIV, is extremely important in developing countries.**
- page 38, paragraph 2, line 13:** **strike the word “identifying” (identifying what?)**
- page 39, paragraph 1, line 6:** **strike “caring for” replace with “assessing risk, prevention, and caring for”**
- page 39, paragraph 2, line 22:** **strike the last sentence. Replace with, “The Health Resources and Services Administration has developed guidances for its CARE Act grantees, supports international clinical conference calls on current topics, funds an AIDS warmline which responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers which provide State**

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of the art HIV clinical information to health care providers. Additionally, HRSA supports a number of conferences featuring clinical updates and information."

page 40, paragraph 2, line 3: strike phrase, "study indicated that primary care physicians miss..." and replace with "study indicated that many primary care physicians miss..."

page 41, paragraph 2, line 7: do you want to add "businesses, churches, schools" etc. ?

page 42, paragraph 2, line 5: what type of "testing programs" ? Also the last sentence is problematic at the moment.

The following comments refer to the appendix:

In general, do you want to list the President's budget (in contrast to the Congressional approach)? Also, in listing constituency groups, it would read better to always list PLWAs first.

Page 3 (Care and Services): paragraph 9: The issue of formularies is tricky, a good idea, but one that is going to require some thought as to how we can do this without creating a system that subsidizes Medicaid and private managed care formularies.

paragraph 12: if this refers to the WIN projects, we now have 10 (3 funded with SPNS dollars.)

paragraph 16: indicators not indicator

Page 4 Paragraph 3: In addition to these broad based efforts, HRSA also supports a variety of focused initiatives such as an adolescent research and clinical network and a cooperative.....

Page 4

Insert:

FY '95:	RWCA Title I:	\$356,500,000
	RWCA Title II:	\$198,147,000
	RWCA Title III:	\$ 52,318,000
	RWCA Title IV:	\$ 26,000,000

President's
Budget

FY '96	RWCA Title I:	\$407,000,000
	RWCA Title II:	\$221,897,000
	RWCA Title III:	\$ 62,568,000
	RWCA Title IV:	\$ 32,000,000

paragraph 5: constituents are also represented on the HRSA
AIDS Advisory Committee

paragraph 8: add, "working with NIMH, SAMSHA and other
relevant agencies to insure access to mental health and substance
abuse services" strike "to provide needed services."

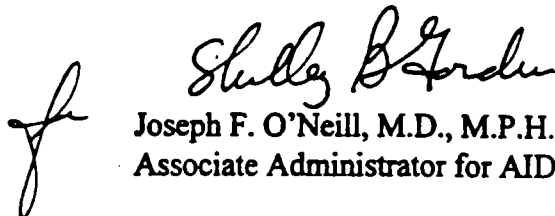
Page 5

Add this paragraph:

From the point of view of the front line provider who may receive
funding from several Federal agencies, a need for improved
coordination within agencies and between agencies is often
apparent. In addition, for example, to the lack of adequate
resources for technical assistance and evaluation, there is also a
need for improved planning and coordination of these activities
between the various CARE activities and between Federal
agencies.

Thanks again for the opportunity to review this document.

Sincerely,


Joseph F. O'Neill, M.D., M.P.H.
Associate Administrator for AIDS

General Comments

- It would be helpful if an "introduction section" could be added to the National Strategy for HIV and AIDS (NSHA) that briefly explains what Federal Departments and independent agencies, and other groups outside the government were involved in the development of this strategy.
- There is a lack of consistency of terminology throughout the NSHA. This is the plan of the Executive Branch of the Federal Government, which includes a number of departments and agencies. The cover memorandum from the Director states that "I believe this document builds on this consensus and articulates the goals and objectives of the entire Federal Government." This may be stated as the "Executive Branch of the Federal Government" since it does not include any Congressional or legislative branch collaboration.
- Before the final NSHA is published, a version with all of the appendices should be circulated for review and final clearance.

Additional Comments

Page 2, paragraph 2, line 2 "This is the first time a government-wide national plan for the United States has been developed for fighting HIV." There have been plans developed earlier in the epidemic (see page 8, paragraph 3, line 1). It would be helpful, and more accurate, to explain as early in the document as possible why this "government-wide national plan" is different than previous plans developed at Coolfont, Charlottesville, and the PHS Strategic Plan.

Page 2, paragraph 5, line 1 "The purpose of this comprehensive national strategy is to set forth overarching national goals and priorities for 1996 in charting our course for combatting the epidemic of HIV and AIDS." It is not clear if the national strategy included collaboration with outside groups. Also, is it the calendar year 1996 or the fiscal year 1996?

Page 3, paragraph 2, line 13 "Medicare and Medicaid is being threatened by funding changes" could be edited to read "threatened by fundamental (or basic) programmatic changes and reductions in funding."

Page 3, paragraph 4, line 1 "The epidemic of HIV and AIDS threatens the economic progress of many countries around the world." What follows in the text is a short discussion of the United States only.

Page 6, paragraph 1, line 1 Footnote 1 (or 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." Since taking AZT is an option, we may need to insert "potentially" before the word could. CDC's guidelines (July 1995) state "To reverse these trends (HIV infection increasing among women and thus becoming a leading cause of death among young children) HIV education and services for prevention and health care must be made available to all women."

Page 7, paragraph 2, line 6 "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."
The discrimination is also based on sexual orientation. Also, strike the "to" after the word "HIV" in that sentence.

page 7, paragraph 3, line 1 In this context, "anytime" should be two words, "any time"

Page 8, paragraph 1, line 4 "To ensure efficient use of Federal, State, local, and private resources, it is imperative to plan and coordinate government-wide efforts." This statement is not clear - how does this strategy ensure efficient use of private and local resources?

Page 8, paragraph 2, line 1 "This is the first time a government-wide national strategy for HIV and AIDS for the United States has been developed." See earlier comments (above) about consistency in the name of the plan and which directly reflects which Federal agencies or other organizations collaborated in its content. In addition, the text should include how State and local governments were involved in its formulation.

Page 8, paragraph 3, line 2 "To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as..." These previous efforts have been

very briefly mentioned in the document. It should be noted and included that the Department of Health and Human Services delegated the responsibility to the Public Health Service to lead the effort to halt the AIDS epidemic. For readers unfamiliar with the Public Health Service, it may be helpful to include a footnote that it includes eight agencies, with the following seven NIH, FDA, CDC, HRSA, SAMHSA, AHCPR, IHS working on various aspects of the HIV/AIDS epidemic. The PHS is the lead Federal agency for health related issues. Also, while the Surgeon General's report on AIDS was not "technically" a plan, it is a benchmark of previous efforts. The public or the Congress may inquire of the NSHA document "How will the "National Strategy" plan be different from or have better results than previous efforts?"

Page 8, paragraph 3, line 9 "Recommendations have also been issued from a number of groups, including the National Commission on AIDS in addition to significant planning efforts on the part of individual agencies." The text, or a footnote, could be included to explain there were Congressionally legislated Commissions with Cabinet officers of different Executive Departments serving on these Commissions, including the Secretary of HHS. The HHS received the recommendations of these Commissions because of its health care mission.

Page 9, paragraph 1, line 15 "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." It is not clear what insights were received. Since the Office of Technology Assessment has been eliminated by the current Congress, it may be better to refer to either specific reports or formal/informal collaborations these various entities have produced on HIV/AIDS or expert advice that they have offered.

Page 9, paragraph 1, line 18 "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." It appears from this statement that the "input" was "indirect" from these groups. Since this is

a Federal government document, it is anticipated that questions on the exact nature of the collaboration with groups and State and local governments will arise.

Page 9, bullet 3

"Ensure appropriate care for and ethical treatment of persons with AIDS." It is not clear what "ethical" treatment involves in this context. Also, it should read "persons living with HIV/AIDS."

Page 9, paragraph 3, line 6

"There was also a common sense that these challenges also represented opportunities for progress --..." Should "common sense" instead read "common objective" or "common goal?"

Page 10, paragraph 3, line 16

"As a result, people with AIDS now live twice as long as they did a decade ago." Survival time in patients with AIDS is believed to have increased considerably during the past few years. There needs to be some context given to this statement, since it is 15 years since the beginning of the epidemic. Treatment (depending on access to care and when in the course of the disease an individual presents for care) and the course of the disease still varies. "Long term AIDS survivor" is a cruelly relative term. Most people infected with HIV take about 7 years to develop symptoms and 8 or more years to fit a diagnosis of the disease. But even with the best available treatment for AIDS, half the patients die within 2 years of being diagnosed and few live beyond 3.

According to the research literature, women and minorities may have a greater risk of a relatively early death but suggest that important factors may involve poorer access to or use of health care resources. The latest survival information can be updated by NIH and CDC.

Page 12, paragraph 1, lines 1-6

"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." The meaning of these two sentences are not clear. In the context of the overall HIV/AIDS epidemic, the Federal government, through HHS, devoted increased resources to address HIV and

AIDS through prevention, research, and services. HUD funding for the Housing Opportunities for Persons with AIDS (HOPWA) was not provided until FY 1992. HHS and HUD have collaborated on housing. Also, the Congress legislated certain funding and programs throughout the epidemic, some with certain restrictions included (e.g., needle exchange, content of education material). The NHSA is based on the knowledge and experience gained in facing the challenges of the HIV epidemic during the 1980s. Clarification is needed.

Page 12, paragraph 2, line 13 "In this case, programs that are specifically targeted towards countries or regions, are included in the international section." Insert "geographic" in front of regions and insert "of the world" after "regions" if this is the intent.

Page 12, paragraph 3, line 5 "There are number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA))..." The agencies mentioned are all Public Health Service agencies, that are part of the Department of Health and Human Services. Each of these agencies has health-related missions that encompasses its HIV-related missions.

Page 13, paragraph 1, line 2 "...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))." The agency and Department mentioned are outside the Department of Health and Human Services, Public Health Service, which was given the lead early on in the AIDS epidemic, because of its health-related mission. As noted in comments (above), the NSHA should clarify the extent of the role of HHS (especially the PHS agencies and HCFA) and then note the relative role of other Departments and independent agencies.

Page 13, paragraph 2 The description of how the report is organized may be confusing. Since HIV/AIDS is a cross-cutting issue across seven of the eight Public Health Service Agencies

that comprise the PHS and HCFA in the Department of Health and Human Services, and further involves a number of cabinet level Departments: Veterans Affairs, Defense, State, for example, and other independent, free-standing agencies, it is recommended that the Office of the National AIDS Policy Director ensures the entire report (including ALL appendices) are provided for comment and review before publication.

Page 14, paragraph 3, line 1 "Prevention activities are currently supported by several Federal agencies. 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." Insert the "HHS" after Public Health Service and see earlier comments to clarify agencies within the same Department early on in the NSHA.

Page 15, paragraph 2, line 1 "The efforts of Federal agencies have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain." After the word "agencies" insert "and Federally funded research, as well as research conducted at universities and private organizations."

Page 16, paragraph 2, line 1 "A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to estimate the burden of HIV illness, gauge future directions of the epidemic, and assess the effectiveness of prevention activities." Potentially, this sentence on surveillance could be interpreted as used to provide economic estimates of "the burden of HIV disease." In general, efforts have been made NOT to further stigmatize HIV and AIDS by emphasizing costs. We have recognized, given the wide variability in both the course of HIV and AIDS and the new treatments (including drugs), that often private third-party payors do not reimburse for the cost of care for patients with HIV/AIDS and instead shift costs to the public sector which includes Federal programs.

Page 20, paragraph 1, line 1 "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." It may be appropriate to insert the words "continue to" after "must" since, for example, the Association of State and Territorial Health Officials (ASTHO) and the National Association of State Alcohol and Drug Abuse Directors (NASADAD), along with SAMHSA, CDC, HRSA, and NAPO sponsored the "National Conference on HIV and Substance Abuse" in November 1990 and the National Commission on AIDS issued a report entitled "The Twin Epidemics of Substance Abuse and HIV" in July 1991.

Page 21, paragraph 1, line 1 "...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." It is not clear how the reorganization reflects "our determination."

Page 22, paragraph 1 In the discussion of incorporation of sexual history and prevention counseling, mention should be made of the need for training to improve primary care providers' skill, comfort level and sensitivity in this area.

Page 23, section on Research The overall role of the Department of Defense in research needs to be expanded in the text, unless it is clear from the appendices.

Page 23, paragraph 2, line 11 "The Agency for Health Care Policy and Research (AHCPR) funds research to help determine which medical approaches are the most cost effective." After the word "funds" insert "health services."

Page 23, paragraph 3, line 1 "The Nation has already reaped the benefits of supporting research in general, and HIV-related research specifically." Insert the words "some of" before "the benefits". Also, this sentence could be edited to include not only the national impact, but the international impact.

Page 24, paragraph 3, line 1 "Due in great part to this Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago." Please see earlier note on survival.

Page 25, paragraph 2, line 5 “—mankind has never before encountered a virus such as this.” According to NIH, changes in microbes and our environment will continue to present new health challenges worldwide. This sentence is not clear.

Page 26, paragraph 2, line 14 “...one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development.” See previous comments regarding the consistency of the use of the Department of Health and Human Services. In this context, it is recommended that NIH and FDA, and other agencies that participated in the ADDTF be specifically cited.

Page 28, paragraph 2, line 3 “...numbers and at record speed,...” The term “record speed” could be better defined.

Page 28, paragraph 3, line 1 “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.” This needs to be rewritten to clarify that FDA/PHS/HHS is charged with this responsibility.

Page 28, paragraph 3, line 12 “As a result, patients may be receiving less effective treatment or combinations of treatments, and Federal programs such as Medicaid and Medicare and Private insurers may be paying for these less effective treatments. Americans are spending millions of dollars per year on such therapies about which little is known.” These sentences are not clear and could potentially be interpreted as a reason to not pay for clinically indicated therapies, and involve several complex issues, including, allowing clinical trials to use surrogate markers of disease progression and of drug efficacy. Also, the Ryan White CARE Act reimburses for prescription drugs.

Page 33, paragraph 1, line 1 “...Treatment and primary care must come before ancillary services.” The document may need to define “ancillary.” This statement could have far reaching policy implications, especially for the AETC Program. The Senate Appropriations Committee language appears to indicate the Senate’s desire to move the decision for

funding provider training to the local planning bodies.
"Increasing access to, and support of, treatment and
primary care...." would be a better choice of words.

Page 33, paragraph 4, line 11 "...schools, and professional organization in addition to
local and Federal governments." Insert "State" after the
word "local."

Page 35, paragraph 1 Four of the five agencies provided as examples in this
paragraph reside in the Department of Health and
Human Services, Public Health Service (SAMSHA,
HRSA, CDC and NIH). While uniform applications are
administratively possible, the statutes and regulations
may have to be amended to accomplish this.

Page 38, paragraph 1, line 5 "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,..." A footnote to
this project may be necessary to those who are not
familiar with its content (source and date).

Page 40, paragraph 1, line 5 "NIH's state-of-the-art conferences have also contributed
to improving the translation of research results into
clinical practice." Examples of what these "state-of-the-
art" conferences are and when they were held would be
useful (it could be as a footnote).

Page 41, paragraph 3, line 16 "The Health Care Financing Administration (HCFA)
also enforces regulations regarding the treatment of
HIV-infected persons." This appears to be the first time
this agency, an agency in the Department of Health and
Human Services that administers the Medicare and
Medicaid programs is specifically mentioned. Also, the
NSHA needs to clarify how the HCFA regulates (perhaps
an example could be included).

Page 42, paragraph 2, line 8 "The Administration will also continue to oppose
Congressional attempts to force discharge of infected
military personnel who are still able to serve their
country." Since the Defense Department's bill has
already been signed by the President, this sentence needs
to be modified and include the Departments that will be
taking the lead in this effort.

(Care and Services)

Page 4, paragraph 1, line 3 Add to "evaluate program effectiveness." "...Agree to common evaluation criteria of CARE Act grants that address program delivery and program outcomes. Also establish evaluation measures that are unique to each Title."

Page 4, paragraph 5 Add to "constituency involvement:" "Nationally, focus groups, workshops, and discussion groups of PWAs, providers of HIV care, State and local officials, and researchers review proposed policies, program directives, and planning and evaluation activities to ensure constituency input."

Page 4, paragraph 8 Unmet Need: Add "...There is need for increased access to 1% evaluation funds for service-related evaluations."

page 6 Regarding question: Are there separate funds for the SPNS evaluation? Answer: No, all of the funds come from 10% tap from Title II.

Add:

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

Action Steps: Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs).

Populations served: CARE Act grantees.

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

page 9 I would suggest adding this to unmet need under the reduction of perinatal transmission: " In particular, it is

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

ASC
Assist. for Legislation
Jerry Klepner

Goal of the National Strategy

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

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

The national strategy for HIV and AIDS presented here is broader in scope than prior planning efforts. To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome, the "Coolfont" and "Charlottesville" reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States. Recommendations have also been issued from a number of groups, including the National Commission on AIDS 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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transmission, and perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

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

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must 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 strategies, 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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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.¹³ Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.¹⁴ 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.¹⁵

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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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.

*many
some
??*

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

There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine was that there is no credible evidence that drug use is increased among participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease.⁴ 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.

*delete
the
personal
"we
believe"*

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.

*Is "we" believe this
then why not have the Surgeon
Gen. approve? I would delete the
reference to HHS & the word in a box!*

National Strategy for HIV and AIDS
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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,

*How this
development
already?
why not
ask DES,
his
Sec. of
HHS to
convene?*

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 net. 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 ~~financed~~ need 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

7

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Draft for Department and Agency Review: 1.30.96

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.

*This depends
from Health
Strategy to
a Political
Document*

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.

*A simple
discussion
on the
importance
of Medicaid
is one
of
Congressional
action will
make this
document more
relevant*

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

*Moreover, these statements could take
the Pres. down a Policy Path that he
may choose, for whatever reason, not to
go down.*

CDC comments on *National Strategy for HIV and AIDS*

Please note: substitute words, phrases and paragraphs are located, with page number, paragraph, line number within the paragraph. In places where the wording is changed or substituted, the recommended replacement words or sentences are shown in *italics*.

(Page 5, first paragraph)

The pandemic of *human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome...* Unlike ~~most~~ other infectious diseases..... This national and international pandemic of HIV diseases, now well into its second decade, is *still progressing virtually unabated in many areas.*

(Page 5, second paragraph)

Reword as follows: As of October 1995, the Centers for Disease Control and Prevention (CDC) *has reported* 501,310 cases of AIDS *among persons* in the U.S.; 311,381 *of these persons have been reported to have died* as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death *among all Americans* to the 8th; *but, it is the leading cause of death among Americans aged 25 to 44. (See Figure 1.)* In 1994 alone, approximately 81,000 new cases of AIDS *and more than 45,000 deaths* were reported to the CDC.....

(Page 5, third paragraph)

~~As we have witnessed a relentless increase in infections, the epidemic in the United States has evolved, the demographics....~~ ; this group now represents less than half (43%) of all new cases. Among the populations being more heavily affected now are young gay men, ~~between 20 and 24 (9%)~~ women (18%), and heterosexual injecting drug users (24%). [Take out percents-they are not comparable, e.g. Women can be IDUs and between 20-24. There can be overlap in most of these groups.]

(Page 5, third paragraph, 11th line)

In 1994 alone, more than 14,000 women were *reported* with AIDS and women now comprise 14 percent of 21 percent It is estimated that if this trend continues, 80,000 American children will have been orphaned *as a result of AIDS* by the ... (Drop the sentence "As of October 1995...." This is not true) In 1994 alone, more than 1,000 new pediatric AIDS cases were reported.

(Page 6, first paragraph, 1st line)

Communities of color *have been* more severely and disproportionately affected *by the epidemic.*

(Page 6, first paragraph, 7th line)

In 1982, ~~persons of color~~ blacks and Hispanics represented ~~only 31 percent~~ of all AIDS cases, as of October 1995 these groups now comprised 51 percent of cumulative AIDS cases. [Drop last sentence of this paragraph]

(Page 6, second paragraph)

[This paragraph is redundant; all data has previously been given]

(Page 6, third paragraph, 2nd line)

The HIV/AIDS pandemic is spreading to *nonurban areas....regions of the South and Midwest.* In fact, between 1993 and 1995 the largest numbers....from the South. [drop the remainder of the sentence.

(Page 6, last paragraph, 2nd line)

The World Health Organizations (WHO) estimates that since *the beginning of the epidemic*, 4.5 million cases of

AIDS have occurred worldwide. (Keep next sentence as is) WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

(Page 7, first paragraph, 6th line)

And unlike other persons living with HIV to have been the target...

(Page 7, second paragraph, 3rd line)

[Drop third sentence "It is, the leading cause.....25 to 44" This is redundant with earlier text]

(Page 7, second paragraph, 8th line)

In terms of years of potential life lost, In 1994, AIDS ranked HIV infection was the fourth among all leading causes of death leading cause of years of potential life lost before age 65.

(Page 14, first paragraph, 3rd line)

The Nation's prevention goal is to provide solid support for..... [Suggest that providing "solid support" is not a goal.] Restate: The Nation's prevention goal is to develop effective prevention strategies that will reduce...

(Page 15, third paragraph, 3rd line)

Recent epidemiologic data show that the HIV epidemic continues to ^{spread} ~~strengthen~~ in the United States among people who engage in injection drug use and their sexual partners, young and minority men having sex with men, ...

(Page 16, first paragraph, 1st line)

A crucial part of the effective prevention in order to estimate the burden impact of HIV illness...

(Page 16, first paragraph, add to the end of paragraph)

Seroprevalence surveys provide information on the level of HIV infections on selected "sentinel" populations.

(Page 16, second paragraph, 3rd line)

Current CDC surveillance systems on the incidence and prevalence of HIV (not AIDS)....

(Page 18, third paragraph, 7th line)

Given the highly....the CDC must give consider-consideration to providing....

(Page 20, second paragraph, 4th line)

It is estimated that x percent of the population...is affected by alcohol and other drugs in addition to injection drug use. [CDC is not aware of any such estimated data - perhaps SAMHSA or NIDA can provide this information.]

(Page 25, 3rd paragraph, 15th line)

Misspelling "sound scientific judgement and ..." The preferred and standard spelling is "judgment". We suggest that a Search and Replace function be used for the entire document.

(Pages 47 through 50, - 4 CDC map illustrations)

Suggest that they be placed in a progressive date sequence (i.e., 1983, 1985, 1989 and 1994).

CDC Prevention Goals and Objectives (No page numbers were given to reference)

We strongly suggest that the information in this section be replaced with the latest version of the *Healthy People 2000 Objectives* (as displayed in *Healthy People 2000 Midcourse Review and 1995 Revisions*). The

NATAIDPLDFT

Page 3

information you have displayed was developed during CDC's 1991-1992 HIV Strategic planning process and although still relevant, will be updated later this year in a new strategic planning activity.

However, if this section is kept, we suggest the following changes:

Under Goal: More accurately monitor the HIV epidemic....

Objective: Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS. [Relevance to goals?] **Comment:** This objective is relevant.

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

Under Goal: Increase the public understanding of, involvement in....

Objectives: Provide leadership in HIV and STD prevention by (1) establishing a national agenda, through the media, that keeps the HIV/AIDS interests "active" on the national agenda as a topic that is routinely covered by local and national news media.

Descriptions: [include *Prevention Marketing Initiative* at the end of the first paragraph, following CDC National AIDS Hotline]

In addition....National AIDS Clearinghouse, the CDC National AIDS Hotline, and the *Prevention Marketing Initiative*.

Descriptions: [following the dollar estimates given for FY 95 and FY 96] include the statement: *These are aggregate estimates provided by States.*

Approval: 
Dir., NCHSTP
2/26/96
Date

2/27/96
Cm

NOTE TO EXEC SEC:

Subject: Document #148506 - National Strategy for HIV and AIDS

The OAR has not had sufficient time to draft our very lengthy review of this document. We have serious concerns about scientific inaccuracies, research priorities, and the structure of the document, which will require significant rewriting.

For these reasons, we must nonconcur with the document at this time.



Jack Whitescarver, Ph.D.
Deputy Director
Office of AIDS Research





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

MAR 8 1996

TO: Executive Secretariat, OS

FROM: Administrator, SAMHSA

SUBJECT: Review of Draft of the National Strategy for HIV and AIDS

Thank you for the opportunity to review and comment on the Draft of the National Strategy for HIV and AIDS. This is a well documented report on the status of this national epidemic. As well, it provides a holistic view of our present Public Health Service activities and strategies that will be necessary in the future. As requested, we have attached our comments regarding our individual plan and comments to the full draft.



Nelba Chavez, Ph. D.

Attachments

NATIONAL STRATEGY FOR HIV AND AIDS
SAMHSA REVISED HIV/AIDS-RELATED ACTIVITY DESCRIPTIONS

The following italicized changes should be included in the final description of SAMHSA's current HIV/AIDS related activities:

CARE AND SERVICES

Descriptions: HIV/AIDS Mental Health Services Demonstration Program
FY96: \$1,500,000 *To Be Determined*
(\$1,400,000 NIH and \$1,500,000 HRSA)

Descriptions: HIV/AIDS Community Outreach Program
FY96: \$7,500,000 *To Be Determined*

Goal: *Improve HIV/AIDS training of clinicians*
Descriptions: AIDS Health Care Worker Training
FY96: \$2,930,000 *To Be Determined*

Descriptions: The Linkage Initiative
FY96: *To Be Determined*
Constituency Involvement: *Service providers, consumers*

PREVENTION

Descriptions: High Risk Youth Program
FY96: \$3,000,000 *To Be Determined*

Descriptions: Demonstration sites and community training in the use of HIV/AIDS curriculum
FY96: \$5,000,000 *To Be Determined*

Objective 3: *Improve training of Faculty Development Program (FDP) grantees*
Descriptions: *Supplementation of Faculty Development Program (FDP) grantees*
FY96: \$650,000 *To Be Determined*
Populations Served: *General public*

PREVENTION

Agency: Health Care Financing Administration

Goal: Reduce perinatal transmission among Medicaid-eligible women.

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

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

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

FY 95: ~~Federal resources to be determined.~~ \$50,000 (Eden Shaw) X

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

Populations Served: HIV positive women eligible for Medicaid coverage.

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

Unmet Need: The pilot project ^{NHIL} will not include women of unknown or negative HIV serostatus. This project should be extended nationwide. X

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

Description: Medicaid primary health care services.

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

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

Populations Served: HIV positive Medicaid-eligible persons.

Constituency Involvement: *More information and activities routinely*

Unmet Need: NA *discussed with external groups at meetings and conferences.*

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

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

Develop directives in implementation of developed guidelines.

FY 95: ~~Federal resources to be determined.~~ \$25,000 (conference and materials)
FY 96: ~~Federal resources to be determined.~~

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

Constituency Involvement: Significant constituent consultation throughout course of project development. ~~Other groups?~~ (provider groups) X

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

Revised 12/20/96.

Administration CARE AND SERVICES

Agency: Agency for Children and Families, DHHS.

Goal: To meet the social and support services needs of children, risk for HIV/AIDS.

Objective 1: Stabilize ^{the} crisis situation and provide needed services to runaway and homeless youth.

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

Descriptions: Runaway and Homeless Youth Program.

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

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

Constituency Involvement: A network of more than 500 grantees, both public and private
~~Advocacy Groups, Service Organizations~~

Unmet Need: ~~More~~ More services and resources need to be available, particularly in the areas of education and prevention.

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

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

Descriptions: Child Welfare Services Program.

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

Populations Served: Children in foster care and those placed in adoption, their parents and extended families.

Constituency Involvement: ~~Advocacy Groups, Service Organizations~~

Unmet Need: ~~More~~ More services and resources need to be available.

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

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

Descriptions: Abandoned Infants Assistance Program.

→ National professional, advocacy, and service organizations such as The Child Welfare League of America, American Public Welfare Association, National Association of Social Workers, and 50 State/Territorial units.

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

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

Constituency Involvement: ~~Public and private providers of these services, granters, and national research~~
~~Advocacy Groups, Service Organizations, etc.~~

Resources to
 serve
 geographic
 areas of
 unmet
 need.

Unmet Need: ☒ ↓

Objective 4: The Head Start program child development
 Provides comprehensive services to children, including those with HIV/AIDS, their parents, and families.

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

Descriptions: Head Start Program.

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

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

Constituency Involvement: National Head Start Association and related early childhood development
~~Advocacy Groups, Service Organizations,~~
organizations such as National Association for the Education of Young Children, etc.

Increased
 resources
 will
 make
 services
 avail-
 able
 to
 more
 children.

Unmet Need: ☒ ↓

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

Action Steps: Support the twenty-seven of the current 51 grantees operating pediatric HIV/AIDS clinics in or associated
with the university.

Descriptions: University Affiliated Program

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

Populations Served: Developmentally disabled persons, including those with HIV/AIDS.

Constituency Involvement: ~~Public and private providers of these services, granters, and national research~~
~~Advocacy Groups, Service Organizations, etc.~~

Unmet Need: ☒ ↓

Although a university pediatric AIDS clinic is located in each state, not all patients have access to the services.

National network of grantees; national
advocacy organizations related
to HIV/AIDS and developmental
disabilities.

Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to people and governments here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. This national and international pandemic of HIV disease, now well into its second decade, is progressing virtually unabated. It also remains a deadly infection for which there are limited treatments, no vaccine, and no cure.

An Expanding Public Health Threat

(Cumulative)
total of

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 (4%), and women (18%), and heterosexual injecting drug users (24%). And although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1995 alone, more than 14,000 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." As of October 1995, pediatric

Of AIDS cases, as of October 1993 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

² 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.

2. where is footnote 2?
why are some footnotes here and others
at the end of the report?

Letter from the Director of the Office of National AIDS Policy

edit

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

National Strategy for HIV and AIDS
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- Suggest that these be listed in the same order as the goals — or indicate different priority.*
- ① Strengthening HIV prevention activities;
 Supporting diversified research approaches;
 Strengthening approaches to substance abuse treatment and prevention;
 - ② Strengthening the health care and services safety net;
 Improving translation of research results into medical practice; and,
 - etc. 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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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 net. 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.

INSERT # 1.
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, ^{health} 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 ^{health} 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. ^{health}

A second major source of ^{health} 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

CARE AND SERVICES - INSERT #1 page 31

In addition to health care and insurance coverage, persons with HIV/AIDS may need a range of social and support services -- for themselves and for relatives, extended family, dependents, and others. These services may include counseling, special education and prevention services for youth, including runaway and homeless youth, group support services, transportation, meals-on-wheels, estate planning, and planning for the adoption or long-term care of dependent children who will become orphaned by the death of parents.

The children with HIV/AIDS, although comparatively small in number, often need specialized in-home foster care and developmental services in addition to appropriate health care.

CARE AND SERVICES --- INSERT #2 page 32

Social and support services are provided under the auspices of a range of public and private agencies and organizations operating at the State and local community level.

The Administration for Children and Families funds broad social programs which serve persons with HIV/AIDS as they would all others in the eligible population. Five major programs which serve pregnant women, children, youth, and families are the Head Start program, the Abandoned Infants Assistance program, the Child Welfare program, the Runaway and Homeless Youth program, and the University Affiliated program of the Administration of Developmental Disabilities -- a program which funds pediatric AIDS clinics at university hospitals.

CARE AND SERVICES -- INSERT #3 page 33

Social and Support Services

The increasing incidence of HIV/AIDS calls for a corresponding increase in those services which will help ensure stability, dignity, and appropriate care for all persons with HIV/AIDS.

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Draft for Department and Agency Review: 1.30.96

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 health 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.

INSERT #2
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

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

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.

Insert # 3 Social and Support Services

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

FDN

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REVISION

46

HOLD THE

B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched farina. PAGE

2. Corn and Rice Products

a. Enriched corn grits. No specific comments were received regarding the addition of folic acid to enriched corn grits. Thus, as proposed, FDA is amending § 137.235 to require fortification of enriched corn grits with the same level of folic acid as that established for enriched wheat flour products, such that each pound of the food would contain at least 0.7 mg of folic acid. FDA is also establishing the proposed upper limit for folic acid fortification of 1.0 mg/lb, which is approximately 50 percent higher than the minimum of 0.7 mg/lb, as it has done for the other B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched corn grits.

The agency notes that it published a proposed rule in the FEDERAL REGISTER of October 13, 1995 (60 FR 53480), that would revoke the standard of identity for enriched corn grits. If comments to that proposal support revocation of this standard of identity, the provisions set forth in this final rule for enriched corn grits will also be revoked.

b. Enriched corn meals. No specific comments were received regarding the enrichment of corn meal products with folic acid. Thus, as proposed, FDA is amending the standard of identity in § 137.260 to provide for a minimum folic acid level that is consistent with that established for enriched flour, such that each pound of the food contains 0.7 mg. Because corn meal

OPTIONAL FORM 95 (7-90)

FAX TRANSMITTAL

of pages ▶ 1

To: JOHN GALLIVAN	From: KEN SMITH
Dept./Agency: DHHS	Phone #:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 23 1996

Agency for Health Care Policy
and Research
Rockville MD 20852

FROM: Administrator

SUBJECT: Review of Draft of the National Strategy for HIV and
AIDS

TO: Director, Office of National AIDS Policy

This is in response to your request for review and comment on the above referenced document.

AHCPR staff have reviewed the text of the draft National Strategy for HIV and AIDS, and find it to be a comprehensive and detailed document which will provide a context for initiatives of the entire Federal government in combatting the HIV/AIDS epidemics.

Our technical comments follow:

- Regarding the reference to the ability of primary care physicians to detect HIV-related findings, I suggest modification of the existing language: "...primary care physicians miss significant HIV-related symptoms during patient examinations..."; to read: "...primary care physicians may miss important HIV-related physical findings during patient examinations." The nature of the study population mitigates against such a broad conclusion as stated in the submitted draft. (See article attached)
- The name of the senior author on the endnote 22 (p. 46) is Paul G. Ramsey (not Ramwey).
- The sentence on page 40, line 11: "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." needs revision. It should read: "Other research indicates that a large number of clinicians do not use universal precautions in the course of routine patient care." The reference for this statement (endnote 23) is: Colombotos J, Messeri P, McConnell MB, et al.: Physicians, Nurses, and AIDS: Findings From A National Study. Rockville, MD: Agency for Health Care Policy and Research; 1995. Grant No. HS06359. (NTIS Publication PB95-129185, attached).

Page 2 - Director, Office of National AIDS Policy

The information in the appendix has been reviewed and confirmed or updated as indicated.

If you have any questions, please have your staff contact Phyllis Zucker at 301-594-2453.

A handwritten signature in black ink, appearing to be 'Clifton R. Gaus', written in a cursive style.

Clifton R. Gaus, Sc.D.

Attachments

RESEARCH

Agency: Agency for Health Care Policy and Research

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

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

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

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

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

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

Action Steps: This study will be the first to obtain a true national random sample of people with HIV infection receiving treatment. Approximately 3200 adult patients in urban and rural areas will be enrolled. Study will be co-sponsored by HRSA, NIMH, NIDR, NIA, NIDA, and the Robert Wood Johnson Foundation.

Descriptions: HIV Costs and Service Utilization Study (HCSUS)

FY 95: \$4,000,000

FY 96: \$3,400,000

Populations Served: HIV-infected individuals receiving treatment.

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

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

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

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

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

Descriptions: Women's Interagency HIV Study (WIHS)

FY 95: 60,000

FY 96: 0

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

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

Unmet Need: None.

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

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

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

Descriptions: Multicenter AIDS Cohort Study (MACS)

FY 95: 65,000

FY 96: 0

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

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

Unmet Need: None

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

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

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

Descriptions: HIV Epidemiological Research Study (HERS)

FY 95: 50,000

FY 96: 50,000

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

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

Unmet Need: None.

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

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

To examine any substitutions of formal for informal home care.

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

Abstract data from Medicaid claims.

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

FY 95: 295,918

FY 96: 39,455

Populations Served: Medicaid recipients with AIDS in New Jersey.

Constituency Involvement: Persons with AIDS residing at home or in community facilities.

Unmet Need: None.

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

Action Steps: Analyzed Medicaid claims and eligibility data from New York State Medicaid files. Completed.

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

FY 95: 392,103 (from FY94 funds)

FY 96:

Populations Served: New York State Medicaid recipients.

Constituency Involvement: N/A

Unmet Need: None.

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

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

Descriptions: Outcomes of Pharmaceutical Therapy in HIV Disease.

FY 95: 527,497

FY 96: 479,952

Populations Served: HIV-infected population in Maryland.

Constituency Involvement: N/A

Unmet Need: None.

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

Action Steps: Analyze Medicaid claims and eligibility data, supplemented with AIDS Registry data. To be completed in FY96.

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

FY 95: 110,704 (from 1994 funds)

FY 96: 0

Populations Served: New Jersey Medicaid recipients.

Constituency Involvement: N/A

Unmet Need: None.

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

Action Steps: Formulate statistical models and associated computer software.

Descriptions: Developing Econometric Models to Estimate AIDS Costs.

FY 95: 248,126

FY 96: 8,002

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

Constituency Involvement: N/A

Unmet Need: None.

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

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

Descriptions: Determinants of Physicians' AIDS-Related Practice Behavior

FY 95: 216,054 (from 1994 funds)

FY 96: To be completed during FY96

Populations Served: Persons with AIDS.

Constituency Involvement: Physicians

Unmet Need: None.

Objective 11: Continuing work previously completed with AHCPR support, will compare outcomes of inpatient care for AIDS provided by dedicated AIDS units versus scattered-bed approaches.

Action Steps: Expand upon original comparative, multi-site observational study of 20 hospitals.

Descriptions: Outcomes of Hospital Dedicated AIDS Units

FY 95: 180,649

FY 96: 214,086

Populations Served: 1300 patients receiving services in study hospitals.

Constituency Involvement: N/A

Unmet Need: None.

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

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

Descriptions: Hospital Cost and Utilization Project

FY 95: 500,000

FY 96: 284,164

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

Constituency Involvement: N/A

Unmet Need: None.

PREVENTION

Agency: Agency for Health Care Policy and Research

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

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

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

Descriptions: Demonstrating Computer Support Impact on AIDS Patients

FY 95: 704,655

FY 96: 36,577

Populations Served: 300 volunteers with advanced HIV infection.

Constituency Involvement: Persons with HIV.

Unmet Need: None.

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

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

Descriptions: Cost-Effectiveness of Preventing AIDS Complications.

FY 95: 346,420

FY 96: 19,731

Populations Served: Persons with HIV.

Constituency Involvement: N/A

Unmet Need: None.

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: Agency for Health Care Policy and Research

Goal: To expedite the dissemination of data from research.

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

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

Descriptions: AIDS Treatment Information Service

FY 95: 75,000

FY 96: 75,000

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

Constituency Involvement: HIV-positive individuals and advocacy groups as well as health care professionals.

Unmet Need: N/A

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

Action Steps: A panel of experts reviewed relevant literature and summarized findings into specific clinical practice guidelines, which stress the importance of preventing HIV-related opportunistic infections and the link between prevention and early diagnosis. Almost 2.7 million copies of guideline-related documents have been distributed.

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

FY 95: 30,000 (to AIDS clearinghouse)

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

Populations Served: Clinical practitioners, individuals with HIV infection, and those persons caring for persons with HIV .

Constituency Involvement: Clinicians, HIV positive persons, and caregivers.

Unmet Need: NA

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

Action Steps: Examined organizational strategies used by several community-based HIV education agencies. Completed in FY 96.

Descriptions: Effective Strategies of AIDS Programs in San Francisco.

FY 95: 198,883 (from 1994 funds)

FY 96: 0

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

Constituency Involvement: Advocacy organizations and persons with HIV were included in the research.

Unmet Need: N/A

Objective 4: This guide and related materials will inform pregnant women with HIV about the use of zidovudine (AZT) for the prevention of perinatal HIV infection.

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

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

FY 95: 15,000

FY 96: 50,000

Populations Served: Pregnant women and women of child-bearing age who have HIV.

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

Unmet Need: NA

Brief Report

Ability of Primary Care Physicians to Recognize Physical Findings Associated With HIV Infection

Douglas S. Paauw, MD; Marjorie D. Wennich, MPH; J. Randall Curtis, MD, MPH; Jan D. Carline, PhD; Paul G. Ramsey, MD

Objective.—To assess the ability of primary care physicians to identify physical findings associated with human immunodeficiency virus (HIV) infection.

Design.—Standardized patient examination.

Participants.—A total of 134 general internists and family practitioners were randomly selected after stratifying by year of medical school graduation, specialty, and experience caring for patients with HIV infection.

Main Outcome Measures.—Recognition of physical findings of Kaposi's sarcoma, oral hairy leukoplakia, and diffuse lymphadenopathy.

Results.—Despite being directed by presenting histories to sites of prominent physical abnormalities, only 23 (25.8%) of 89 physicians evaluating a patient with Kaposi's sarcoma and 22 (22.7%) of 97 physicians evaluating a patient with oral hairy leukoplakia detected and correctly diagnosed the abnormalities. Twenty-three (17%) of 133 physicians detected diffuse lymphadenopathy in a patient complaining of fatigue, fever, and arthralgias. Physicians with the most experience treating patients with HIV infection more frequently identified oral hairy leukoplakia, but HIV experience did not influence identification of Kaposi's sarcoma or detection of lymphadenopathy. There were no differences between general internists and family practitioners or among physicians by year of medical school graduation in identifying the three physical findings associated with HIV infection.

Conclusions.—Primary care physicians may frequently miss important physical findings related to HIV infection during patient examinations.

(JAMA. 1995;274:1380-1382)

SEVERAL physical findings are strongly associated with human immunodeficiency virus (HIV) infection. Kaposi's sarcoma (KS), a rare tumor in individuals who are not HIV infected, is the most common tumor in patients who are HIV-positive,^{1,2} and the presence of KS strongly suggests HIV infection. Oral hairy leukoplakia (OHL) is also strongly associated with HIV infection.^{3,4} In a study of 155 patients with OHL, all were found to be HIV infected or at risk for HIV disease.⁵ Diffuse lymphadenopathy, although associated with many diseases, is a common finding in HIV-positive individuals.⁶ In some patients, these or other physical findings may be the initial manifestations of HIV infection in otherwise asymptomatic individuals. However, little is known about physicians' skills at identifying

physical findings commonly associated with HIV infection.

This study used standardized patients to assess the ability of primary care physicians to identify three common physical findings associated with HIV infection: KS, OHL, and diffuse lymphadenopathy. Standardized patients are individuals trained to enact a specific case presentation and to evaluate physicians' performance.^{7,8} Use of standardized patients permits assessment of physicians' skills while controlling the patient presentation.

Methods

As part of a larger study using standardized patients,¹⁰ physicians came to a university clinic and saw as many as 16 standardized patients during 1 day of testing. Standardized patients presented a variety of symptoms and physical findings. Each standardized patient received at least 25 hours of training concerning specific medical histories to present, providing consistent responses to questions from physicians, and evaluating physicians' performance in history-taking skills, physical

examination, and counseling using objective criteria. Individuals who had prominent physical findings were selected for the patient roles, and their presenting histories were designed to direct physicians to the anatomic areas where the physical findings were located. The patient with OHL told physicians that he had a sore throat and also had noticed white spots on his tongue. On oral examination, the patient had white adherent plaques located on the lateral aspect of his tongue (Figure 1). The patient with KS had lesions on his left ear (Figure 2) and right shoulder. He gave a history of a resolving left earache and a painful right shoulder. The KS lesion on his right shoulder was 1×2 cm, purple, and had sharp margins. The patient with diffuse lymphadenopathy presented with a history of persistent fatigue, fever, and arthralgias and described joint pain in his knees, elbows, and shoulders. He had enlarged lymph nodes greater than 1 cm in diameter in the posterior cervical chains, anterior cervical chains, preauricular and postauricular areas, and axillae bilaterally. All physical findings were evaluated and their presence was agreed on by three physicians with considerable clinical experience in management of patients with HIV infection.

Two standardized patients had cardiac murmurs related to aortic insufficiency, and performance of physicians in detecting these murmurs was evaluated as a comparison with detection of HIV-related findings. The standardized patient with lymphadenopathy had a diastolic murmur related to aortic insufficiency resulting from childhood rheumatic fever. A fourth patient without HIV infection also had a diastolic murmur due to aortic insufficiency and told physician-subjects that he had a resolving upper respiratory infection and pleuritic chest pain. Both patients with diastolic murmurs also had systolic murmurs. These patients were examined by cardiologists and general internists prior to the standardized patient examination, and the underlying causes of the murmurs were confirmed by echocardiography. Both murmurs were graded as being at least III/VI.

From the Departments of Medicine (Drs Paauw, Curtis, and Ramsey, and Ms Wennich), Medical Education (Dr Carline), University of Washington School of Medicine, Seattle.

Corresponding author: Paul G. Ramsey, MD, Department of Medicine, Box 356420, University of Washington, Seattle, WA 98195-6420.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville MD 20857

FEB 22 1996

NOTE TO SUSAN GRIFFITH

Emmett Chase, M.D., National AIDS Program Coordinator, Indian Health Service (IHS), reviewed the draft National Strategy for HIV and AIDS report and provided the following comments:

Agreement with content of report as is.

Referencing the IHS appendix, Unmet Need: is unknown at this time.

Suggest replacing the word **activates** with **dissemination**.

Thank you for the opportunity to review this important document.

W.C. VANDERWAGEN MD

W. Craig Vanderwagen, M.D.
Acting Associate Director
Office of Health Programs

Standardized Patient's Physical Finding	Physicians Who Saw Standardized Patient, No.	Physicians Who Detected Abnormality, No. (%) ^a	Physicians Who Correctly Diagnosed Abnormality, No. (%) [†]
Kaposi's sarcoma	89	42 (47.2)	23 (25.8)
Oral hairy leukoplakia	97	54 (55.7)	22 (22.7)
Diffuse lymphadenopathy	133	23 (17.3)	Not applicable

^aDetection of abnormalities was assessed through physicians' responses to a written questionnaire completed after seeing each standardized patient concerning pertinent physical examination findings, including abnormalities and important negatives. Accepted responses included any mention of presence of skin or mucocutaneous lesions for the dermatologic cases and any mention of lymphadenopathy for the patient with fatigue and weight loss.

[†]Correct diagnosis of Kaposi's sarcoma and oral hairy leukoplakia were determined from physicians' responses to a written questionnaire completed after seeing each standardized patient concerning the most likely diagnostic considerations for each patient.

nificant differences in identifying OHL or KS by specialty or by medical school graduation year, and there were no differences by any of the physician variables in detecting lymphadenopathy.

For the patient with arthralgias and fatigue, 75 physicians (56.4%) described a diastolic murmur or aortic insufficiency murmur. Among 58 physicians who did not correctly identify this murmur, 25 (43%) described only a systolic murmur, 11 (19%) did not mention the murmur, and 22 (38%) mentioned the presence of an undifferentiated murmur or misidentified the murmur. A total of 77 physicians (57.5%) described a diastolic or aortic insufficiency murmur in the patient with pleuritic chest pain. Among the 57 physicians who did not correctly identify this murmur 25 (44%) described a systolic murmur, 12 (21%) did not mention a murmur, and 20 (35%) mentioned the presence of an unspecified murmur. Of the 133 physicians who evaluated both patients with diastolic murmur, 51 (38%) correctly identified both murmurs, 33 (25%) did not correctly identify either murmur, and 49 (37%) identified one of the murmurs correctly.

Seventy percent of the internists identified the murmur for the patient with arthralgias and fever compared with 44% of family practitioners ($P=.004$), and 70% of internists identified the murmur for the patient with pleuritic chest pain compared with 47% of family practitioners ($P=.009$). For the patient with pleuritic chest pain, 23 (77%) of 30 physicians who graduated medical school between 1967 and 1974 correctly identified the murmur compared with 29 (50%) of the 58 physicians who graduated between 1975 and 1981, and 25 (54.3%) of 46 physicians who graduated between 1982 and 1988 ($P<.05$).

Comment

Human immunodeficiency virus infection is a disease with cardinal physical findings, and early identification of HIV infection is important for directing treatment that can reduce morbidity. Yet there is ample evidence that preventable morbidity and mortality occur in individuals

with undiagnosed HIV infection, as evidenced by low CD4 cell counts at diagnosis,¹³ presentation of *Pneumocystis carinii* pneumonia at the time of HIV diagnosis,¹⁴ and hospital admissions for preventable conditions among patients with previously undiagnosed HIV.¹⁵ Inadequate history-taking skills associated with assessment of risk for HIV infection have been documented,¹⁶⁻¹⁸ but physicians' ability to identify physical signs associated with HIV disease had not been studied.

In this study, we examined primary care physicians' ability to recognize three common findings associated with HIV infection: KS, OHL, and diffuse lymphadenopathy. The physicians frequently missed the three HIV-related physical findings and did not make the associated diagnoses.

Among physicians who performed physical examinations on the patients with KS and OHL, approximately half did not detect the lesions as physical examination abnormalities, even though they were alerted by histories to the lesion sites. Among physicians who did describe the lesions, approximately half did not correctly diagnose the lesions based on physical examination. Among all physicians seeing these two patients, approximately three fourths did not correctly detect and identify each lesion. For the patient with diffuse prominent lymphadenopathy, few physicians (17%) detected the abnormality. In comparison, more physicians detected and correctly identified prominent diastolic murmurs. However, 40% or more of physicians either did not detect each murmur or incorrectly identified the type of murmur. These data indicate deficiencies in HIV-related physical diagnosis skills among primary care physicians and also suggest more general deficiencies at physical diagnosis.

Experience with HIV-infected patients appeared to influence the ability to recognize OHL, but not KS or lymphadenopathy. Given the small number of cases studied, however, the power to detect differences in performance based on training experience and other variables is low. Prior experience with HIV infection and other variables may have a greater im-

pact on performance than suggested by the limited number of cases in our study. This study is also limited by the voluntary nature of physician participation. Physicians who volunteer to participate in a study related to clinical skills may be more confident in their skills and perform better than physicians who do not volunteer. Therefore, the findings reported here may overestimate performance among practicing primary care physicians.

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The authors are grateful to David Spach, MD, for his comments on the manuscript.

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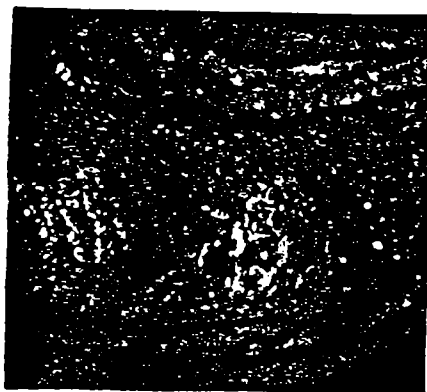


Figure 1.—White, adherent plaques of oral hairy leukoplakia located on the lateral aspect of the tongue.

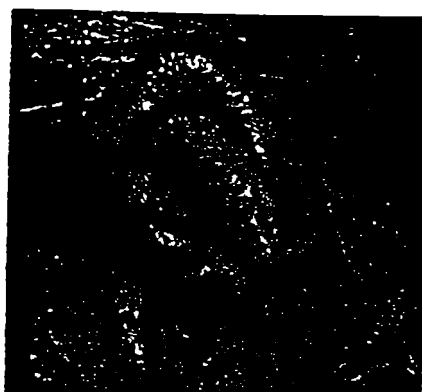


Figure 2.—Distinct, raised reddish-purple lesion of Kaposi's sarcoma on the superior aspect of the helix.

Physical signs were verified by a clinician weekly before the standardized patient sessions to ensure that the signs were present and stable. Because of illness and absences among the standardized patients, not all participating physicians saw all standardized patients.

Primary care physicians (general internists, family practitioners, and general practitioners) from Washington, Alaska, Montana, Idaho, and Oregon identified in the *American Medical Association Directory* were recruited by mail. Recruitment methods are documented elsewhere.¹¹ The study was presented to potential subjects as a continuing medical education course in conjunction with a research project to document primary care practice patterns and clinical skills. Physicians were informed that the standardized patients would present histories and physical findings related to a broad range of diseases. Human immunodeficiency virus infection was listed among diseases that might be presented to the physicians. Physicians were not informed that one focus of the study was identification of physical signs related to HIV infection. The study design was approved by the University of Washington Human Subjects Review Committee, and physicians gave informed consent for participation.

Entry criteria for physician-subjects included spending at least 50% of professional time providing primary care, graduation from medical school in 1967 or later, and specialty in internal medicine, family practice, or general practice. Power calculations indicated that study of 120 physicians would provide sufficient power to detect differences in performance on key variables across a large number of cases; a slightly larger number was selected to compensate for possible dropouts. Among 599 interested and eligible physicians, 134 were randomly selected to participate after stratifying by prior experience with HIV-positive patients, year of medical school graduation, and specialty in either internal medicine or family medicine.

For each patient, physicians had 20 min-

utes to perform a focused history and physical examination. For these cases, physicians spent a mean of 14 minutes (median, 15 minutes) with each patient. After evaluating each patient, the physicians answered written questions concerning the history and physical examination, diagnostic work-up, differential diagnosis, and management plan. These responses provided the information that would be available in an office record, but also prompted the physicians to list any physical abnormalities that they detected.

Detection of each physical finding by a physician was determined from the written information completed by physicians concerning physical examination findings pertinent in developing a diagnosis, other physical examination abnormalities, and important negative findings. Acceptable responses included any mention of presence of lesions for the KS and OHL cases and any mention of lymphadenopathy for the patient with fatigue, fever, and arthralgias. Correct diagnoses of KS and OHL were determined by responses to a question for each case concerning the most likely diagnostic considerations.

Group comparisons were performed by the experience of the physician treating patients with HIV infection, board-certified specialty, and year of medical school graduation. An overall variable that combined the physician's training and practice experience with treating HIV-infected patients was developed from measures related to medical school experience, residency experience, and self-reported practice-based experience. Physicians were divided into those with least experience ($n=57$), moderate experience ($n=47$), and most experience ($n=30$) with treating HIV-infected patients from the three sources. By board-certified specialty, there were 66 general internists and 60 family practitioners, with eight noncertified physicians excluded from these analyses. By medical school graduation year, 30 physicians graduated between 1967 and 1974, 58 graduated between 1975 and 1981, and 46 graduated

between 1982 and 1988.

Group comparisons were performed for the percentage of physicians who correctly identified each physical sign among all physicians seeing each patient. For KS and OHL, comparisons were performed of the percentage of physicians who correctly diagnosed the lesion. For the patient with lymphadenopathy, comparisons were performed of the percentage of physicians detecting any lymphadenopathy. For patients with diastolic murmurs, comparisons were made of the percentage of physicians who described a diastolic murmur or mentioned an aortic insufficiency murmur in the differential diagnosis.

The Mantel-Haenszel test for linear association¹² (χ^2 for trend) was used to compare performance in detecting or identifying each physical sign by the experience of the physicians treating HIV-infected patients and year of medical school graduation. The χ^2 analyses were used to assess performance by board-certified specialty. For all analyses, the α level for a significant difference was set at $P<.05$.

Results

Despite being directed by the presenting history to the lesion sites and despite prominent lesions, only 42 (47.2%) of the 89 physicians who saw the patient with KS noted the presence of any abnormality, and only 54 (55.7%) of the 97 physicians who saw the patient with OHL mentioned the mouth lesion as a physical examination abnormality (Table). Among the physicians who detected an abnormality, many did not provide the correct diagnosis (19 [45%] of the 42 physicians who noted the presence of lesion in the patient with KS and 32 [59%] of the 54 physicians who noted the presence of a mouth lesion in the patient with OHL). Thus, among all physicians seeing each patient with a lesion, approximately one quarter both detected and correctly identified the lesion (Table). Among physicians who detected but did not correctly identify these two abnormalities, the most frequent diagnosis for the patient with KS was a lesion of unknown etiology ($n=11$), and the most frequent diagnosis for the patient with OHL was oral candidiasis ($n=18$). Only 23 (17.3%) of the 133 physicians performing a physical examination on the patient with prominent diffuse lymphadenopathy mentioned lymphadenopathy when asked about physical examination abnormalities.

Eleven (46%) of the physicians with the most training and practice experience in treating patients with HIV infection correctly identified OHL compared with five physicians (16.7%) with moderate experience and six physicians (14%) of physicians with the least experience ($P=.007$). There were no sig-



U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
Washington, D.C. 20507

FEB 15 1996

Ms. Jane Sanville
Office of National AIDS Policy
The White House
Washington, D.C. 205

Dear Ms. Sanville:

This is in response to the Interdepartmental Task Force on HIV/AIDS (IDTF) memorandum dated February 6, 1996.

I have reviewed the draft of the National Strategy for HIV and AIDS and have made a few comments. I have marked these pages with post-its for your convenience.

If you have any questions, please call me at (202) 663-4503.

Sincerely,

Peggy R. Mastroianni

Peggy R. Mastroianni
Assistant Legal Counsel

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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.

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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, smallpox, many forms of cancer, and other scourges in the history of our planet. We will be able to win our battle with HIV and AIDS with commitment, courage, and leadership.

Scope of the HIV/AIDS Pandemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to people and governments here in the United States and worldwide. Unlike other infectious diseases that have arisen over the course of history, HIV is infectious for life and almost always fatal. This national and international pandemic of HIV disease, now well into its second decade, is progressing virtually unabated. It also remains a deadly infection for which there are limited treatments, no vaccine, and no cure.

An Expanding Public Health Threat

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

As we have witnessed a relentless increase in infections, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half (43%) of all new cases. Among the populations being more heavily affected now are young men between 20 and 24 (%), and women (18%), and heterosexual injecting drug users (24%). And although gay men no longer represent the majority of new cases, this groups represents the majority of persons living with HIV and AIDS. In 1995 alone, more than 14,xxx women were diagnosed with AIDS and women now comprise 21 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned by AIDS by the end of this decade.^{1a} As of October 1995, pediatric

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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

¹ 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 have been the target of violence, rejected by their families, and suffered discrimination based on their HIV status.

AIDS is a disease that can strike at anytime but most often affects people in the prime of life. It disproportionately kills people during their most productive years. It is the leading cause of death among Americans 25 to 44, the age group that constituted 54% of the civilian labor force in 1992.³ Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In terms of years of potential life lost, in 1994 AIDS ranked fourth among all leading causes of death. In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children.

Goal of the National Strategy

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

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

The national strategy for HIV and AIDS presented here is broader in scope than prior planning efforts. To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency 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 appropriate care for and ethical treatment of persons with AIDS.

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

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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.

Opportunities for Progress

Modes of Transmission

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

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

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

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must 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

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

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

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

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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

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

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

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

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

Treatment for Sexually Transmitted Diseases and Tuberculosis. Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, even by as much as 20 times. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{15, 16} These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs.

Persons who are HIV positive are at significant risk for developing of *M. tuberculosis* (TB) disease. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.¹⁷ In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

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

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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.

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.

RESEARCH

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

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

Contributions of Research

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

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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.

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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

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,

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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.

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

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

The development of this important prevention approach will depend on strong support for the basic and clinical research. Topical Microbicides are a promising approach, but will require preliminary support before they reach a stage where the private sector can assume a lead role. Given that worldwide over 80% of HIV infections are acquired heterosexually, and given that the risk of becoming infected or infecting others is substantially increased by the presence of other STDs¹⁹, topical microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

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

Due in part to the FDA's accelerated approval 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 be 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.]

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

It is also unlikely that the free market will conduct head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research. Similarly, it is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. Americans are spending millions of dollars per year on such therapies about which little is known.

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

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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.

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 net. 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

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.

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.

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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.

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.

Due in part to Federally-sponsored information dissemination activities, dramatic changes in the way HIV is treated have taken place over the last 15 years. In the beginning of the epidemic little was known about effective treatments; care was primarily hospital-based and focused on the most severe complications of late-stage HIV disease. Now, with more knowledge about the course of HIV disease available to clinicians, there is an increased focus on prophylaxis for a range of infections in a primarily outpatient setting. Individual agency projects have

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

Opportunities for Progress

However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians miss significant HIV-related symptoms during patient examinations.²² Other research indicates that a disturbing number of clinicians are not aware of or do not use universal precautions in the course of routine patient care.²³ We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study which demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard-of-care. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

Coordination of Federal Activities. The most pressing need in the area of information dissemination is to improve coordination among Public Health Service agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a high level of cooperation and coordination among Public Health Service agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, good models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons on the frontlines of the epidemic. Here again, the Public Health Service must take the lead in ensuring that information which can be used to stem the tide of new infections reaches those who can make a difference.

CIVIL RIGHTS

One of the Nation's common goals is to ensure the ethical treatment of persons with AIDS. Discrimination based on HIV status, is illegal and morally wrong. It undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV. As a result they remain unaware of their HIV status and cannot take advantage of care that could help them live longer more productive lives. In addition, opportunities to educate people are lost.

Opportunities for Progress

The Nation has made progress in fighting discrimination. There are now laws in place to protect people against HIV-related discrimination in employment, housing, and public accommodations. However, the enactment of laws is insufficient to end discrimination. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility that must be shared among Federal agencies, states, communities, and the citizens of this country.

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

with disabilities

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.

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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 Bein 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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NCCR	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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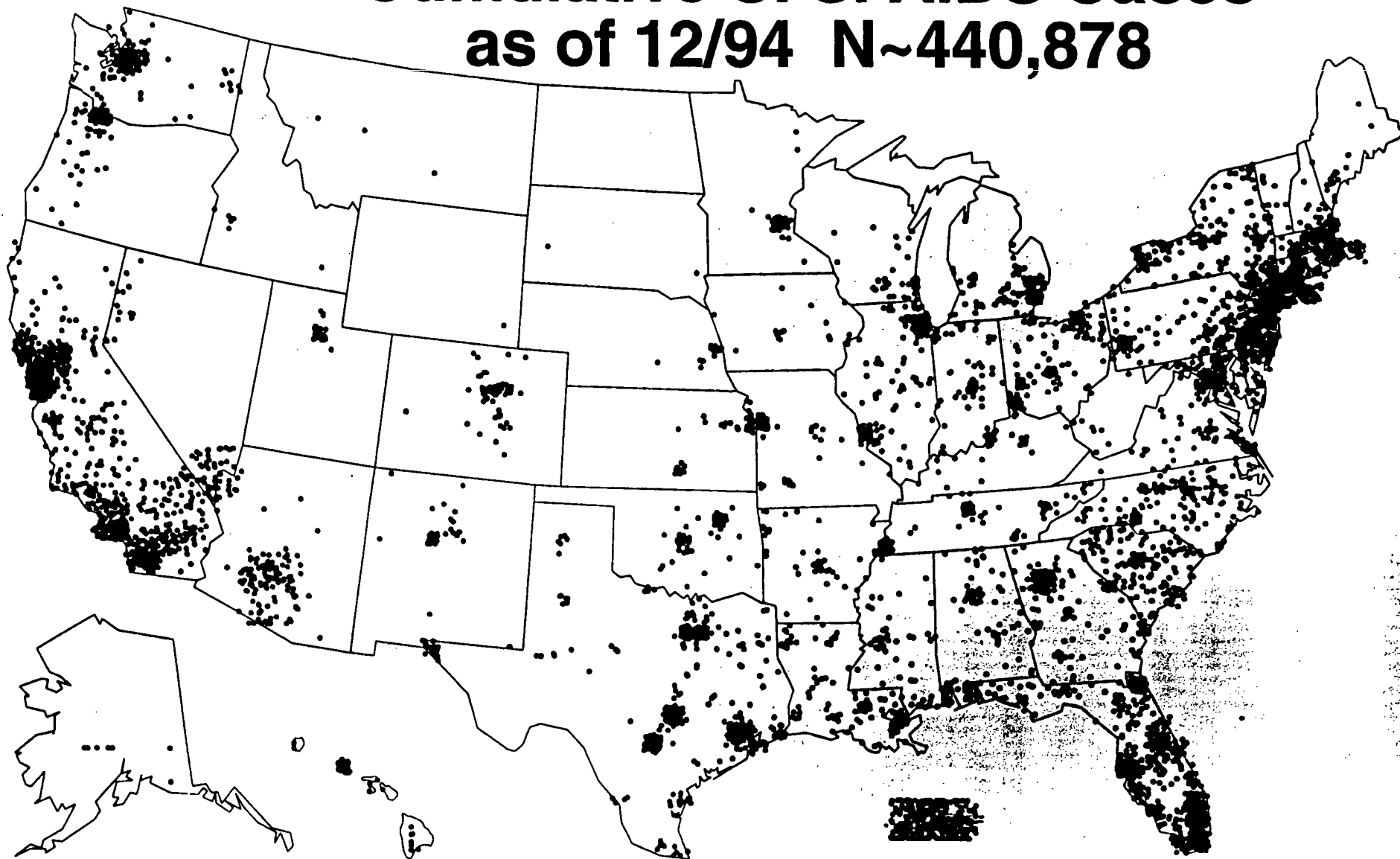
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CHART #2

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



Each point = 30 cases

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



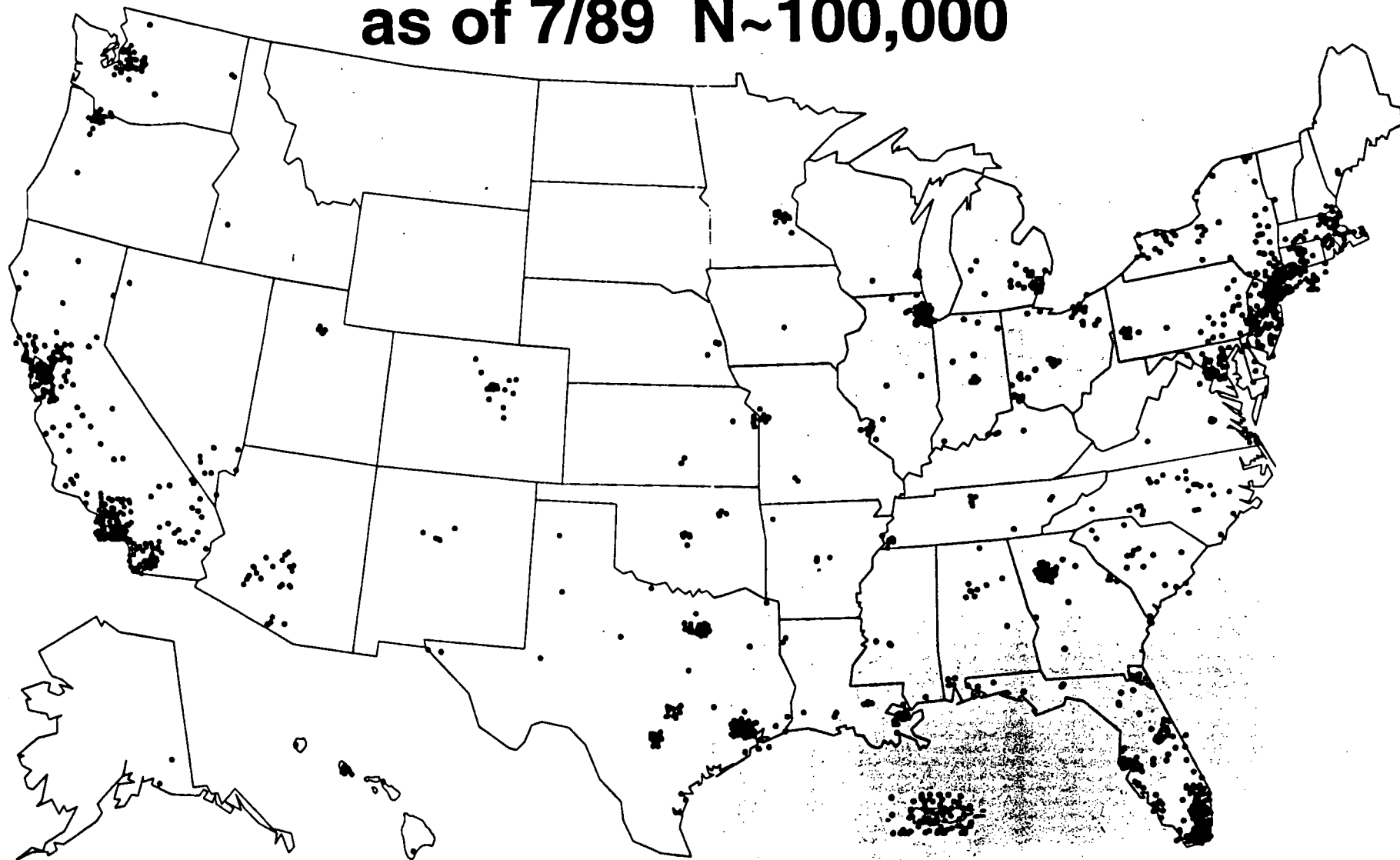
Each point = 30 cases

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



Each point = 30 cases

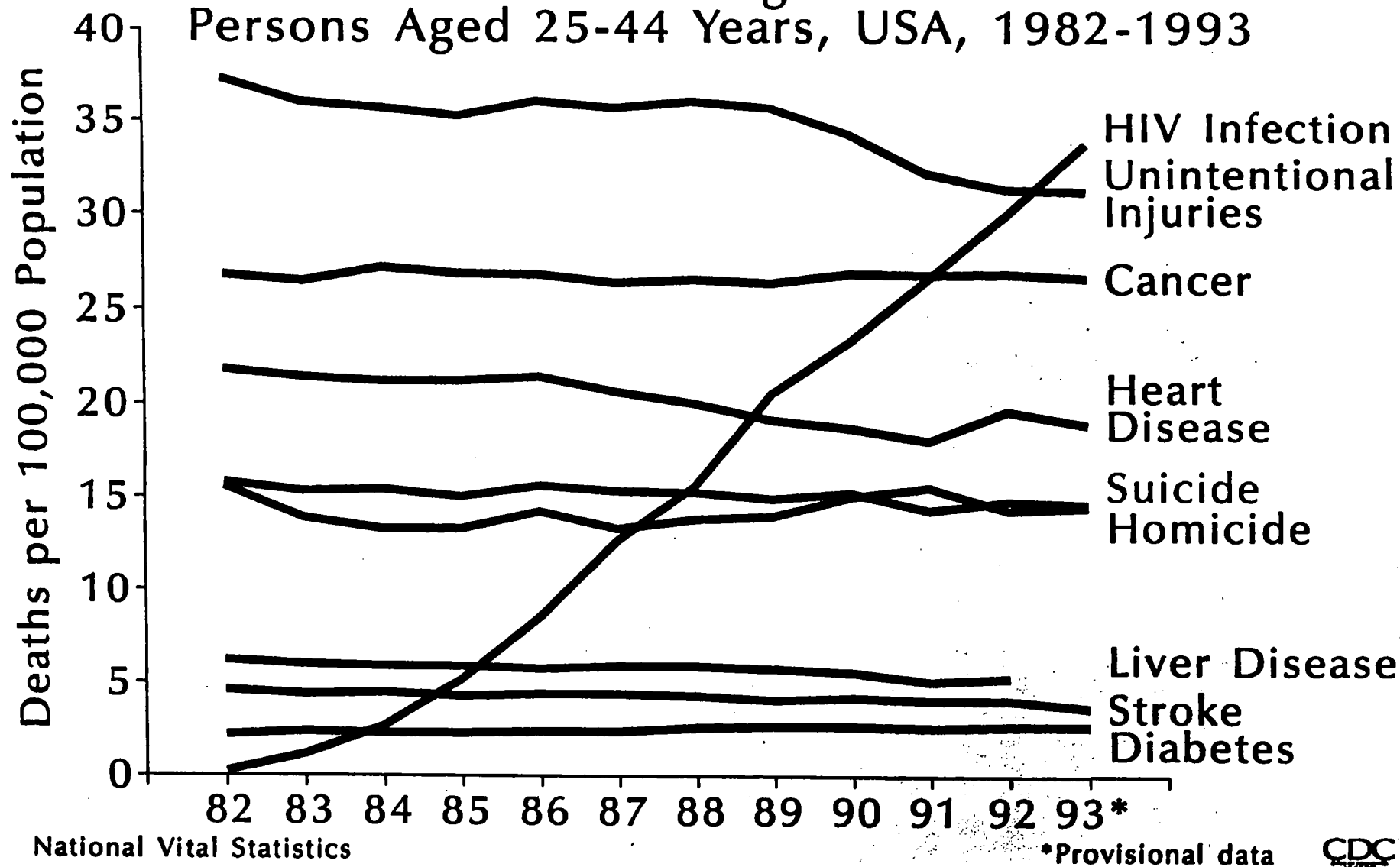
Cumulative U.S. AIDS Cases as of 7/89 N~100,000



Each point = 30 cases

CHART #1

Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982-1993



CIVIL RIGHTS

Agency: U.S. Equal Opportunity Commission

Goal: To eliminate employment discrimination against persons with HIV disease.

Objective: Enforce Title I of the Americans with Disabilities Act (ADA), which protects job applicants and employees with HIV disease from employment discrimination.

Action Steps: Receive, investigate, and ^{resolve}~~settle~~ ADA discrimination complaints from job applicants and employees with HIV disease; ✓

Litigate ^{select}~~meritorious~~ cases involving employment discrimination against persons with HIV disease; and ✓

Educate the public regarding ADA's protections for job applicants and employees with HIV disease.

Descriptions: Enforcement of Title I of the ADA.

FY 95: Part of EEOC's general operating budget.

FY 96: Part of EEOC's general operating budget.

Populations Served: Job applicants and employees with HIV disease.

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

Unmet Need: An increase in the Commission's investigative and legal staff would provide for quicker resolution of all EEOC complaints, including HIV-related complaints brought under the ADA.

Jane: I assume that when this information is presented in context, it will be clear that this is EEOC's goal with respect to persons with HIV disease and not its overall enforcement goal.