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Collection/Record Group:	Clinton Presidential Records
Subgroup/Office of Origin:	National AIDS Policy Office
Series/Staff Member:	Patsy Fleming
Subseries:	National AIDS Strategy

OA/ID Number:	9004
FolderID:	

Folder Title:
ONAP [Office of National AIDS Policy] Review 7/22/96 [2]

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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~~ ^{can not}, 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~~ ^a 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 ^{Public-Private} ~~Federal-local~~ partnership. Through this effort, it ^{has been} ~~is~~ possible to establish joint goals for the prevention of HIV that ^{are} ~~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 effective priority setting and decision making.

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

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated, however, care and prevention services for HIV and substance are not. It is vital to continue

and strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

Key to
A ~~second avenue~~ for controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is a ^{*main*} form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is also substantial evidence that use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMSHA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage prevention and treatment for this population is critical. *HIV*

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 *ab*users to seek treatment. We also need to ensure that drug treatment services are available in ~~sufficient numbers~~ for a range of addictions 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 ^{new} ~~this~~ issue^s has begun and will continue. ~~The~~ CDC has ^{an} initiated State-by-State discussion, including meetings with State Legislators and the National Conference of State Legislatures, regarding HIV prevention issues. SAMHSA's new ¹¹ Knowledge Development Application ^(KDA) ~~program~~ program will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. In addition, CDC, HRSA, NIDA, and SAMSHA ^{AB} are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Treatment for Sexually Transmitted Diseases and Tuberculosis.

Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, ~~even~~ ^{Twenty-} by as much as 20 fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{20,21} 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. NIH-supported research to

further understanding of the effect of STD treatment on HIV transmission is underway and should continue.

HIV positive people are at very high for developing ~~of~~ *tuberculosis* (TB) **disease**. People infected with both HIV and TB are more likely to develop TB disease than people who infected with only TB. 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.²² 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.

~~Further, there is strong evidence that the HIV epidemic has contributed to the increase in the number of TB cases. Geographic areas that have been most affected by the HIV epidemic have also reported the largest increase in TB cases. Moreover, from 1985 to 1992, the largest increase in TB cases among people ages 25 to 44, the age group most affected by the HIV epidemic.²³~~

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 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

To reduce perinatal transmission,
All pregnant women should be
offered HIV counselling and testing and
information about and access to
AZT during preg. & child birth. ~~before~~
~~born to HIV positive women~~
and infant born to these women
should receive AZT for six weeks.

Counseling & Testing

voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. It ~~also means~~ ^{all} 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.

Recpp
Prisoners. ~~Populations~~ in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

Given that the incarcerated population is often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Studies have found that programs using peer counselors have been effective in delivering HIV treatment and prevention messages.

Research has also shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

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 an awareness that a reconfiguration of some program priorities may be required.

HIV/AIDS RESEARCH

One of the Federal government's goals is to provide strong support for ^{biomedical} 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 ^{These} ~~will~~ ^{continuously} require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, ^{Heb's} communities where research is conducted, charitable organizations, pharmaceutical ^{manufact} companies, biotechnology firms, and other parts of the private sector. It ~~will~~ also require ^{s/} an ongoing dialogue between the public and private sectors.

At present, ^{Several} ~~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) ^{directs} supports the largest portion of these efforts, ~~NIH supports~~ ^{ing} HIV-related activities in the areas of natural history and epidemiology, etiology and pathogenesis, drug discovery and

therapeutics, vaccines, behavior^{al} and social sciences, and research training. The ^{Dept. of Vet Aff.} ~~Veterans Administration~~ (VA) also supports a broad range^{of} basic and applied research efforts. 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. ^{CDC} ~~The Agency~~ also supports facilities employing sophisticated methods for identifying viral variants.

Contributions of Research

The Nation has already realized benefits of supporting research in general^x and HIV-related research specifically. The effort to understand HIV and AIDS has ~~led to~~, and will continue to result in, scientific ^{advances} ~~strides~~ that benefit research on many other diseases.

AIDS research has accelerated study of the human immune system. This basic immunologic information is being applied to research to better understand and treat many other diseases, such as cancer, and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. AIDS research ~~also~~ contributes to the prevention of other infectious diseases and ~~has~~ provided a new paradigm for treatment of viral diseases.

Advances made in the treatment and prevention of ~~the~~ opportunistic infections ~~that complicate HIV disease~~ have had an impact on the care of patients with other immunodeficiency states who are susceptible to many of the same pathogens. ~~The~~ research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, ~~or~~ the treatment of diseases caused by heightened immune responses.

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent of Kaposi's sarcoma. Such approaches may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia,

multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of more viral diseases and led to development of treatments for many other diseases.

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

Due in great part to Federally-sponsored research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs. One of the recent research advances has been the development of new

class of drugs, protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, and possibly improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, 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, requires 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, evaluate, 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. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained. With such a large research enterprise involving almost every area of clinical medicine and scientific

investigation, 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.

Add language about the Levine Report?

~~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 ^{and have} ~~Multiple~~ Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths.

~~Moreover,~~ this research is often carried out collaboratively. For example, the CDC, FDA, DoD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and ~~there exist~~ strong linkages between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV-related opportunistic infections.

The National AIDS Strategy
Draft for ONAP Review, 7.22.96

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this, the Director of the Office of National AIDS Policy ^{created} ~~coordinated~~ an inter-departmental working group, chaired by the Director of the Office of AIDS Research, ~~whose charge it was to develop~~ ^{d/with} a coordinated plan and budget ^{ing} ~~specifically~~ for HIV and AIDS research across all Agencies, ~~Departments.~~

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 ^{further} 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 ^{inhibit?} ~~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.

One group of
~~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~~ 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.

would NIH agree?

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. 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 developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public-private partnership ^{is} ~~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 ^{must} ~~will~~ continue.

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.

Microbicides. Many scientists believe that in the absence of a ¹

effective vaccine, the development of a safe, effective, female-controlled mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections, could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. 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 (STDs²⁵). An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide, *as well as their partners.*

Latex Condoms, 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 *Latex* condoms will reduce the risk of acquiring and transmitting HIV and other STDs. *However,* 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 that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge.~~

new initiative
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~~ *companies* 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.

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. 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 Adolescent Medicine HIV/AIDS Research Network, cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA) serves as an important model of collaboration in this area of research. The network has been developed to improve our understanding of disease and health in adolescents; several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. 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 program²⁶, 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 long-term clinical effectiveness are 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.

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.

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.

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.

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

Research: An Investment for the Future. And finally, research is an

investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead 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 prolonging and improving the quality of 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. 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 and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net.

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably

served those living with HIV. Taken together, these efforts form a valuable if incomplete safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of this safety net is programs funded 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. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

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.²⁷

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.

Housing assistance 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.

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. The program is representative of HUD's "Continuum of Care" approach to building local systems to address homelessness. Moreover, 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.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. 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 to 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 ^{HIV} care and services to have the most beneficial impact, they should be ~~offered~~ as part of a continuum of care. For organizations ^{at} on the front lines of the epidemic, building a comprehensive integrated program requires ^{support from} ~~applying to~~ numerous Federal Agencies. For example, ~~creating~~ a community ^{based} program that integrates primary care, ^{with} substance abuse treatment, ~~and~~ prevention, ~~and~~ sexually transmitted disease screening, ^{AIDS} prevention, access to clinical trials, and housing assistance ^g would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

Efforts to simplify ~~F~~ederal 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 ^{high}supported programs can and should consistently provide ^{high} quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV ^{high}positive persons is possible, but ^{high} 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.

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^{million} 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~~ ^{30 million to 40 million} people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In ^{nations of} 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.²⁸ 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 ^a ~~the~~ reduction in the number of healthy men and women able to serve in the government and the military.

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. 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).²⁹ 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. 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 "Lessons without Borders Project" initiative brings lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas. This initiative creates linkages between U.S. community organizations and international projects. 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, and U.S. based non-governmental organizations.

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.

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 must develop a mechanism for identifying and coordinating this effort.

TRANSLATION OF RESEARCH 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 the standard practice of clinicians, service providers, and health educators 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 worldwide audio tele-conferencing. NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example of these materials is 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 that responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers that provide state of the art

HIV clinical information to health care providers.

Opportunities for Progress

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.³⁰ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.³¹

We are also at a stage in the epidemic where research advances are coming frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this therapeutic regimen, a policy change on the part of the Health

Care Financing Administration (HCFA) was required.

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

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

Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-

sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, 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 that 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 that services provided to persons living with HIV 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, insurance, 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). 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. In addition, the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) is responsible for implementing portions of the ADA, including investigating and resolving Title II complaints of discrimination by health care and social service programs.

Federal Agencies and recipients of Federal funds are prohibited from discriminating against people with disabilities under Section 504 the Rehabilitation Act of 1973. The DHHS' Office of Civil Rights is also responsible for enforcing Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. 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 those against clinicians who have refused to care for HIV-positive 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.

Footnotes

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
2. Communication, Department of Labor.
3. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
4. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
5. *Journal of the American Medical Association*, July 28, 1993. Add page number/complete reference.
6. 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 (SAMHSA), 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.
8. Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341-348, July-August 1986.
9. Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988.
10. The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.

11. AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993.
12. 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.
13. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.
14. Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.
15. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy Press, Washington, D.C., 1994. p.79.
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17. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.
18. JAMA article used in PRIM&R speech
19. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226-1231.
20. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229
22. Personal communication from CDC Division TB Elimination.
23. Epidemiology of Tuberculosis, Self-Study Module on Tuberculosis, Module Number 2, Division of Tuberculosis, Nation Center for HIV, STD, and TB Prevention, the Centers for Disease Control and Prevention.
24. This section focus primarily on biomedical and health services research. Discussion of behavioral and social science research is presented in the Prevention section.
25. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.
26. 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.
27. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.
28. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.
29. 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.
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July 22, 1996

To: Patsy
Jeff
Richard
LaHoma
Daniel
✓ MC
Sherry

From: Jane

Subject: Final ONAP of the National AIDS Strategy

When The final ONAP review is scheduled for Wednesday July 25th from 10:00am to 1:00pm and 2:00pm to 4:00pm.

What The goal is to walk through the text and finalize the text. ***This is the last chance to make changes.*** If you are recommending a change, please propose specific replacement language. If there is time, we'll do the same with the appendices, otherwise appendix comments can be provided to me in writing. The most important part conceptually is the text -- the appendices are a pretty straightforward accounting of Federal activities.

For those of you who have involved with developing the Strategy over the last year, your comments from past drafts have incorporated.

For those of you who have not been directly involved, your "layman's" perspective will be very helpful.

Materials In the attached packet are the main text and appendices A - F.

Timeline We are on a tight timeline for completing the Strategy. The final copy must to the printers by July 31st if we are to stay on track for the August 8th event.

Thank you for all for help, we have a lot of territory to cover. If you have questions or do not understand what anything please don't hesitate to stop by my office.

Mc

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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 promote efficient and collaborative policy and program efforts.

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

Combating HIV disease will require nothing less than the best innovative and cooperative efforts of State, local and federal

The National AIDS Strategy
Draft for ONAP Review, 7.22.96

governments, the private sector, and 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 development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work.

* Add paragraph to end of section

In developing the document, we depended heavily upon groups outside of government as well -- they, too, have been, and will continue to be, essential partners in developing solutions that capitalize on the opportunities for progress that are now before us. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC), 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-positive persons, their families, friends and care givers have been central to identifying areas for focused attention. The insights provided by the National

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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.

This document is a snapshot of where we are ^{as a nation} and where we think we need to go. ~~Collaboration is one of the hallmarks of this~~ ^{at where we think we need to go. It serves as a reference point} Administration's approach to AIDS policy and Strategy serves as a ~~reference point~~ for lengthier dialogues and collaborative efforts between the public and private sectors.

*move
to p 4* * 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 epidemic challenges us 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 this country to look at things that are difficult to face.

Another challenge is

~~There is also~~ fear -- fear of contracting this disease and 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.

AIDS also brings to light many of the cross-cutting problems that exist in our Nation's patchwork of health care, legal, and social service systems. *This is a big N.S. is needed.* For example, AIDS orphans are a hidden epidemic within the larger context of HIV/AIDS. Some are HIV-infected, all are HIV-affected. Many of these children already have or will become wards of the state, shuffled between foster and group homes, often separated from their siblings. They often fall through the cracks of a system that is not prepared to care for them.

We are seeing an increasing number of grandparents becoming parents of their grandchildren, even as they deal with the illness and

death of their own child. The myriad of Federal and State Agencies (i.e. ...) charged with overseeing child welfare issues, coupled with a legal code not designed to dispense compassionate remedies for these orphaned children, ^{create} has created a bureaucratic nightmare for dying parents seeking to provide a safe and caring home for their children. There is a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of a child's parent(s). *It is to be expected that the system will be challenged by the HIV crisis and the need for a more efficient and compassionate system.*

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, ^{we} as a Nation, we, too, can ^{rise} collectively ~~rise~~ to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are ^{at} ~~at~~ ^{high} risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease.

*8/20/96
Please
not September
OK*

Today we are facing great challenges, ^{but} we are also facing

to be a more compassionate system

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equally great opportunities. ~~While~~ AIDS is a terrible tragedy that has already affected far too many people around the world; ~~I~~

~~believe it~~ ^{AIDS} is a disease that we can defeat -- just as we have eradicated polio from the western hemisphere and smallpox from the world. The National ^{AIDS} Strategy for HIV and AIDS lays a foundation for the public-private partnerships that are essential to our success. Together, with ^{continued} steadfast commitment, courage, and leadership, we will be able to win the battle against HIV and AIDS.

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. *Some see HIV as a global pandemic and a threat to the world's health.*

Since the discovery of the first AIDS cases in the ¹⁹⁸¹early-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 ¹⁰ten or even ⁵five 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 ^{development of an effective}a vaccine is possible. Nonetheless, the epidemic continues. ^{More than 40,000 Americans}More people ^{are every year}are infected every year, ^{in every}in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. ^{Young people are increasingly vulnerable to HIV infection.}And youth ~~are at~~ increasing risk. ^{Globally}Internationally, the epidemic is threatening the economic stability

of a number of developing nations. (See) *the text*

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

? relevant to the text of the report.

solutions. The National ^{AIDS} Strategy must incorporate innovative ideas, careful planning, and the strength of public-private partnerships.

The Strategy as a Catalyst for Change

The National ^{AIDS} Strategy is intended to ^{assist} 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 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.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. 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, private sector organizations, and the community.

Executive Summary

== Place Holder ==

I. INTRODUCTION

Scope of the HIV/AIDS ^{Epidemic} Pandemic

The ^{epidemic} pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. While we have made significant progress in understanding the disease and developing treatments since the first case was identified by the 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. *Has been made*

An Expanding Public Health Threat

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

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the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See Figure 1.) In 1995 alone, approximately 74,000 new cases of AIDS were reported to the CDC. More than 46,000 AIDS-related deaths were reported to the CDC in 1994. ~~The~~ CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has ^{evolved} evolved, the demographics of the epidemic have ^{changed} 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); ^{today} this group ~~now~~ represents less than half of all new cases. Among the populations ^{that are} being more heavily affected ~~now~~ ^{today} are young gay men, women, and heterosexual injecting drug users and their partners as well as ^{women} non-injecting ~~drug~~ users ^{and} i.e., crack cocaine and ^{alcohol} ~~alcohol~~. Although gay men no longer represent the majority of new cases, this group ^{still} represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported with AIDS, ^{to the CDC as having been diagnosed} and ~~now~~ ^{now} women comprise 14 percent of cumulatively reported AIDS cases. ^{to the trend continues,} It is estimated that ~~if this trend continues~~, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new pediatric AIDS cases were reported. ~~It is~~ ^{It is}

however, hoped that with greater use of AZT by HIV-positive mothers during pregnancy and delivery, and administration to their babies after birth, the number of new cases in newborns can be reduced. pg 601-2

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} ~~special~~ risk. The CDC estimates that one in four new HIV infections in the U.S. occur among young people. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier ^{ages} ~~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. under age 21

Communities of color have been disproportionately affected by the epidemic. ~~In 1995~~, African-Americans ^{in 1995} accounted for 40 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population, Hispanics ^{also} represented ^{only} 19 percent of new cases reported in 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of December 1995 these groups comprised 52 percent of cumulative AIDS cases.

an ^{urgent} problem. The HIV/AIDS ^{epidemic} pandemic is

AIDS is no longer just an urban problem. The HIV/AIDS pandemic is

Internationally, the toll of the epidemic is greater still. The

~~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 ^{epidemic} pandemic. ~~WHO also projects that~~ ^{By} the year 2000 ^{UNAIDS} ~~estimates~~ 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. ^{People} Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been ^{discharged} discharged from

their jobs and evicted from their homes. ^{Some People} *Many persons living with HIV have been the target of violence, rejected by their families, and suffered discrimination because of their HIV status.

AIDS is a disease that most often affects people in the prime of life; ^{it} It 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% ^{percent} 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} ~~many~~ cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of years 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 ^{? most} to 84,000 for Cancer⁴, and \$119,000 for HIV/AIDS⁵. And although ~~cancer and heart disease costs may be attributable to~~ striking older and frailer persons, overall DHHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS.

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In FY 1995 DHHS spent approximately: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$6.0 billion for AIDS.

In developing countries, ^{epidemic} 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, ^{a majority} 95-percent of hospital beds are occupied by AIDS patients. Moreover, the ^{UNAIDS} WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000. The human toll has been staggering and is likely to continue.

The Evolving Challenge of the HIV/AIDS Epidemic

The four decades prior to the report of the first AIDS case in the ¹⁹⁸¹ early 1980s encompassed a period of unprecedented success in controlling infectious diseases. ^{Hypothesis} The emergence of HIV~~x~~ and the subsequent epidemic of HIV and AIDS~~x~~ ^{have} 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. ^{As a result of} Thanks to this work, we now know the risk factors and the etiologic agent for HIV~~x~~, ~~and we~~ have a test to ascertain HIV serostatus and can, therefore, protect the blood supply with a high degree of certainty.

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, ^{as a result} developing therapies for HIV infection and its associated opportunistic infections and malignancies. New and more powerful therapies that offer ^{greater} hope for treatment and prevention have been developed. Scientists now believe ^{the development of an effective} ~~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 ^a~~the~~ new generation of therapeutics for HIV, its associated ~~and~~ opportunistic infections and malignancies.

~~Since the beginning of the epidemic,~~ ^{behavioral} research designed to understand the behavioral, social, cognitive, and biological factors that place individuals at risk ^{at} for acquiring HIV infection has provided important insights for prevention efforts. ~~Practical~~ ^{Community-based} 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 ^{approaches to} ~~programs that will~~ reach even more individuals at risk ^{for} ~~for~~ infection.

The progress in developing therapies and prevention programs has also created 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.~~ 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 and their babies after birth. 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 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.~~ ^{is delivery of services} There is a ^{greater} trend towards decentralizing the role of the Federal government in health care and placing more responsibility at the State and local levels, ^{transferred} coupled with a movement to managed care systems, these changes will influence efforts to ~~strengthen prevention efforts~~ and ensure health care and ^{prevention} services for people with HIV/AIDS.

From a societal perspective, while we have made tremendous progress in overcoming fear and discrimination, we still have a long way to go. ^{is no basis} There ~~are no~~ grounds for discriminating against persons with HIV, ~~infection and~~ yet such action has thwarted access to health care, health insurance, housing, employment, and even funeral

services. We must continue in our vigilance to ensure that the protections provided under ~~the~~ law are extended to all HIV-infected persons.

? Eliminate all laws that discriminate against people with HIV

Goal of the National Strategy

The goal of the National AIDS Strategy is to capitalize upon the progress ~~which~~ ^{that} 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 realize this ambition we will need innovative ideas, careful planning, and the strength of public-private partnerships, ~~to make these plans a reality.~~

The text and appendices 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. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

Development of the Strategy

The National Strategy for HIV and AIDS presented here is broader in scope than any prior planning efforts. ^{AIDS} ~~To date,~~ ^{Previously} planning has been focused primarily in the Public Health Service (PHS)⁶, Department

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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. There have also been planning efforts on the part of various Agencies and Departments, such as the Department of State's United States International Strategy on HIV/AIDS, the ~~congressionally mandated~~ annual NIH plan for HIV-related research, and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS. 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. 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 along with the ~~counsel~~ ^{advice} of HIV-infected persons and their advocates, the private sector, and the Presidential Advisory Council on HIV and AIDS.

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^{Members of}
~~Through~~ the Interdepartmental Task Force on HIV and AIDS (IDTF),
^{HIV-related}
a formal request went out for the executive branch Agencies to
^{identify} identify their activities, goals, and objectives. These ^{pertinent} pertinent
data have been compiled uniformly and are ^{comprise} contained within the
appendices of the Strategy. The IDTF members, with their
specialized knowledge of a broad range of HIV-related issues, have
^{instrumental} been crucial in identifying areas ^{that} requiring special attention.

There has ~~also~~ been a reliance on groups outside of government, ~~and~~
^{I have} the same groups that have been and 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 Presidential Advisory Council on
HIV and AIDS (PAC) have been invaluable. ^{recommendations} The advice and counsel of ^{have also been} of ^{weeks} ^{from}
^{National & community-based organizations} 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.

Common Objectives and Opportunities for Progress

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

- To provide ^{Continuing strong} strong support for research in order to find ^{effective} treatments, ~~and~~ a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- To provide ^{Continuing strong} solid support for effective prevention strategies so as to reduce the number of new infections each year until there are no new infections; and,
- To ensure that ~~treatment of~~ ^{People} persons living with HIV is ^{have access to services} caring, ^{that are} ethical, ^{affordable,} and in accordance with legal standards. ^{High quality response to HIV}

4th Bullet on being social

Alternative language: To ensure that persons living with HIV are not subject to discrimination and receive services that are caring, ethical, and in accordance with legal standards.

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

4th bullet

To ensure that people living w/ HIV are not subject to
(unlawful or unwarranted) discrimination

-- 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

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., persons living with HIV, AIDS 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.

Each issue raised in the Strategy 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 small number of Agencies and organizations, while others will require extensive thoughtful effort on the part of many committed participants 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.

Organization of the National AIDS Strategy

The National AIDS 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 ^{includes} ~~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~~^{by} administrative structures, but by area. In cases where a single Agency may have responsibility for more than one ^{topic} area, such as prevention and research, documentation of ^{it} ~~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 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 ^{that} 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~~^{and}, 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 ^{each} ~~an~~ Agency's level of involvement.

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

The scope and nature of the HIV/AIDS epidemic have 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 its 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 \$6.8 billion. (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 Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally-sponsored activities include direct support for research, training, 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 ^{also} ~~are responsible for~~ responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for surveillance, prevention, research, and health care responsibilities carried out by State and local governments, academic institutions, private foundations, health care institutions, and community-based organizations.

PREVENTION

The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each year until there are no new infections.¹⁹ Achieving this goal will require a dedicated alliance between the Federal government, States, local governments, ~~communities~~ ^{to a coalition}, businesses, the academic community, professional and ~~non-governmental~~ ^{international} organizations, families, health care professionals, 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.²⁰ 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 Americans ~~will become~~ ^{are becoming} 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

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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 behaviors~~ sex and ^{for} drug use. To be effective, HIV prevention programs must reach ~~tens of millions of Americans who~~ ^{People who are} are characterized by a ~~diversity~~ ^{diversity} of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

^{Also} Prevention activities ~~are~~ ^{are} currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention ~~efforts~~ ^{support} are ~~funded~~ ^{provided} 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 ^{are} reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV-prevention responsibility^{ies}, 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. The National Institutes of Health (NIH) supports biomedical,

behavioral, and social science prevention research. The National Institute on Drug Abuse (NIDA, ^{a part of} NIH) 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 government-supported research conducted at universities and private organizations, have been instrumental in expanding our knowledge base about HIV prevention. However, significant ^{information} gaps remain. We know from both 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

*showing
of
4
R...*

ensure lasting behavior change.

Prevention priorities must be guided toward gaining knowledge that ~~will~~ improve our efforts to develop effective prevention programs.

decision in this program
We need to: improve our understanding about the major modes of transmission; close gaps in scientific knowledge, *which includes* including identifying effective prevention models and strategies; and work towards ~~eliminating~~ gaps in program areas.

Opportunities for Progress

Modes of Transmission

An important aspect of strengthening prevention activities is to have a clearer understanding of ~~who is being~~ *those who are* 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~~ *most of the* among people who engage in injection drug use, ~~which includes the sharing of drug paraphernalia, and/or having sex with an injecting drug user,~~ and their sexual partners, young and minority men ~~having sex with men, through heterosexual transmission~~ *who have* and perinatal transmission. Moreover, ~~the youth of our country~~ *young people* are becoming infected at an alarming rate; ~~50 percent of new~~ *add*

infections in the United States are ~~in~~^{among} persons under ~~25 years of~~^{age} age. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities ~~are~~^{are} also disproportionately represented among ~~new~~ HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. ~~Over~~^{More than} 50 percent of women with HIV/AIDS are African American or Hispanic. These trends in the epidemic must ~~be taken into consideration~~^{continue to be considered} when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies ~~includes~~^{is} supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic~~x~~ and assess the effectiveness of prevention interventions. Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, CDC's AIDS case and case death reporting system provides ~~useful~~^{important} 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. ~~While~~ ^{Suppose} effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV ^{prior to an AIDS diagnosis} ~~(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. ^{Confidentiality is a major concern.}

The CDC ^{recognizes} ~~has recognized~~ the value of this approach and has incorporated data collection design into its community planning process. ^{Still} ~~These~~ shifts in data needs ^{combined} ~~coupled~~ with fiscal ^{changes} ~~restrictions~~ may also require that ~~the~~ CDC reevaluate and reconfigure its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies¹³, ~~the~~ CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes; ~~and~~ ^{and} this work should continue. ^{There's a danger}

Prevention Research¹⁴

Factors that place individuals at risk for acquiring HIV infection

~~are~~ are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not ~~assume we~~ ^{must} 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. Many significant scientific questions exist in the field of HIV-related behavioral research. The three main areas ^{in our knowledge} where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research. Richard
Hays

Basic Behavioral Research. Information provided by ~~the conduct of~~ basic behavioral research should serve as ^a ~~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 ^{to} improve HIV prevention programs that are targeted to reach a ^{diverse population} ~~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, ^{great} further ^{understanding} elucidation of the mechanisms underlying addictive behavior ^{could} may assist in the development of new therapeutic approaches to addiction, ^{This} which may, in turn, reduce the number of new infections.¹⁵ ^{There is} 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~~ ^{that} approaches may be most effective for an individual or a community.¹⁶

Intervention Research. A second major gap ~~is~~ ^{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 ^{smoking} 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 ^{and to} ~~to~~ reducing unhealthy behaviors.

In HIV and AIDS, this intervention research can focus on both

individuals and communities, ^{social} ^{add new} 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 change~~x~~ in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.¹⁷ Studies have shown that community-based HIV risk reduction programs that are gender-relevant and culturally-sensitive can be effective.¹⁸ 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.¹⁹

^{Have indication}
However, despite ~~this evidence~~ of success, there is more that we need to know if we are to develop effective prevention programs, ~~for~~ ^{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^{is} change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior^{is} 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 fields will ~~invariably~~ improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research ^{use as a foundation for} ~~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.

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

=== Addendum for Prevention Section, Prevention Programs
subsection, beginning on p. 44 ===

Prisoners. Populations in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

*Confusing - 1st
sentence needs
more - 60
less*

Given that the incarcerated population is often at increased risk for HIV infection, offering educational programs during incarceration provides a unique opportunity to reach these persons. Research has shown that individuals who are well informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

condoms contraband -

behavioral change in someone not getting out?

"

"

when the choice not yours - rape in prison

Same info in p. 50-51

of substance(?)

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 cannot,} ~~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} ~~who is infected & who is becoming infected~~ local epidemiology.

Change language of sentence

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 ^{Public-Private} ~~federal-local~~ partnership. Through this effort, it ^{is} ~~is~~ possible to establish joint goals for the prevention of HIV that ^{are} ~~will~~ meet Federal standards while remaining responsive to local needs. However, this process is early in its development and ^{will} requires ^{continued} ~~significant~~, ~~ongoing~~ leadership and technical assistance from ~~the~~ CDC, ~~if it is to fulfill its potential for effective priority setting and decision making.~~

*add
Technical
assistance from CDCs*

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

First, we need to improve the integration of HIV prevention activities and substance abuse treatment and prevention programs. The epidemics of substance abuse and HIV in this country are overlapping and highly interrelated, however, care and prevention services for HIV and substance are not. It is vital to continue

add language

and strengthen efforts to integrate HIV prevention into current substance abuse programs and integrate substance abuse prevention into HIV prevention.

^{key to}
A ~~second avenue~~ for controlling the spread of HIV among substance abusers is enrollment into drug treatment programs. Substance abuse treatment is ^{major} a form of HIV prevention. Moreover, substance abuse problems that contribute to the spread of HIV are not limited to injecting drug use. There is also substantial evidence that use of non-injectable drugs such as alcohol and crack cocaine can adversely influence risk-taking behavior. SAMHSA supports the urgent need for the integration of substance abuse prevention and treatment and HIV prevention services for those who use drugs, however, SAMSHA recognizes that there is a "hardcore" segment of the population that refuses treatment and will not practice HIV prevention. The need to encourage prevention and treatment for this population is critical.

shading?
new language from SAMHSA

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 ^{sufficient} drug treatment services ~~are available in sufficient numbers~~ for a range of addictions 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~~ ^{these} issues has begun and will continue. ~~The~~ CDC has ~~an~~ initiated State-by-State discussion, including meetings with State Legislators and the National Conference of State Legislatures regarding HIV prevention issues. SAMHSA's new Knowledge Development Application ~~(KDA)~~ Program will address emerging issues in the fields of substance abuse and mental health, including a focus on HIV and AIDS. In addition, CDC, HRSA, NIDA, and SAMSHA are co-sponsoring a national meeting of State and local officials from the fields of public health and drug abuse prevention to develop an action plan that more effectively integrates HIV and substance abuse prevention efforts.

Treatment for Sexually Transmitted Diseases and Tuberculosis.

Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, ~~even~~ ^{twice} by as much as 20-fold. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.^{20,21} These data suggest treating STDs can be ^{a highly} ~~an~~ effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs. NIH-supported research to

further understanding of the effect of STD treatment on HIV transmission is underway and should continue.

HIV positive people are at very high ^{risk} for developing ^{of} ~~active~~ tuberculosis (TB) ^{who are} disease. People infected with both HIV and TB are more likely to develop ^{active} TB disease than people who ^{are} infected with only TB. Studies suggest that the risk of developing ^{active} 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.²² 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 ^{active} TB.

Further, there is strong evidence that the HIV epidemic has contributed to the increase in the number of ^{active} TB cases. Geographic areas that have been most affected by the HIV epidemic have also reported the largest increase in TB cases. Moreover, from 1985 to 1992, the largest increase in TB cases among people ages 25 to 44, the age group most affected by the HIV epidemic.²³

It is important that Federal and State efforts to reduce the incidence of sexually transmitted diseases (STDs) include an HIV

prevention element~~x~~ and~~x~~ 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~~x~~STD~~x~~and TB Prevention at CDC ~~reflects~~ the importance of integrating ~~these~~ ^{and} interdependent aspects of the epidemic and illustrates ~~our~~ ^{the} 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~~ ^{use} history when a medical history is taken, offering HIV-related counseling and

voluntary testing, and providing prevention education to HIV-positive individuals so they do not infect others is also important. It also means offering ^{all} pregnant women information about ^{← change} 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.

Prisoners. Populations in prisons are at high risk for both substance abuse and HIV disease. Moreover, there is often a high prevalence of both HIV and substance abuse behaviors in people entering prison.

^{the result,}
Given ~~that the~~ incarcerated population is often at increased risk ~~for HIV infection,~~ offering educational programs during incarceration provides a unique opportunity to reach these persons. Studies have found that programs using peer counselors have been effective in delivering HIV treatment and prevention messages.

Research has also shown that individuals who are well-informed about HIV and substance abuse issues do modify their risk-taking behaviors. It is important the Federal government build upon the knowledge and opportunity that currently exists and further improve HIV prevention efforts for incarcerated persons.

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 an 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 ^{biomedical} research in order to find treatments, ~~and~~ a cure for those currently infected, and a preventive vaccine to protect the uninfected.²⁴ 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 ^{these} ~~this~~ goal ^{continuing} ~~will~~ require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, ^{health care professionals} ~~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, ^{several} ~~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) ^{directs} ~~supports~~ the largest portion of these efforts, ^{NIH} ~~NIH~~ ^{Supports} ~~supports~~ HIV-related activities in the areas of natural history and epidemiology, etiology and pathogenesis, drug discovery and

therapeutics, vaccines, behavior and social sciences, and research training. ^{Dept} The Veterans Administration (VA) also supports a broad range ^{of} basic and applied research efforts. 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 ^{laboratory} facilities employing sophisticated methods for identifying viral variants, ^{among other activities,}

Contributions of Research

The Nation has already realized benefits of supporting research in general, and HIV-related research specifically. The effort to understand HIV and AIDS has led to, and will continue to result in, scientific ~~strides~~ that benefit research on many other diseases.

AIDS research has accelerated study of the human immune system. This basic immunologic information is being applied to research to better understand and treat many other diseases, such as cancer, and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and has ^{provided} ~~has provided~~ a new paradigm for treatment of viral diseases.

Advances made in the treatment and prevention of ^{HIV-related} the opportunistic infections ^{enormous} ~~that complicate HIV disease~~ have had an impact on the care of patients with other immunodeficiency states who are susceptible to many of the same pathogens. ^{the} ~~The~~ research effort has enhanced the care of cancer patients, patients who have received immunosuppressive therapy for transplants, ~~of~~ ^{the} the treatment of diseases caused by heightened immune responses. ^{change last part of sentence}

HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of the etiologic agent ^{of} ~~of~~ Kaposi's sarcoma. ^{These} Such approaches may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells cross the blood/brain barrier, providing valuable clues for research on Alzheimer's disease, dementia,

multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, prior to the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of ^{additional} ~~more~~ viral diseases and led to development of treatments, ~~for many~~ ~~other diseases~~.

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

Due in great part to Federally-sponsored research, a number of new and exciting research advances have brought optimism and opened new areas for investigation. Breakthroughs in our understanding of the genes and proteins of the human immunodeficiency virus have allowed the development of increasingly effective anti-retroviral drugs. One of the recent research advances has been the development of ^anew

class of drugs, ^{known as} protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream^X and ^{Possible} ~~possible~~ improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before, and ~~faster than any~~ ^{change position} ~~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, requires 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 ^{at this magnitude} requires ^{the} coordination efforts at two levels: ^{the} 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, evaluate, 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. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

It is crucial that the authority granted OAR in the revitalization legislation, including the consolidated appropriation, be supported and maintained. With such a large research enterprise involving almost every area of clinical medicine and scientific

investigation, 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.

Add language about the Levine Report? — *Yes*

~~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. ⁹ Multiple ~~Federal Departments and Agencies~~ have responded with research initiatives that bring to bear their unique capabilities and strengths.

Moreover, this research is often carried out collaboratively. For example, the CDC, FDA, DoD, and NIH hold monthly discussions on protecting the country's blood supply. The DoD and NIH collaborate in the conduct of clinical trials, and there exist strong linkages between basic and applied biomedical studies on HIV disease sponsored by the DoD, NIH, and VA. In addition, the CDC and VA jointly sponsor surveillance studies on the incidence of HIV-related opportunistic infections.

The National AIDS Strategy
Draft for ONAP Review, 7.22.96

For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy ^{created} coordinated an inter-departmental working group, chaired by the Director of the Office of AIDS Research, ~~whose charge~~ ^{with} ~~it was to~~ develop a coordinated plan and budget ~~specifically~~ for HIV and AIDS research across all Agencies, Departments.

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. 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 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.

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.

Microbicides. Many scientists believe that in the absence of a

vaccine, the development of a safe, effective, female-controlled mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. 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 STDs²⁵. An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

Condoms, 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 and transmitting 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 that can be employed by women is based on the prevalence of non-consensual sex, sex without condom use, and HIV risk behaviors that occur without partner knowledge.

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.

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^{ily} focused^{on} two specific populations, infants and adults.

^{There is, however,}
~~But~~ Scientific information ^{exists to indicate} ~~exists to indicate~~ that HIV may behave differently in infected adolescents. 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; ^{therefore,} 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~~ ^{be more significantly} the research process.

~~The~~ NIH and the Food and Drug Administration ^(FDA) 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 ^a need for adolescent-relevant information ~~on the part~~ ^{for} of clinicians and researchers. The Adolescent Medicine HIV/AIDS Research Network, cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA) serves as an important model of collaboration in this area of research. ^{This} ~~The~~ network has been developed to improve our understanding of disease and health in adolescents. ^{Several} ~~Several~~ PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. 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 program²⁶, 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 long-term clinical effectiveness are 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.

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.

Public-Private Partnerships. ~~As has been noted previously,~~ ^{to more specifically,} ~~i.e.,~~ ^{areas} 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, 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.

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 ^{Dept} ~~Veteran's Administration~~ ^{Office} 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 ^{to include} ~~the~~ NIH, studies of alternative therapies have been conducted, ~~These are~~ important efforts ~~that~~ should continue.

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

Research: An Investment for the Future. And finally, research is an

investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead 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 ^(DOD) Veteran's Administration ^{Admiral} also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue ^{to make} this investment.

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. ~~Achieving the goal of~~ Ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance ^{including} among the Federal government, States, the private sector, local communities, community-based organizations, clinics, families, and individuals.

Background

^{People} Persons living with HIV finance ^{needed} health care services ⁱⁿ through a variety of ^{ways} mechanisms. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net. *Statistics must be correct*

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community that have admirably

served those living with HIV. Taken together, these efforts form a valuable, if incomplete, safety net for some of the most vulnerable people in our Nation.

After Medicaid, the centerpiece of ^{the national} ~~this~~ safety net ^{consists of} ~~is~~ programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). ^{The CARE Act programs were} ~~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 ^{of} reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

Other sources of primary care supported by the Federal government include the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service ^(IHS) ~~AIDS~~ which provides health care for HIV-^{Positive} infected Native Americans and Alaska Natives. Additionally, the Bureau of Prisons within the Department of Justice provides care for HIV-positive ^{People} ~~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. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that ^{People} ~~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 90 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 ^{people} ~~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 ^{more} ~~most~~ powerful methods of recruiting people into primary care is knowledge of serostatus ^{HIV} ~~persons~~ ^{since people} who know they are HIV-positive are more likely to seek health care. Counseling and testing services can serve as a gateway to ^{accessing} ~~this~~ care. 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 ^{people} ~~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.

Against a backdrop of prevention,
~~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~~ *people* 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~~ *people* living with HIV and ~~AIDS~~ will become homeless or are at risk for becoming homeless during the course of their illness.²⁷

People
~~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.

Housing assistance 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.

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. The program is representative of HUD's "Continuum of Care" approach to building local systems ^{that} to address homelessness. ^{significantly that the} Moreover, ~~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.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. 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 ^{upon} ~~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 to 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, ^{and} strengthening linkages between prisons and outside public health Departments and Agencies, ~~and~~ ^{Success at} ~~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 ^{HIV} care and services to have the most beneficial impact, they should be offered as part of a continuum of care. For organizations ~~on~~ ^{at} 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~~ ^{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.

the benefit of HIV-infected people

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,~~ ^{Still,} this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV-positive ~~persons~~ ^{people}. Achieving this goal, ^{goal,} will require the cooperation of Federal Agencies, States, professional organizations, professional and 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 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, ³⁰thirty to ⁴⁰forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.²⁸ 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.

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~~X~~ 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. 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).²⁹ 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. 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 "Lessons without Borders Project" initiative brings lessons learned abroad home to inner city and rural areas with problems similar to those experienced overseas. This initiative creates linkages between U.S. community organizations and international projects. 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, and U.S. based non-governmental organizations.

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.

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 must develop a mechanism for identifying and coordinating this effort.

TRANSLATION OF RESEARCH 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 the standard practice of clinicians, service providers, and health educators 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 worldwide audio tele-conferencing. NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE. In addition the toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS) is co-sponsored by NIH, CDC, and FDA. The Centers for Disease Control and Prevention (CDC) disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse.

The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example of these materials is 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 that responds to questions from clinicians across the country, and directs a nationwide system of AIDS Education and Training Centers that provide state of the art

Widows
orphans
on

HIV clinical information to health care providers.

Opportunities for Progress

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.³⁰ Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.³¹

We are also at a stage in the epidemic where research advances are coming frequently. In the case of the NIH study that demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard of care and action by a number of Federal Agencies. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this therapeutic regimen, a policy change on the part of the Health

6/90
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 for their patients. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients be provided in a timely manner.

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

Coordination of Federal Activities. Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy (OHAP) has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-

sponsored programs are modified to reflect the new standard, requires a continued high level of cooperation and coordination among Public Health Service Agencies.

Improved information dissemination efforts are also needed in the area of primary prevention models. As noted in the prevention section, 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 that 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 that services provided to persons living with HIV are 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, insurance, 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). 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. In addition, the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) is responsible for implementing portions of the ADA, including investigating and resolving Title II complaints of discrimination by health care and social service programs.

Federal Agencies and recipients of Federal funds are prohibited from discriminating against people with disabilities under Section 504 the Rehabilitation Act of 1973. The DHHS' Office of Civil Rights is also responsible for enforcing Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. 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 those against clinicians who have refused to care for HIV-positive 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.

Footnotes

1. *Morbidity and Mortality Weekly Report*. U.S. Department of Health and Human Services, Public Health Service. November 24, 1995, vol. 44, No. 46.
2. Communication, Department of Labor.
3. For 5 years of care after initial heart attack. Source: *American Journal of Cardiology*, 1990.
4. Depending on stage diagnosed -- early or late. Source: Swartz & Rollins, *Business and Health*, 1985, 85, 24-6.
5. *Journal of the American Medical Association*, July 28, 1993. Add page number/complete reference.
6. 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 (SAMHSA), 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.
8. Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341-348, July-August 1986.
9. Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988.
10. The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.

11. AIDS: An Expanding Tragedy. The Final Report of the National Commission on AIDS. Washington, DC. 1993.
12. 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.
13. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.
14. Information on NIH-supported behavioral and epidemiological research relevant to primary prevention can be found in Appendix B: Research.
15. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy Press, Washington, D.C., 1994. p.79.
16. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.
17. *AIDS and Behavior: An Integrated Approach*. Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.
18. JAMA article used in PRIM&R speech
19. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226-1231.
20. Heiner Grosskurth, Frankc Mosha, James Todd, Extra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Chagalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229
22. Personal communication from CDC Division TB Elimination.
23. Epidemiology of Tuberculosis, Self-Study Module on Tuberculosis, Module Number 2, Division of Tuberculosis, Nation Center for HIV, STD, and TB Prevention, the Centers for Disease Control and Prevention.
24. This section focus primarily on biomedical and health services research. Discussion of behavioral and social science research is presented in the Prevention section.
25. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.
26. 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.
27. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.
28. *HIV/AIDS Policy Guidance*. U.S. Agency for International Development. September 1995.
29. 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.
30. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramsey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. JAMA. 1995; 274:1380-1382.

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

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III. APPENDICES

DHHS Appendices:

The Administration for Children and Families (ACF)
The Agency for Health Care Policy and Research (AHCPR)
The Centers for Disease Control and Prevention (CDC)
The Food and Drug Administration (FDA)
The Health Care Financing Administration (HCFA)
The Health Resources and Services Administration (HRSA)
The Indian Health Service (IHS)
The National Institutes of Health (NIH)
The Office of International Affairs (OIA)
The Office of Population Affairs (OPA)
The Substance Abuse and Mental Health Services Administration (SAMSHA)

CARE AND SERVICES

Agency: Administration for Children and Families

Goal: To meet the social and support service needs of children, youth, and families with or at 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.

FY 97:

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

Constituency Involvement: A network of more than 500 grantees, both public and private.

Unmet Need: 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.

FY 97:

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

Constituency Involvement: National, professional, advocacy, and service organizations such

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as the Child Welfare League of America, American Public Welfare Association, National Association of Social Workers, and 56 State/Territorial grantees.

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

Objective 3: Support 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.

Descriptions: Abandoned Infants Assistance Program.

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

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

FY 97:

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, grantees, and national resource agencies.

Unmet Need: Resources to serve geographic areas of unmet needs.

Objective 4: The Head Start Program provides comprehensive child development 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.

FY 97:

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

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Constituency Involvement: National Head Start Association and related early childhood development organizations, such as National Association for the Education of Young Children.

Unmet Need: Increased resources will make services available to more children.

Objective 5: Support the independence, productivity, and integration into the community of persons with developmental disabilities.

Action Steps: Twenty-seven of the current 51 grantees operate 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.

FY 97:

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

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

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

RESEARCH

Agency: Agency for Health Care Policy and Research

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

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

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

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

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

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

Action Steps: This study will be the first to obtain a true national random sample of people with HIV infection receiving treatment. Approximately 3200 adult patients in urban and rural areas 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: \$4,000,000

FY 97:

Populations Served: HIV-infected individuals receiving treatment.

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

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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

FY 97:

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

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

Unmet Need: None.

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

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

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

Descriptions: Multicenter AIDS Cohort Study (MACS)

FY 95: \$65,000

FY 96: \$0

FY 97:

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

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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

FY97:

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.

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FY 95: \$394,557

FY 96: \$39,455

FY 97:

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

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

FY 95: \$392,103 (from FY94 funds).

FY 96: \$0

FY 97:

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: \$527,287

FY 96: \$420,000

FY 97:

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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.

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

FY 95: \$110,704 (from 1994 funds)

FY 96: \$0

FY 97:

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

FY 97:

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

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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 interviews with physicians, who are currently in their sixth post-graduate year.

Descriptions: Determinants of Physicians' AIDS-Related Practice Behavior

FY 95: \$216,054 (from 1994 funds)

FY 96: \$0

FY 97:

Populations Served: Persons with AIDS

Constituency Involvement: Physicians

Unmet Need: None.

Objective 11: Continuing work previously completed with AHCPR support, 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

FY 97:

Populations Served: 1300 patients receiving services in study hospitals.

Constituency Involvement: N/A

Unmet Need: None.

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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

FY 97:

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 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

FY 97:

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

FY 97:

Populations Served: Persons with HIV.

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Constituency Involvement: N/A

Unmet Need: None.

TRANSLATION OF RESEARCH 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 approved 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

FY 97:

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. Approximately 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)

FY 97:

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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: N/A

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

FY 97:

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 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

FY 97:

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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: N/A

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$141,076,000

FY 96: \$140,917,000

FY 97:

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

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

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

Descriptions: Many of the activities cited above are carried out at local demonstration sites and in coordination with community planning efforts. In addition, specialized projects and

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studies also serve to focus attention on these activities, these include projects entitled: National Health Communications, Prevention Collaborative Partners, the CDC National AIDS Clearinghouse, and the CDC National AIDS Hotline, and the Prevention Marketing Initiative.

Also, linkage efforts with business, labor, and community groups have received special attention. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs have focused on issues such as: HIV/AIDS workplace policies, supervisor and labor leader training, employee education, employee family education, and community service and volunteerism. Partnerships have also been forged among a variety of communities including business, labor, religious, voluntary and the media. And, national and regional minority organizations have also been sought out in forging these important linkages.

FY 95: \$45,970,000

FY 96: \$46,869,000

FY 97:

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

Conduct evaluations of the effectiveness of existing school-based interventions to reduce

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behaviors that result in HIV infection and related health problems;

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000

FY 97:

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

Constituency Involvement: Consultation with a wide range of constituency groups was established to: (1) improve existing programmatic efforts; (2) improve assistance and resources provided by CDC; and, (3) explore strategies that the Nation might take to improve the health status of young people. These groups include representatives from: (1) every state education agency and 18 local education agencies; (2) national nongovernmental health or education organizations, 3) colleges and universities, 4) state public health departments, as well as young people themselves. Meetings included an annual constituency meeting, quarterly training programs, and communication through an electronic bulletin board and network.

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

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

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

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of CDC staff to plan, administer, and evaluate behavioral change strategies and community-based interventions to provide public health leadership and assist our prevention partners in designing and managing effective strategies for HIV prevention programs;

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

FY 97:

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

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

Unmet Need: There is currently a lack of behavioral risk surveillance data for program planning and evaluation purposes. There is also a need to develop a more effective

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application of behavioral science findings to HIV prevention programs. And there is a special need to develop and maintain prevention efforts that target high risk women, youth and gay men of color.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets?

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

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

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

FY 97:

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

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

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

RESEARCH

Agency: Food and Drug Administration

Goal: Ensure the safety and effectiveness of HIV-related therapeutic agents.

Objective: Expedite access and approval of safe and effective drugs and biologics.

Action Steps: Encourage quality applications and data submissions to review division to ensure timely and efficient pre- and postmarket review.

Descriptions: Conduct meetings with sponsors to discuss drug development plans, expanded access programs, and accelerated approval options.

Facilitate scientific review of drugs and biologics by FDA advisory committees.

FY 95: \$25,235,000

FY 96: \$25,536,000

FY 97:

Populations Served: All persons who may benefit from approved therapeutic agents.

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

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

RESEARCH

Agency: Food and Drug Administration

Goal: Ensure the safety and effectiveness of HIV-related preventive and therapeutic vaccines.

Objective: Expedite regulatory review of promising products for preventive and therapeutic vaccines.

Action Steps: Expand partnership between FDA and its counterparts from outside organizations involved in vaccine development.

Descriptions: Encourage early consultation with sponsoring companies, develop guidance documents, exchange information, and work with other agencies and international organizations. Facilitate scientific review by FDA advisory committees.

FY 95: \$11,863,000

FY 96: \$12,005,000

FY 97:

Populations Served: All persons who may benefit from approved preventive and therapeutic vaccines.

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

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

RESEARCH

Agency: Food and Drug Administration

Goal: Ensure the effectiveness of test methodologies for HIV detection and measurement.

Objective: Expedite improved test methodologies (such as diagnostic reagents and test kits) for HIV detection, confirmation, and viral load measurement.

Action Steps: Ensure timely and efficient pre- and postmarket review.

Descriptions: Encourage early consultation with sponsor and develop guidance documents. Facilitate scientific review of drugs and biologics by FDA advisory committees.

FY 95: \$8,732,000

FY 96: \$8,836,000

FY 97:

Populations Served: All persons who may benefit from approved test methodologies for HIV detection and measurement.

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

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

PREVENTION

Agency: Food and Drug Administration

Goal: Reduce transfusion-transmitted HIV infection.

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

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

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

FY 95: \$17,458,000

FY 96: \$17,667,000

FY 97:

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

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

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

RESEARCH

Agency: Food and Drug Administration

Goal: Ensure the safety and effectiveness of HIV-related medical devices.

Objective: Expedited access and approval of safe and effective medical devices.

Action Steps: Encourage quality application and data submissions to ensure timely and efficient pre- and postmarket review.

Descriptions: Conduct meetings with sponsors on study design; produce guidance documents. Facilitate scientific review of drugs and biologics by FDA advisory committees.

FY 95: \$9,457,000

FY 96: \$9,570,000

FY 97:

Populations Served: All persons who may benefit from approved HIV-related medical devices.

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

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

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, FL, and NJ.

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

FY 95: \$50,000 (Federal share)

FY 96:

FY 97:

Populations Served: HIV positive women eligible for Medicaid coverage.

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

Unmet Need: The pilot project will not initially include women of unknown or negative HIV serostatus. This project should be extended nationwide.

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

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

Develop directives in implementation of developed guidelines.

FY 95: \$25,000 (Conferences and materials)

FY 96:

FY 97:

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

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

Unmet Need: Implementation of directives dependent on nature and resources of each project partner.

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)

FY 97:

Populations Served: HIV positive Medicaid-eligible persons.

Constituency Involvement: Information and activities routinely discussed with external groups at meetings and conferences.

Unmet Need: ????