

# FOIA MARKER

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

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| <b>OA/ID Number:</b> | 9005 |
| <b>FolderID:</b>     |      |

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**Folder Title:**  
Budget Numbers for Appendices [2]

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# Research

Commerce

Defense

Energy

HHS - AHCPR

FDA

NIH

Dept. Justice

Dept. of VA

Treasury

- spell checked

**Agency:** Department of Defense

**Goal:** Carry out state-of-the-art research on the prevention and treatment of HIV infection to promote medical readiness in U.S. military forces.

**Objective:** Support the development of a safe and effective HIV vaccine.

Support the development of new biochemical and genetic strategies to slow HIV disease progression

Support natural history studies for the purpose of evaluating the efficacy of intervention strategies.

**Action Steps:** Define the global molecular epidemiology of HIV to assist with candidate vaccine selection;

Explore novel vaccine technologies;

Conduct vaccine trials in endemic areas;

Assess the immune response and efficacy of vaccine candidates;

Evaluate potential therapies for treatment of HIV infection and potential for immune reconstitution;

Evaluate prevalence of drug resistance, develop rapid genetic assay for resistant mutants, and methods for genetic targeting of novel therapies *in vivo*;

Participate in national surveillance of AZT resistance;

Develop a comprehensive panel of immunologic, virologic, and functional parameters for management of HIV infection; and

Support natural history studies and specimen repositories.

**Descriptions:** Vaccine, therapeutic, and epidemiological research, including vaccine design, development and testing in the U.S. and overseas locations; epidemiologic studies of vaccine field studies; and reduction or conclusion of drug treatment and behavior studies.

**FY 95:** \$37,000,000

**FY 96:** \$26,600,000

**FY 97:** \$9,611,000

**Populations Served:** Active duty personnel.

**Constituency Involvement:** Clinicians, researchers, and active duty personnel.

**Unmet Need:** Increased resources would permit more aggressive research on promising therapies and vaccine candidates.

**Agency:** Department of Health and Human Services, the 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:** \$4,150,657

**FY 96:** \$3,468,114

**FY 97:** \$3,131,582

**Populations Served:** HIV-infected individuals receiving treatment.

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

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

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

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

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

**Descriptions:** Women's Interagency HIV Study (WIHS)

**FY 95:** \$60,000

**FY 96:** \$0

**FY 97:** \$0

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

**Constituency Involvement:** A broad representation of researchers and patient advocates had input in the development of the 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:** \$0

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

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

**Unmet Need:** None

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

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

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

**Descriptions:** HIV Epidemiological Research Study (HERS)

**FY 95:** \$50,000

**FY 96:** \$50,000

**FY 97:** \$50,000

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

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

**Unmet Need:** None.

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

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

To examine any substitutions of formal for informal home care.

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

Abstract data from Medicaid claims.

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

**FY 95:** \$295,918

**FY 96:** \$39,456

**FY 97:** \$0

**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:** \$0  
**FY 96:** \$0  
**FY 97:** \$0

**Populations Served:** New York State Medicaid recipients.

**Constituency Involvement:** N/A

**Unmet Need:** None.

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

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

**Descriptions:** Outcomes of Pharmaceutical Therapy in HIV Disease.

**FY 95:** \$527,497  
**FY 96:** \$479,952  
**FY 97:** \$505,000

**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:** \$0  
**FY 96:** \$0  
**FY 97:** \$0

**Populations Served:** New Jersey Medicaid recipients.

**Constituency Involvement:** N/A

**Unmet Need:** None.

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

**Action Steps:** Formulate statistical models and associated computer software.

**Descriptions:** Developing Econometric Models to Estimate AIDS Costs.

**FY 95:** \$248,126

**FY 96:** \$8,003

**FY 97:** \$0

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

**Constituency Involvement:** N/A

**Unmet Need:** None.

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

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

**Descriptions:** Determinants of Physicians' AIDS-Related Practice Behavior

**FY 95:** \$0

**FY 96:** \$0

**FY 97:** \$0

**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:** \$214,708

**FY 97:** \$0

**Populations Served:** 1300 patients receiving services in study hospitals.

**Constituency Involvement:** N/A

**Unmet Need:** None.

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

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

**Descriptions: Hospital Cost and Utilization Project**

**FY 95:** \$500,000

**FY 96:** \$0

**FY 97:** \$500,000

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

**Constituency Involvement:** N/A

**Unmet Need:** None.

**Agency:** Department of Health and Human Services, the 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:** \$11,863,000

**FY 97:** \$11,863,000

**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.

**Agency:** Department of Health and Human Services, the 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:** \$8,732,000

**FY 97:** \$8,732,000

**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.

**Agency:** Department of Health and Human Services, the 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:** \$9,457,000

**FY 97:** \$9,457,000

**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.

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

**Goal:** To support natural history and epidemiological research to improve the understanding of HIV transmission, disease progression, and the risk factors associated with HIV infection and AIDS.

**Objective 1:** Develop and assess intervention strategies to reduce or prevent HIV transmission in both domestic and international settings.

**Action Steps:** Develop and maintain the infrastructures to define populations in the United States and throughout the world with incidence and prevalence suitable for vaccine and other intervention trials (e.g. microbicides, barriers, treatment, behavioral) for preventing HIV transmission.

Support development and evaluation of improved, acceptable, effective physical and chemical barrier methods and conduct research on existing barrier methods to prevent sexual transmission of HIV and STDs.

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

Develop and assess the efficacy of strategies that may decrease transmission of HIV among drug users.

Develop and evaluate biological and behavioral interventions to control STDs as cofactors in HIV transmission.

Develop strategies that enhance safe sex behaviors and provide information on safe and effective contraceptive choices for at-risk women.

Develop methods to prevent infection in hard-to-reach gay male populations such as young, substance-using, and minority gay and bisexual men.

Develop methods of accessing hard-to-reach populations to identify factors that contribute to recruitment (and retention) into prevention and intervention activities.

Evaluate access to, acceptability of, and compliance with interventions such as AZT for perinatal transmission, condoms, and virucides.

Evaluate improved procedures for screening, monitoring, and inactivating HIV and other retroviruses in the blood supply; and develop and evaluate alternatives to blood transfusion.

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

Develop effective drug treatment strategies for addiction, particularly focused on heroin and cocaine use.

**Description:** The development of biologically based interventions to interrupt transmission is an essential component of a comprehensive HIV prevention strategy that also includes behavioral intervention strategies as well as efforts to develop a vaccine(s). International studies should be supported with the goal of developing prevention strategies that can be used to reduce HIV transmission in the United States. Research is ongoing in these areas.

Epidemiologic studies, including vaccine preparedness research, provide opportunities for intervention research in defined cohorts of well-characterized populations. Strategies that employ therapies, devices, and other approaches, such as needle/syringe exchange programs using HIV seroconversion end points, are useful approaches for providing epidemiologic causation and evaluating effectiveness in preventing or reducing HIV transmission.

In addition, despite the fact that the blood supply in the United States is safer than it has ever been, it is important to develop even better methods for maintaining and improving its safety.

**Objective 2:** Characterize the risk factors and mechanisms of HIV transmission in both domestic and international populations, with the goal of preventing transmission.

**Action Steps:** Evaluate HIV transmission in relationship to: viral factors such as virus load in the blood and at mucosal sites, characteristics of HIV (genotype and phenotype), and pre-existing infection with other agents; host factors such as contraceptives, pregnancy, menstrual cycle, substance abuse, and nutritional, immunologic and genetic determinants; local factors including intercurrent STDs, exogenous irritants, oral and anogenital inflammation, mucosal immunity, circumcision and cervical ecotopy.

Further define the timing and mechanisms and risk factors in perinatal transmission, including breast-feeding.

Study mechanisms of resistance to HIV infection in persons who remain uninfected despite perinatal, sexual or parental exposure.

Define the determinants of high-risk behavior for transmission through drug use and sexual practices.

Characterize the dynamics of HIV transmission in epidemiologic studies of at-risk groups, including evaluation of sexual and drug-using networks, social and geographic mixing patterns, and turnover rates of at-risk populations.

Characterize the transmission and host immune responses of related retroviruses.

**Description:** Understanding the role of risk factors and mechanisms of HIV transmission is critical to the development of biologically and behaviorally based strategies to interrupt transmission of HIV. Epidemiologic studies provide important biological and behavioral

information including the role of cofactors that may reduce or enhance transmissibility.

**Objective 3:** Elucidate the progression of HIV infection, from its earliest stages through long-term sequelae, with the goal of understanding, preventing, and treating those factors.

**Action Steps:** Use epidemiologic studies to identify pathogenic mechanisms and cofactors for disease progression and disease-specific outcomes in well-defined subsets of individuals, individuals, including those with different rates of progression.

Conduct epidemiologic studies to understand the initiation and progression of early HIV infection, according to route of exposure, viral dose, viral genotype and phenotype, and host response, and how these early events influence disease progression.

Use epidemiologic studies to investigate the influence of viral genotype and phenotype on transmission efficacy and disease progression.

Use epidemiologic studies to evaluate the extent of dissemination of drug-resistant strains of HIV and its impact on pathogenesis.

Study the natural history of related retroviruses to elucidate retroviral pathogenesis.

Elucidate the mechanisms of HIV-associated carcinogenesis to improve strategies for early diagnosis and intervention.

Study HIV-infected children to determine: (1) mechanisms that contribute to impaired growth and neurodevelopment; (2) impact on childhood infectious diseases and the safety and efficacy of immunization; (3) impact on childhood psychosocial development, and (4) childhood-specific complications.

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

Study the progression of HIV-related disease in adolescents who have acquired their diseases as a result of drug use and/or sexual activity.

Study the natural history of HIV infection in the nervous system, including cognitive impairment, dementia, and neuropathy.

Describe the full spectrum of HIV-related diseases in HIV-infected populations.

Maintain and effectively utilize national specimen repositories for HIV-related studies.

**Description:** Epidemiologic studies provide a critical knowledge and resource base for more basic investigations of HIV pathogenesis. A better understanding of the diversity of HIV-related disease outcomes, cofactors for progression, and predictors of disease progression will be important in furthering attempts to develop HIV vaccines and more effective

therapeutic interventions against HIV and its sequelae.

**Objective 4:** Undertake epidemiologic research to reduce or prevent the occurrence of opportunistic illness in HIV-infected persons.

**Action Steps:** Study the impact of HIV infection on the emergence of new human pathogens and the impact of HIV infection on the reemergence of infectious diseases domestically and internationally.

Identify risk factors for the acquisition of opportunistic pathogens.

Study the determinants of the continuing occurrence of preventable opportunistic illnesses.

Study the role of transmissible and other preventable exposures in the etiology of AIDS-associated cancers and other outcomes.

**Description:** Most morbidity and mortality in HIV-infected persons result from the occurrence of opportunistic illnesses, including both infections and malignancies. Strategies to prevent these illnesses include prevention of exposure to the etiologic agents, prevention of disease in those who are exposed, and prevention of disease recurrence. Additional epidemiologic data are needed to design more effective strategies to prevent the occurrence of these opportunistic illnesses.

**Objective 5:** Develop and evaluate new laboratory assays, behavioral methods, and statistical techniques for epidemiologic studies.

**Action Steps:** Promote development and evaluation of virologic and immunologic assays to elucidate mechanisms of HIV transmission and disease.

Develop new survey and interview techniques to better measure HIV risk behaviors.

Develop new biostatistical techniques, including mathematical models, to better characterize transmission dynamics and disease progression.

Develop innovative approaches for record linkages to study HIV-associated diseases and mortality.

Characterize the epidemiologic features of emerging HIV variants, including drug-resistant strains, diverse genotypes, and newly recognized geographic distribution.

**Description:** Epidemiologically defined populations contain well-characterized cohorts that can provide insights into HIV transmission, including resistance and susceptibility to infection and infectiousness, and into progression of HIV-related disease, from early infection through long-term sequelae, including cancer and neurocognitive impairment. The application of innovative biomedical research and behavioral strategies to such populations will greatly increase understanding at the biological level and will help to identify strategies for

prevention of transmission and for clinical management of patients.

**FY 95:** \$192,624,000

**FY 96:** \$205,812,000

**FY 97:** \$203,285,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$33,986,000 over the FY 97 figure.

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

**Goal:** To support etiology and pathogenesis research to improve the understanding of the causes and progression of HIV disease.

**Objective 1:** Delineate the cellular and molecular mechanisms associated with the viral immunopathogenesis of HIV-related immune dysfunction.

**Action Steps:** Delineate the direct and indirect mechanisms underlying HIV-induced depletion and dysfunction of target cells/tissues.

Define the virologic (load, phenotype, and genotype), immunologic (specific and nonspecific), pharmacologic, and environmental factors that contribute to disease progression and non progression.

Delineate the mechanisms of virally triggered immunopathogenesis, including immune activation, induction of nonresponsiveness, and production of host factors, including cytokines, in pathogenesis.

Delineate the molecular mechanisms by which virus-encoded genes, gene products, and cellular factors regulate HIV replication and influence pathogenesis, with special emphasis on the use of primary virus isolates and cells.

Delineate the mechanisms of host genetic factors that mediate resistance or sensitivity to infection and influence disease progression.

Delineate the physiology and HIV-related pathophysiology of primary and secondary lymphoid organs, including hematopoietic precursor cells and their microenvironment.

Study the mechanisms of HIV infection that uniquely influence the developing immune system.

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

Establish and expand programs to facilitate access to and sharing of key patient samples, animal model resources, laboratory reagents, information databases, and quantitative virologic and immunologic assays.

**Description:** Basic scientific information regarding the cellular and molecular mechanisms that underlie HIV-related immune dysfunction and viral pathogenesis is critical to all areas of AIDS research.

**Objective 2:** Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression.

**Action Steps:** Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection.

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

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

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

Determine the role of viral phenotype/genotype and load on transmission of cell-free and cell-associated virus.

Elucidate unique aspects of HIV transmission and disease progression in under-researched populations.

Determine the mechanisms of vertical HIV transmission.

**Description:** The mechanisms of HIV transmission and the early events in the establishment of infection, and their relationship to disease progression, need to be better understood.

**Objective 3:** Elucidate the etiologic factors and cofactors in the pathogenesis of AIDS-associated disease states. Enhance a bidirectional flow between basic and clinical observations and intervention programs on HIV-related complications and foster interdisciplinary collaborations.

**Description:** Knowledge of AIDS-associated disease pathogenesis is urgently needed.

**Sub-Objective 3a:** Elucidate the etiologic factors, cofactors, and mechanisms in the pathogenesis of HIV-related malignancies.

**Description:** Knowledge about the origins and pathogenesis of HIV-related cancers is urgently needed.

**Action Steps:** Elucidate the role of HIV infection, immune dysfunction, and interactions with potential cofactors in the development of HIV-associated malignancies.

Identify the characteristics of the host that predispose to development of malignant disease, including genetic, hormonal, and growth factors and immunologic characteristics.

Identify the pathogenic contributions of oncogenes, suppressor genes, carcinogens, and non-HIV viral and other microbial genes and proteins to HIV-associated malignancies; correlate these molecular factors with epidemiologic studies.

Establish and expand programs to facilitate development and sharing of *in vivo* animal models and patient specimens for HIV-associated malignancies.

**Sub-objective 3b:** Elucidate the pathogenic mechanisms involved in HIV-associated neurological disease and neurobehavioral dysfunction.

**Description:** The damage that leads to both central and peripheral nervous system dysfunction must be better understood through studies of HIV-associated neuropathogenesis.

**Action Steps:** Investigate the characteristics of lentiviruses that invade the nervous system and the mechanisms by which these viruses cause nervous system impairment.

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

Employ animal models of CNS-lentivirus infection that are crucial to understanding neuropathophysiology.

Delineate the role of OIs and drug treatment in neurologic complications of AIDS, including CNS dysfunction and peripheral neuropathies.

Investigate biological and environmental factors that may affect nervous system function in the context of HIV-1 infection, emphasizing the role of psychoactive drug use.

Study mechanisms of HIV infection that uniquely influence the developing nervous system.

Develop technologies for correlative structural-functional analysis of progressive HIV-associated neurological and behavioral disorders and the progression of CNS disease.

**Sub-objective:** Elucidate the pathogenic mechanisms of HIV-related opportunistic infections.

**Description:** It is critical to understand the pathogenic mechanisms responsible for the development of HIV-associated OIs.

**Actions Steps:** Elucidate the mechanisms of immune function that mediate protection against OIs.

Study the effects of OIs on immune dysfunction and HIV disease progression.

Conduct studies of the basic biology and pathogenic mechanisms of opportunistic pathogens and their interactions with the host.

Develop *in vitro* techniques and animal models to propagate the opportunistic pathogens associated with HIV disease.

Develop and validate diagnostic assays for the reliable and rapid identification of HIV-

associated OIs.

Identify biologic markers that are correlative for susceptibility and disease progression for HIV-associated OIs.

Identify and elucidate the genetic and environmental risk factors associated with susceptibility to and development and progression of OIs.

**Sub-objective 3c:** Elucidate the etiology and pathogenesis of HIV-related disorders: gastrointestinal, renal, endocrine, cardiovascular, cutaneous, hematologic, oral, pulmonary, and other diseases.

**Description:** It is critical to understand various other organ/tissue-specific complications of HIV infection.

**Action Steps:** Investigate the etiologic and pathogenic mechanisms of HIV-associated gastrointestinal disease.

Identify the etiologic and pathogenic mechanisms of HIV-associated nephropathy.

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

Elucidate the etiology and pathogenesis of HIV-related autoimmune disorders and cardiovascular, cutaneous, hematologic, oral, pulmonary, and other organ/tissue-specific disorders.

**FY 95:** \$344,303,000

**FY 96:** \$382,903,000

**FY 97:** \$400,182,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$20,801,000 over the FY 97 figure.

**Agency:** Department of Health and Human services, the National Institutes of Health

**Goal:** To support preclinical and clinical research for the purpose of developing new therapies and improving treatments for HIV infection, HIV-associated conditions, and HIV prevention.

**Objective 1:** Improve understanding of the structure and function of molecular targets in order to develop improved assays for such targets; conduct screening, discovery, and preclinical development of novel anti-HIV agents and strategies (such as gene transfer technology and interruption of transmission) directed to the virus and/or host cell; and foster activity by and in collaboration with industry.

**Description:** Identify and develop novel anti-HIV therapies, particularly those therapies that impact at different stages of the life cycle of the virus.

**Action Steps:** Identify and characterize promising targets for anti-HIV therapy and extend knowledge of their mechanisms of action, develop relevant assays for identifying drugs active against those targets, and develop new compounds active at those targets, with emphasis placed on identifying agents active at novel targets other than reverse transcriptase inhibitors; emphasize agents that can effectively cross the blood-brain barrier.

Complete preclinical development, in cooperation with industry when appropriate, of promising new compounds and combinations of compounds and novel natural products, including assessment of toxicity, immunologic effects, pharmacokinetics, teratogenicity, and fertility in animal models and development of analytical method and chemical formulations.

Continue and accelerate domestic and international collection screening of large numbers of natural and synthesized compounds for anti-HIV activity in the AIDS Drug Screen, with a particular emphasis on the detection of agents that act at unique steps of the HIV life cycle with the intent of identifying lead compounds that can be modified for increased potency and other attributes (such as bioavailability and central nervous system penetration); develop and screen combinatorial libraries.

Emphasize basic and applied research to advance cross-NIH development of gene therapy; support development of preclinical laboratories to advance gene therapies; advance gene therapies, including new strategies for streamlining or eliminating ex vivo manipulation of cells; develop more efficient and safe viral and nonviral gene delivery vectors; target tissue cells and subcellular compartments; develop effective antiviral genes; standardize evaluation of different gene therapies singly and in combination; and develop suitable lentivirus animal models for in vivo efficacy and safety studies.

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

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

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

Develop formulations that would be suitable for infants and children for both existing and experimental agents.

Evaluate transplacental passage of antiretroviral and other agents as well as the effects of these drugs on placental function and on the embryo/fetus in animal models.

**Objective 2:** Conduct clinical trials and develop new trial methodologies for the treatment of HIV infection. Trials should be designed in order to rapidly develop new therapeutic strategies, optimize clinical efficacy and proper use of available modalities, define factors that affect the success of therapeutic strategies (including the role of resistance), and advance our understanding of disease pathogenesis and progression.

**Description:** Trials to evaluate new antiretroviral therapies alone and in combination will provide important information regarding resistance and synergistic effects of drugs that may eventually prolong the disease-free state and survival in HIV-infected individuals.

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

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

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

Increase the understanding of the pathogenesis of HIV disease based on the evaluation of antiretroviral agents in clinical trials; establish effective mechanisms to evaluate therapeutic interventions and elucidate the pathogenesis of acute/early HIV infection.

Foster collaboration and better interactions with industry in drug development and evaluation efforts.

Evaluate safety, toxicity, and pharmacokinetics of retroviral agents provided to pregnant women, including transplacental passage of the agent, safety to the fetus/infant, and pharmacokinetics of drug elimination in the newborn. (Also noteworthy, assess the potential efficacy and feasibility of obstetric interventions to prevent vertical transmissions, such as cesarean deliveries and other aspects of intrapartum care.)

Enhance utilization of GCRCs for the conduct of single and multi-institutional clinical trials.

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

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

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

Coordinate studies to encourage co-enrollment of patients on all trials where appropriate (co-enrollment would not only allow for better utilization of limited resources but also enable assessment of concomitant medications and their interactions, improving the efficiency of the primary study).

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

Support clinical trials to evaluate the safety and pharmacokinetics of existing and experimental agents for use in treating HIV-infected infants and children; evaluate the effects of puberty on the pharmacokinetics of antiretroviral agents and other drugs for the treatment/prophylaxis of HIV infection and the pharmacokinetics of drugs in adolescents.

Evaluate potential late toxic effects of antiretroviral therapy given to infants and children.

**Objective 3:** Develop and evaluate strategies that will enhance, restore, and/or maintain the immune systems of HIV-infected individuals and extend our understanding of immunopathogenesis.

**Description:** Essential to HIV research efforts are studies directed toward finding therapies that can restore, enhance, or maintain the integrity of the immune system.

**Action Steps:** Evaluate therapeutic approaches that test specific hypotheses of HIV immunopathogenesis,

Develop and validate new methods for evaluating immune function in the context of clinical trials.

Continue and accelerate the testing of cytokines, modulators of cytokines, and other immunomodulating agents either singly or in combination with antiretroviral agents for the purpose of reconstituting the deficient immune systems of HIV-infected individuals.

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

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

Develop new therapeutic strategies based on gene therapy approaches to protect hematopoietic stem cells and thereby reconstitute the immune system with HIV-resistant lymphoid, monocytic and other cellular compartments.

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

Increase collaboration of ICDs by joint funding of projects to facilitate the conduct of immune-based therapeutic trials and to enhance pathogenesis-related research in HIV-infected individuals.

Foster collaboration and better interactions with industry in developing and evaluating immunorestorative/immune-enhancing agents.

Define the mechanisms of immunomodulating agents and proceed with preclinical studies of the most promising agents.

**Objective 4:** Discover, develop, and evaluate potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection.

**Description:** Opportunistic infections (OIs) are the most common cause of morbidity and mortality in HIV-infected individuals. Continuing to develop and evaluate therapies for preventing and treating OIs is essential for decreasing morbidity and improving survival.

**Action Steps:** Support basic research on OIs in order to increase fundamental knowledge and to identify new therapeutic targets and strategies and understand how pathogens contribute to morbidity. Determine the high resolution molecular structures for OI proteins and apply these structures to the rational design of drugs as part of the targeted drug development program and determine generalizable and effective approaches for the use of macromolecular structure in designing drugs to combat OIs associated with AIDS.

Support discovery and preclinical programs to develop therapies especially targeting cryptosporidia, microsporidia, JC virus, HPV, and azole-resistant fungal organisms, with emphasis on bioavailable agents with favorable pharmacokinetics. Develop *in vitro* culture systems for OIs such as *Pneumocystis carinii* (PCP).

Further conduct clinical trials for the prophylaxis and treatment of HIV-associated OIs in HIV-infected individuals. Important OIs include *Mycobacterium tuberculosis* infection (TB), *Mycobacterium avium* complex, cytomegalovirus infection, cryptosporidiosis, microsporidiosis, cryptococcal disease, azole-resistant fungal infection, toxoplasmosis, PCP, acyclovir-resistant herpes infections, progressive multifocal leukoencephalopathy (PML), bacterial infections, and other infections whose course is affected by HIV. Evaluate immune-based therapies as adjuncts for treating OIs.

Determine the optimal strategies and combinations of agents to prevent and treat multiple OIs (by simultaneous prophylaxis of multiple opportunistic pathogens) and determine their effects in combination with antiretroviral agents. Strategies need to focus on the subgroups at increased risk, time of initiation, compliance, pharmacologic interactions, toxicities and adverse reactions (e.g. trimethoprim sulfamethoxazole reactions), and minimizing development of resistance; studies should include quality-of-life assessments and cost-benefit analyses.

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

Develop clinically useful assays for the rapid diagnosis of disease, treatment response, and sensitivity testing of OIs, especially TB, MAI, enterics, and infections produced by CMV, fungi, Toxoplasma, and JC virus, including use of specimens in existing repositories.

Determine the role and capability of preexisting immunity (both induced and natural) to control OIs and the ability of HIV-infected individuals to respond to vaccination throughout the course of infection and disease; assess possible interaction of vaccination and HIV replication.

Explore the bidirectional interactions between OIs and HIV infection including possible impact of opportunistic pathogens on the clinical expression and acceleration of HIV disease and vice versa.

Support clinical trials to evaluate the safety and pharmacokinetics of existing and experimental agents for use in preventing and treating OIs in HIV-infected infants, children, and pregnant women.

**Objective 5:** Develop, evaluate, and implement strategies for interrupting vertical transmission of HIV from mother to child and extend out understanding of perinatal transmission and the pathogenesis of early infection (treatment of children will be addressed in other objectives).

**Description:** Vertical transmission of HIV from mother to child is the predominant mode of transmission for pediatric HIV infection. The identification, development, and testing of interventions should be based on the pathogenesis of transmission.

**Action Steps:** Support the rapid translation of basic research observations to strategies for the interruption of vertical transmission; apply the results of clinical trials to the investigation of pathogenesis and to clinical practice.

Support national and international collaborative studies to retrospectively and prospectively evaluate potential obstetric factors associated with vertical transmission including non-protocol use of antiretroviral agents.

Develop and evaluate strategies for interrupting the vertical transmission of HIV from pregnant women to their offspring that are simpler and less costly than the current AZT regimen and derive information on pathogenesis of transmission from the study of these strategies. Such strategies include antiviral agents, anti-HIV immunoglobulin, monoclonal antibodies, vitamin supplementation (e.g. vitamin A), HIV vaccines, adjuvants, virucides, and other intrapartum interventions alone and in combination.

Evaluate the safety, toxicity, pharmacokinetics, and antiretroviral activity of anti-HIV agents in pregnant women and newborns; explore the use of highly active agents that may develop resistance rapidly and could be used in this setting.

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

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

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

Expand the obstetrical and pediatric infrastructure for the conduct of perinatal trials through collaborative efforts, particularly in the international setting.

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

Evaluate the risk of vertical transmission of drug-resistant virus.

Evaluate incorporation of ACTG 076 AZT regimen into clinical practice in the United States.

Evaluate therapeutic strategies for treating infants during acquisition of HIV to determine whether disease progression can be significantly altered.

**Objective 6:** Discover, develop, and evaluate improved strategies for the treatment and

prevention of HIV-associated malignancies and extend our understanding of the risk factors for and pathogenesis of such malignancies.

**Description:** HIV-associated malignancies have a significant impact on morbidity and mortality, and some are expected to become increasingly common as survival with severe immune dysfunction is prolonged and as the demographics of HIV infection change. The development of methods to identify persons at high risk for subsequent malignancy, and the identification, development, and clinical testing of new therapeutic strategies for these malignancies are essential.

**Action Steps:** Support basic research on HIV-associated malignancies to increase fundamental knowledge of the etiology, pathogenesis, and biology of these neoplasms; develop preclinical models for testing potential therapeutic strategies.

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

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

Develop *in vivo* models (SCID/nude mouse) for pathogenesis and drug sensitivity testing.

Develop *in vitro* models of KS as well as assays for angiogenesis inhibitors.

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

Continue and expand screening, discovery and development of novel therapeutic agents with activity against HIV-associated malignancies (e.g. agents with better CNS penetration, agents with better safety profiles).

Develop trials to optimize existing therapies for malignancies in HIV-infected patients, including therapeutic adjuncts such as hematopoietic colony-stimulating factors and supportive care; develop and validate quality-of-life assessments.

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

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

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

Foster prompt referral of patients (co-registration) from antiretroviral trials to trials for AIDS-related malignancies.

**Objective 7:** Develop strategies for assessing, preventing, and treating central and peripheral nervous system dysfunction in the course of HIV infection.

**Description:** Nervous system impairment, including AIDS-related cognitive/motor dysfunction (formerly AIDS dementia complex), and peripheral nerve/spinal cord dysfunction are serious sequelae of HIV disease.

**Action Steps:** Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction, e.g inhibitors of quinolinic acid, excitatory neurotransmitters, gp160/120, and other potential neurotoxins.

Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop strategies directed at the prevention and treatment of this complication of HIV infection; utilize insights from the impaired state to better understand the course of normal neurocognitive development.

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

Develop therapeutic agents and/or delivery systems that are capable of crossing the blood-brain barrier and develop carriers that capitalize on different mechanisms to deliver drug to the CNS and are active against HIV infection; assess the safety of these different preparations; develop an understanding of physical and physiological mechanisms involved in penetration of the blood-brain barrier, and possibly develop agents that could conceivably block HIV entry into the CNS.

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

Develop and utilize *in vitro* and animal models of CNS impairment and AIDS-related cognitive/motor dysfunction to further identify agents that can reverse HIV neuropathogenesis.

Implement assessments and approaches for the diagnosis of HIV-related dementia in clinical studies; improve implementation of standardized adult, adolescent, and pediatric neuropsychologic and neurologic assessment batteries in clinical studies and evaluate

treatment-induced changes in neurocognitive impairment in a linguistically and culturally sensitive context.

Develop alternative methods for detecting and assessing response to treatment of central and peripheral nervous system dysfunction including brain structural, spectroscopic, and functional imaging (for dementia); develop quantitative summary testing and examination of cutaneous nerve fibers in neuropathy.

**Objective 8:** Develop and evaluate therapies for the treatment and prevention of serious HIV-associated complications, especially

wasting syndrome and growth failure, as well as other disorders including hematologic, dermatologic, renal, metabolic, pulmonary, and oral manifestations.

**Description:** Important clinical sequelae of HIV infection include wasting syndrome, growth failure, metabolic disorders, dermatologic disorders, ITP, nephropathy, oral diseases, and other symptoms and serious complications. Drugs and strategies that can treat these sequelae are needed to ameliorate these conditions.

**Action Steps:** Develop and evaluate therapeutic strategies for preventing and ameliorating the various sequelae of HIV infection (listed above in the Description) and increasing understanding of their pathogenesis.

Develop and validate quality-of-life parameters for adults and children for the various sequelae of HIV infection (listed above in the Description).

Develop and evaluate therapeutic strategies for alleviating the various symptoms of unclear etiology in HIV-infected persons (listed above in the Description) and improving the quality of life.

**FY 95:** \$462,929,000

**FY 96:** \$472,944,000

**FY 97:** \$470,042,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$75,363,000 over the FY 97 figure.

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

**Goal:** To support basic and clinical vaccine research for the purpose of developing a preventive HIV vaccine.

**Objective 1:** Increase scientific knowledge of host defense mechanisms leading to protection against HIV infection and disease.

**Description:** More basic knowledge is needed to define protective immune responses to HIV in order to facilitate the development of vaccines and other immunologic strategies to prevent and control HIV infection.

**Action Steps:** Develop animal models that are practical and as much as possible are representative of the spectrum of HIV infections and AIDS; models should be amenable to use in evaluating protection by vaccines and, where this can be demonstrated, determining the correlates of protective immunity.

Determine the mechanisms of immunologically mediated control of infection with HIV and other related retroviruses, including the role of specific and nonspecific immunity in inhibiting viral replication.

Additional basic knowledge is needed to determine:

- factors, including persistence of antigens, that favor establishment of memory and development of long-term protective immunity;
- the heterogeneity of specific responses to an immunogen within distinct compartments of the immune system;
- factors that promote development of particular effector cell types;
- mechanisms resulting from exposure to HIV that interfere with induction or propagation of vaccine-induced effector responses;
- mechanisms of virus neutralization.

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

Define and characterize viral B cell and T cell epitopes that induce protective immunity; understand their structure and antigenicity and determine whether and how their immunogenicity can be exploited in vaccine development; and define epitopes in which substitutions cannot be tolerated by the virus.

Determine whether infection with one strain of HIV or related retroviruses confers protection against subsequent infection with a second strain; determine the protective mechanism and timing.

Understand how and why HIV and related lentiviruses evade or escape from humoral and cellular arms of the immune response.

Explore strategies to elucidate the obligate mechanisms for protective immunity against HIV, including amplification of selected responses by passive transfer of Ab or immune cells and subtraction by deletion of selected components of the immune system.

Study chronic infection with attenuated viruses, such as SIV variants shown to induce strong protection against virulent SIV strains in macaques, to understand what properties of the virus and the immune system are responsible for lack of disease induction and protection from challenge with wild-type virus.

Explore the molecular epidemiology and serology of HIV-1 populations relevant to vaccine trials and collect clinical material from these populations for scientific analysis. Acquire epidemiological information to assist in interpretation of these analyses.

Develop quantitative measures of HIV concentration in bodily fluids to determine whether there is a relationship between HIV concentration and transmission and to determine the effect of concurrent STDs on HIV shedding.

**Objective 2:** Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models, and foster collaboration with industry in the research and development of candidate vaccines.

**Description:** The identification of viral antigens and vaccine delivery methods that elicit long-lasting protective immune responses against a broad range of HIV isolates will facilitate development of effective vaccines.

**Action Steps:** Support the design and development of potential vaccines, including vaccines composed of:

- whole-killed HIV and genetically engineered, noninfectious HIV mutants that lack the viral RNA genome or have a defect in a critical gene necessary for replication but contain an array of HIV genes for expression of antigenic proteins;
- live, recombinant viral and bacterial vectors engineered to express one or more HIV proteins;
- naturally occurring and genetically engineered, live-attenuated strains of HIV;
- synthetic peptide candidates capable of inducing and boosting both cellular and humoral immunity;

- DNA coding for viral proteins;
- agents that stimulate mucosal immune responses;
- a combination of the above agents and preparations;
- other novel agents and preparations.

Evaluate the efficacy of vaccine strategies in animal models of HIV and related lentiviruses. To accomplish this:

- test vaccine strategies in animal models that most closely mimic the HIV infection in humans;
- determine the effect of vaccine formulation and regimen as well as the nature, timing, and route of vaccine challenge on the characteristics and effectiveness of the vaccine-induced immune response;
- define the impact of different vaccine approaches on kinetics of immune responses, kinetics and localization of viral replication, disease progression, and biologic characteristics of breakthrough virus including transmissibility;
- conduct long-term followup of vaccinated animals that become chronically infected to determine the impact of vaccination on disease progression;
- develop assays to distinguish between infection and serological responses due to immunization.

Support design and development of methods to improve or modulate immune responses (qualitatively or quantitatively), including:

- novel adjuvants and presentation methods;
- vaccines incorporating cytokines or other biologically active molecules;
- establishment of physical or biological reservoirs for long-term antigen presentation;
- other novel strategies.

Encourage development of candidate vaccines of suitable antigenic types and possessing stability and route of administration

characteristics appropriate for international as well as domestic use.

Characterize and evaluate the potential negative side effects of candidate vaccines, including

production antibodies enhancing neurotoxicity and oncogenicity.

Develop better *in vitro* methodologies to measure immune responses to primary viral isolates.

Develop infrastructure, and address scientific, legal, and regulatory issues to foster and encourage participation by, and collaboration with, industry and other agencies in the research, development, production, and clinical testing of candidate vaccines.

**Objective 3:** Select candidate vaccines or concepts suitable for Phase I and Phase II trials and conduct these trials.

**Description:** Suitable candidate vaccines need to be selected and evaluated in Phase I and Phase II trials to determine safety and immunogenicity.

**Action Steps:** Support the conduct of Phase I and Phase II coordinated clinical trial that will determine long-term and short-term safety and compare immunologic responses to preventive vaccine candidates; include a broad range of humoral, cell-mediated, and mucosal immune parameters;

Develop a mechanism to evaluate the suitability of vaccine candidates for entry into Phase I and Phase II trials; evaluation criteria should include originality and intrinsic value of the concept and animal model data.

Develop strategies at the local and national levels to reduce social and economic risk to volunteers in Phase I and Phase II trials to facilitate broad participation.

Design and conduct Phase II trials using promising HIV vaccines that are also genetically or immunologically related to HIV isolates circulating in the proposed trial population and of an appropriate size to facilitate decisions regarding efficacy trials. Analyze immune responses in vaccines and appropriate controls. Isolate and characterize virus and follow clinical course and immune responses of vaccines who become HIV-infected.

Study viral isolates from participants in HIV vaccine trials and selected controls to explore the possible effects of vaccination on the characteristics of transmitted viruses.

Conduct behavioral research on trial participants to establish whether their risk behavior has been influenced by participation in a vaccine trial, with emphasis on individuals who become infected while participating.

Closely coordinate the evaluation of research findings on prophylactic AIDS vaccines with preclinical research and immunotherapeutic interventions.

**Objective 4:** Identify mechanisms of protective immunity to HIV in newborns and infants and support the development of safe and effective immunologic strategies for preventing or controlling HIV infection in this population.

**Description:** Distinct approaches and infrastructure are needed to achieve protection of newborns and infants because of the unique nature of their immune responses and modes of exposure to HIV.

**Action Steps:** Determine what viral, immunologic, and nonimmunologic host factors influence transmission of HIV-1 from mother to infant;

- Compare virus isolates that are and are not transmitted from mother to infant;
- Seek maternal and infant immune responses that might prevent transmission to infants.

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

Determine the safety and immunogenicity of various HIV vaccines and adjuvants in relevant animal models of maternal-fetal and maternal-infant transmission to evaluate safety, immunogenicity, and efficacy of candidate vaccines.

Select and evaluate antibody and/or cellular preparations in passive or passive/active HIV prevention studies.

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

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

**Objective 5:** Identify appropriate domestic and international population and develop infrastructure and collaborations with government, communities, and industry necessary for ensuring adequate performance of Phase III efficacy trials.

**Description:** Preparation for HIV vaccine efficacy trials requires development of an infrastructure and a series of studies and planning activities to ensure their feasibility.

**Action Steps:** Develop domestic and international sites with access to populations at high risk for acquiring HIV infection, where vaccine or other prevention research activities may be feasible.

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

For international trials, work closely with national (host) governmental and regulatory authorities, collaborating institutions, vaccine manufacturer(s), and the World Health Organization to plan and conduct vaccine efficacy trials adhering to the highest ethical and scientific standards.

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

Maintain the necessary laboratory infrastructure at designated sites for conducting domestic and international vaccine efficacy trials.

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

Evaluate other biomedical and behavioral interventions that could prove of benefit in decreasing the incidence of HIV infection in the populations identified for future vaccine efficacy trials and assess their potential impact on the evaluation of vaccine efficacy.

Conduct behavioral research in populations at high risk for HIV infection to determine, for example, appropriate risk-reduction interventions and to estimate risk behavior and recruitment, adherence, and retention strategies pertinent to the design and execution of a successful efficacy trial, especially for populations that have been historically underrepresented in clinical trials.

Determine possible adverse social, economic, or legal consequences of participation in clinical trials, and develop strategies for mitigating potential harm.

Determine optimal methods of achieving informed consent for vaccine efficacy trials.

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

Encourage linkage between vaccine preparedness studies in high-risk populations and other research activities including research on TB and STDs; and integrate research on vaccines against opportunistic infections as appropriate.

**Objective 6:** Select suitable vaccine candidates and support efficacy trials when appropriate criteria are met.

**Description:** Conduct HIV vaccine efficacy trials of the most promising candidate vaccines in well-characterized, high-risk populations to identify effective vaccines for the control of HIV infection.

**Action Steps:** Establish criteria with concurrence of an advisory group that has the requisite scientific, public health, government and community expertise.

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

- Evaluate HIV vaccine candidate efficacy against infection and disease;
- Evaluate additional virologic, immunologic, and behavioral outcomes, particularly correlates of protective immunity.
- Ensure that trials are conducted with the highest regard for social and ethical standards.

**FY 95:** \$100,399,000

**FY 96:** \$109,533,000

**FY 97:** \$116,132,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$38,639,000 over the FY 97 figure.

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

**Goal:** To support behavioral and social science research for the purpose of furthering understanding of behaviors associated with HIV transmission in addition to developing and improving HIV prevention interventions.

**Objective 1:** Support research to develop and evaluate social and behavioral interventions at the societal, community, organizational, and individual levels to reduce HIV transmission by reducing HIV-related risk behaviors and increasing protective behaviors. Multi-site and cross-national studies are encouraged.

**Description:** Studies have demonstrated that HIV-related risk behaviors can be measured and modified. In response to the evolving epidemic, an expanded HIV prevention research agenda is called for on what works, for whom, where, for how long, and at what cost.

**Action Steps:** Develop and evaluate the effectiveness and cost-effectiveness of demographically and culturally appropriate behavioral and social interventions in different domestic and international settings and populations to reduce high-risk HIV-related behaviors and HIV transmission (e.g. through safer sexual practices, increased use of condoms and other barrier methods, use of sterile injection equipment, and reduction of high-risk drug-related behaviors).

Support research on a range of HIV prevention strategies in a variety of settings for both emerging populations and groups that continue to be at high risk for HIV.

Support research to increase the effectiveness and cost-effectiveness of drug abuse, mental health, and alcoholism treatment, including the development of new pharmacotherapies, to reduce HIV-related risk behavior in different settings and populations.

Support research (including multi-site and cross national studies) on comprehensive interventions that integrate various HIV and STD prevention and family planning approaches.

Support research to improve the access to, delivery of, evaluation, and cost-effectiveness of services that reduce HIV risk behaviors and transmission.

Design and test interventions to increase recruitment, retention, and adherence to protocols for HIV prevention research, including prophylactic vaccines.

Support research to improve the transfer of effective interventions to and from community planning processes.

**Objective 2:** Support basic research to strengthen the understanding of determinants and processes that influence HIV-related risk behaviors and the consequences of HIV disease.

**Description:** Understanding the basic factors influencing behavior and behavior change at the societal, community, organizational, and individual levels is necessary for the development of

interventions to prevent the transmission of HIV and to ameliorate its adverse consequences. Research is needed to define the behavioral, psychological, cognitive, and social consequences of HIV infection, disease progression, and treatment.

**Action Steps:** Develop models of behavior and behavior change that integrate biological, psychological, and social perspectives to explain and predict the acquisition, change, and maintenance of HIV-related behaviors among individuals and groups in various settings.

Study the social, structural, and cultural factors such as class, ethnicity, sexual identification, age, and gender that influence HIV-related behavior, affect access and delivery of care, and determine intervention strategies.

Study the development and maintenance of HIV-related risk and preventive behaviors in specific social contexts such as the sexual dyad, peer groups, social and drug-using networks, families, and communities.

Conduct research on decision-making processes, which may include disclosure of one's HIV-status, choice of treatment options, and adoption of protective behaviors.

Support research to understand the processes of how communities become involved in HIV intervention research.

Identify the behavioral, psychological, cognitive, and social consequences of HIV disease for HIV-seropositive individuals, their support systems (e.g. partners, family members, and other care givers), and their communities.

Support studies in animal models in behavior and behavior change relevant to HIV infection and prevention.

Conduct research that identifies the social and behavioral factors affecting recruitment, retention, and adherence in clinical trials.

Conduct research on the barriers to preventive actions based on lack of trust and misinterpretations of meaning of information related to HIV.

**Objective 3:** Support research for the discovery, development, and evaluation of strategies for preventing or minimizing the negative physical, psychological, cognitive, and social consequences of HIV, including stigmatization of persons with or at-risk for HIV infection. Support research strategies for promoting effective health care utilization among persons with HIV infection.

**Description:** Enhancement of the quality of life of seropositive individuals and facilitation of HIV treatment require further research on interventions to affect the physical, behavioral, psychological, cognitive, and social consequences of HIV infection, disease progression, and treatment. Research is also needed to improve delivery of care to diverse population groups.

**Action Steps:** Develop and evaluate interventions for promoting quality of life and to delay or prevent physical, behavioral, psychological, cognitive, and social consequences.

Promote research to identify and remove barriers to effective health care utilization among persons with or at-risk of HIV infection, including access, engagement, followup, and adherence to health and social services across the care continuum (e.g. testing and counseling, health care-seeking behavior, adherence, case management, and home/hospice care). This strategy may entail developing and testing innovative models of treatment delivery for HIV disease at all illness stages.

Develop and evaluate interventions for promoting increased recruitment, adherence, and retention, especially in underrepresented populations, in HIV treatment and clinical trials.

Test models of care-giving for people living with HIV disease, their significant others, extended family members, and care providers.

Develop and evaluate interventions for preventing social stigmatization of persons with or at-risk of HIV infection and AIDS in different settings (e.g. workplaces, schools, health care facilities, and prisons).

**Objective 4:** Support research to advance innovative quantitative and qualitative methodologies to enhance HIV behavioral and social science research.

**Description:** Behavioral and social science methods have greatly advanced our understanding of HIV transmission and health maintenance. Further refinement of established methods and rapid development of emerging technologies are essential to continued improvement of our knowledge of HIV-related behaviors; our understanding of linkages between HIV-related risk behaviors, transmission, and disease progression; and the evaluation of interventions.

**Action Steps:** Develop improved qualitative and quantitative methodologies for studying behavioral and social factors associated with HIV, including improved methods for validating self-report data, improved measurement tools for surveys, and the measurement of change over time.

Develop improved sampling strategies for subpopulations and culturally and linguistically sensitive and appropriate research instruments.

Develop improved methods and techniques for dealing with subject attrition and missing data.

Encourage secondary data analysis by developing techniques to protect confidentiality and by using of meta-analysis.

Develop and refine techniques for measuring social networks associated with HIV.

Develop and refine research techniques for measuring responses by organizations to HIV and for characterizing organizations working in the HIV field.

Encourage studies that will support multi-site studies and cross-national comparisons.

Develop and refine mathematical models for linking behavior change interventions with reduction in HIV transmission.

**FY 95:** \$170,984,000

**FY 96:** \$174,077,000

**FY 97:** \$180,238,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$25,655,000 over the FY 97 figure.

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

**Goal:** To support training and infrastructure development programs for the purpose of improving the training and resources available to HIV researchers.

**Objective 1:** provide both domestic and international training in biomedical and behavioral research on HIV.

**Description:** Meeting the needs of research on HIV/AIDS requires recruiting and training basic, clinical, and behavioral scientists in the United States and abroad in the many disciplines necessary to carry out this diverse scientific agenda.

**Action Steps:** Increase predoctoral and postdoctoral training, as well as advanced research training, in a range of AIDS-related disciplines to a level comparable (about 3 percent of the budget) to that of other training programs within NIH.

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

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

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

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

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

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

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

Expand both predoctoral and postdoctoral training in structural biology.

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

Expand both pre- and post-doctoral domestic and international AIDS-related training in

epidemiology, biostatistics, and behavioral methodologies.

Establish and expand appropriate career training programs for laboratory investigators, clinical investigators, and translational scientists (i.e. making the transition from bench to patient).

Enhance training of investigators in applied immunobiology.

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

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

Collaborate with other PHS agencies in the development of training regarding HIV prevention, treatment, research, and education for health care providers, AIDS service providers, and health educators.

**Objective 2:** Establish appropriate infrastructure for the conduct of HIV research domestically and internationally.

**Description:** The conduct of HIV research in the United States and abroad requires establishment of infrastructure to carry out this research program, including facilities and instrumentation, computers, data communications, laboratories, and animal colonies.

**Action Steps:** Provide additional facilities to study animal models of pediatric AIDS.

Foster animal models to study HIV-related malignancies.

Continue the Research Facilities Infrastructure Program (RFI) and General Clinical Research Centers (GCRC) Program.

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

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

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

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

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

Provide additional laboratory and biocontainment facilities for primate research.

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

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

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

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

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

Provide further support for the development of SPF macaque colonies.

**FY 95:** \$46,483,000

**FY 96:** \$44,643,000

**FY 97:** \$44,335,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$14,368,000 over the FY 97 figure.

**Agency:** Department of Veterans Affairs

**Goal:** Utilize the unique resource of the VA-served patient population to further biomedical, health services, and rehabilitation research on HIV and AIDS.

**Objective 1:** Support AIDS-related research as a high priority area within the VA-served patient population utilizing the unique resources.

**Action Steps:** Fund research with high technical and scientific merit.

Continue to fund AIDS-related research through existing funding mechanisms, i.e., investigator-initiated studies, cooperative studies, and research centers.

Collaborate with other federal departments and agencies in initiating and conducting AIDS relevant research (including joint funding of projects), thereby making the unique resources of VA available to collaborating investigators.

Provide applicants for research support with feedback on the technical and scientific quality of their proposals.

**Objective 2:** Develop and maintain AIDS Research Centers to stimulate and emphasize importance of HIV/AIDS research in VA's unique population.

**Action Steps:** Establish AIDS Research Centers based on competitive proposal basis.

**Objective 3:** Encourage collaboration with other Federal departments and agencies in initiating and conducting AIDS-related research.

**Action Steps:** Facilitate investigator requested funding by NIH, other Federal agencies.

Support participation in community trials on individual investigator and medical center basis.

**Objective 4:** Disseminate research findings.

**Action Steps:** Publish and present findings of research in peer reviewed journals, and at national and international conferences.

**Description:** Research activities.

**FY 95:** \$ 5,400,000 \*

**FY 96:** \$ 5,700,000 \*

**FY 97:** \$ 5,700,000 \*

(\* Estimated expenditures for HIV/AIDS research are part of the general Medical and Prosthetics Research budgets. FY 1996 and FY 1007 estimates are based on the

resource levels contained in the President's budget.)

**Populations Served:** Veteran patients, general public, researchers.

**Constituency Involvement:** Veteran patients, scientific community, general public at large.

**Unmet Need:** Increased funding would enhance ability to involve VA's unique population in research and thereby increasing patients' access to research and the research knowledge base.

**Agency:** Department of Energy

**Goal:** Provide infrastructure support for physical chemical research, termed structural biology, including indirect support for HIV-related research.

**Objective:** In collaboration with other Federal agencies, provide access to sophisticated equipment and specially trained scientific personnel.

**Action Steps:** In collaboration with all relevant agencies (NIH, NSF, DOE) and the scientists they support, provide continued essential support for structural chemistry and biology facilities. Provide both the academic and the industrial community access to the facilities for further studies on the structural biology of HIV.

**Descriptions:** The National Synchrotron Light Source at Brookhaven National Laboratory includes a Department of Energy supported x-ray beam line extensively used by structural biologists studying virus structure, including the structure of HIV. In addition, through its National Laboratory system, DOE provides user facilities at other synchrotron light sources and at neutron beam facilities, which can be used by researchers to characterize the structural configuration of intact HIV, and HIV's biochemical components, often in complexes with inhibitors. These studies assist in the development of novel therapies, as well as advance our understanding of the pathogenesis and fundamental biology of HIV growth.

**FY 95:** Part of DOE's general operating budget.

**FY 96:** Part of DOE's general operating budget.

**FY 97:** Part of DOE's general operating budget.

**Populations Served:** The scientific community.

**Constituency Involvement:** Access to resources through peer review.

**Unmet Need:** Stable funding, guaranteed access for scientists to the facilities for the foreseeable future.

**Agency:** Department of Commerce

**Goal:** To foster, serve, and promote the Nation's economic development and technological advancement, including encouraging HIV-related advances and innovation through the Department's collaborative efforts with the global business community.

**Objective:** Support activities which can assist in forwarding AIDS research by expanding the role of public-private partnerships in developing a vaccine and therapeutics.

**Action Steps:** Through the Advanced Technology Program (ATP), promote advances in biotechnology and provide funding to small and start-up research and development companies;

Support the Patent and Trademark Office's (PTO) AIDS-related patent database, developed in partnership with the National Science Foundation;

Through the National Technical Information Service, disseminate HIV-related training and technical materials;

Through data collection and analysis programs conducted by the Bureau of the Census and the Bureau of Economic Analysis, provide data for decision-making regarding the distribution of funds and other resources for private and public health initiatives, including HIV-related research, treatment, and service programs;

Through scientific standards, methodologies and technologies developed through the programs of the National Institute of Standards and Technology, set standards for laboratory procedures and equipment calibration at research facilities, including those conducting HIV-related research; and

Through the Patent and Trademark Office Biotechnology Examining Groups, review applications for a range of proposed HIV-related patents.

**Descriptions:** Advance Technology Program, Patent and Trademark Office reviews, National Technical Information Service, Bureau of the Census, and the National Institute of Standards and Technology.

**FY 95:** Part of overall operating budget

**FY 96:** Part of overall operating budget

**FY 97:** Part of overall operating budget

**Populations Served:** Start-up companies, biotechnology and pharmaceutical companies, academic institutions, and researchers.

**Constituency Involvement:** The Department supports public-private partnerships to encourage innovative research.

**Unmet Need:** An increase in support for valuable programs such as ATP and the Patent and Trademark Office's innovative AIDS-related patent database would enhance Department of Commerce's ability to serve both public and private sectors.

**Agency:** Department of Justice

**Goal:** To estimate the prevalence of HIV/AIDS among the corrections and parole population and to monitor the HIV/AIDS-related policies of Federal, State, and local correctional agencies.

**Objective:** Data collection and dissemination of periodic reports.

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

**Descriptions:** When published, the 1995 Survey on Probation, the 1996 Survey of Inmates in Local Jails, and the 1997 Survey of State and Local Federal Inmates in Adult Correctional Facilities will contain estimates of HIV prevalence among probationers and inmates, and characteristics of this HIV positive population.

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

1994 Survey of HIV/AIDS in Correctional Facilities.

Publication of 1996 report "HIV/AIDS and STDs in Juvenile Facilities."

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

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

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

**FY 97:** Part of overall operating budget.

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

**Constituency Involvement:** None.

**Unmet Need:** Funding for research into requirements for effective management of HIV positive inmates.

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

## Goals

- ✓ **DOD** Carry out state-of-the-art research on the prevention and treatment of HIV infection to promote medical readiness in U.S. military forces.
- ✓ **DHHS, AHCPR** To provide national estimates of the cost and use of HIV-related medical and non-medical services.
- ✓ **DHHS, FDA**
  - Ensure the safety and effectiveness of HIV-related therapeutic agents.
  - Ensure the safety and effectiveness of HIV-related preventive and therapeutic vaccines.
  - Ensure the effectiveness of test methodologies for HIV detection and measurement.
  - Ensure the safety and effectiveness of HIV-related medical devices.
- ✓ **DHHS, NIH**
  - To support natural history and epidemiological research to improve the understanding of HIV transmission, disease progression, and the risk factors associated with HIV infection and AIDS.
  - To support etiology and pathogenesis research to improve the understanding of the causes and progression of HIV disease.
  - To support preclinical and clinical research for the purpose of developing new therapies and improving treatments for HIV infection, HIV-associated conditions, and HIV prevention.
  - To support basic and clinical vaccine research for the purpose of developing a preventive HIV vaccine.
  - To support behavioral and social science research for the purpose of furthering understanding of behaviors associated with HIV transmission in addition to developing and improving HIV prevention interventions.
  - To support training and infrastructure development programs for the purpose of improving the training and resources available to HIV researchers.
- ✓ **VA** Utilize the unique resource of the VA-served patient population to further biomedical, health services, and rehabilitation research on HIV and AIDS.
- ✓ **Energy** Provide infrastructure support for physical chemical research, termed structural biology, including indirect support for HIV-related research.

✓ Commerce To foster, serve, and promote the Nation's economic development and technological advancement, including encouraging HIV-related advances and innovation through the Department's collaborative efforts with the global business community.

✓ DOJ To estimate the prevalence of HIV/AIDS among the corrections and parole population and to monitor the HIV/AIDS-related policies of Federal, State, and local correctional agencies.

✓ Treasury

DOD

DHHS, ACF

DHHS, HCFR

HRSA

SAMSHA

CHS

HUD

DOJ

D, VA

COPNS

CPM

SSA

**Agency:** Department of Health and Human Services, the 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:** NA -- HIV services integrated into overall budget.

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

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

**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:** NA -- HIV services integrated into overall budget.

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

**Constituency Involvement:** National, professional, advocacy, and service organizations such 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:** NA -- HIV services integrated into overall budget.

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

**Constituency Involvement:** Public and private providers of these services, 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:** NA -- HIV services integrated into overall budget.

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

**Constituency Involvement:** National Head Start Association and related early childhood development 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:** NA -- HIV services integrated into overall budget.

**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. Agency: Department of Health and Human Services, the 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:** \$1,970,000,000 (Federal share)

**Populations Served:** HIV positive Medicaid-eligible persons.

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

**Unmet Need:** Since Medicaid is an entitlement program any unmet need is a result of State budgeting limitations.

**Agency:** Department of Health and Human Services, the 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:** NA

**FY 97:** NA

**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.

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

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

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

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

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

Develop and coordinate distribution of HIV provider materials.

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

**FY 95:** \$16,287,000

**FY 96:** \$12,000,000

**FY 97:** \$16,287,000

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

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

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

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

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

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

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

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

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

**FY 95:** \$6,937,000

**FY 96:** \$6,937,000

**FY 97:** \$6,937,000

**Populations Served:** Children and adults living with HIV.

**Constituency Involvement:** American Association of Dental Schools, American Association of Hospital Dentists, and the American Dental Association.

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

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

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

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

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

Increase patient access to clinical research.

Establish quality guidelines and evaluate program effectiveness.

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

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

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

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

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

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

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

Provide leadership, training, and technical assistance;

Convene youth and family leadership conferences and distribute findings;

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

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

Evaluate program effectiveness through development of common evaluation criteria of CARE Act grants that address program delivery and program outcomes and establishment of evaluation measures that are unique to each Title.

**Descriptions:** Provide RWCA-supported services through individual grantees and service organizations. In addition to these broad-based efforts, support a variety of focused initiatives such as the adolescent research and clinical network and a cooperative agreement with Institute of Family-Centered Care to provide training and technical assistance to youth and families.

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

**FY 96:** RWCA Title I: \$391,700,000  
RWCA Title II: \$260,847,000  
RWCA Title III: \$ 56,918,000  
RWCA Title IV: \$ 29,000,000

**FY 97:** RWCA Title I: \$423,943,000  
RWCA Title II: \$284,954,000  
RWCA Title III: \$ 64,568,000  
RWCA Title IV: \$ 34,000,000

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

**Constituency Involvement:** The input and guidance of PLWAs and affected communities is gathered through a variety of avenues. Constituents are represented on the HRSA AIDS Advisory Committee, RWCA planning councils, with the input of broad-based local representation, guide local prioritization of RWCA funds.

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

In addition, focus groups, workshops, and discussion groups of PLWAs, providers of HIV care, State and local officials, researchers, and national groups such as the Pediatric AIDS Foundation and the National Positive Youth Alliance review proposed policies, program directives, and planning and evaluation activities to ensure constituency input.

**Unmet Need:** Access to mental health and substance abuse services. Funds for existing projects are inadequate to meet rapidly growing caseloads and increased demand care and training. Meeting these will require collaborative efforts with NIMH and SAMSHA in addition to expanding programs in general and especially for adolescents such as mental health, substance abuse, and family case management services. For the RWCA Title IV, funds were available for only one third of grant applicants in FY 1995. There is also a need for increased access to 1% evaluation funds for service-related evaluations.

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

For frontline providers who may receive funding from several Federal Agencies, there is a need for improved coordination within and between Agencies. In addition, for example, to the lack of adequate resources for technical assistance and evaluation, there is also a need for improved planning and coordination of these activities between the various CARE activities and between Federal agencies.

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

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

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

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

**Descriptions:** Special Projects of National Significance (SPNS).

**FY 95:** \$2,092,302

**FY 96:** \$4,000,000

**FY 97:** \$????????

**Populations Served:** Persons living with HIV and their families.

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

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

**Objective 2:** Ensure that services provided under SPNS program are fully evaluated for both utilization and impacts and increase the evaluation capacity within community-based providers' organizations.

**Action Steps:** Increase emphasis on evaluation;

Increase the representation of evaluation researchers on review groups; and

Provide technical support for evaluation activities.

**Descriptions:** Evaluation of Special Projects of National Significance

**FY 95:** \$2,000,000

**FY 96:** \$4,000,000

**FY 97:** \$???????

**Populations Served:** SPNS grantees.

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

**Unmet Need:** There is a need to develop more effective linkages

between providers and evaluation researchers.

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

**Goal:** To provide a range of high quality mental health services to people affected by or living with HIV and AIDS.

**Objective 1:** To change risk behaviors and prevent further HIV transmission, evaluate the effectiveness and efficiency of the different approaches or models used for organizing and providing those services, and determine the outcome of those services on the quality of life of the individuals served.

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

Disseminate information about successful service models;

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

Increase productive work capacity as result of receiving services.

**Descriptions:** HIV/AIDS Mental Health Services Demonstration Program.

**FY 95:** \$1,500,000 (With \$1,400,000 from NIH and \$1,500,000 from HRSA)

**FY 96:** \$1,500,000 (With \$1,400,000 from NIH and \$1,500,000 from HRSA)

**FY 97:**

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

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

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

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

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

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

Facilitate entry into substance abuse treatment;

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

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

Evaluate program effectiveness.

**Descriptions:** HIV/AIDS Community Outreach Program.

**FY 95:** \$7,500,000

**FY 96:** \$7,500,000

**FY 97:**

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

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

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

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

**Goal:** Improve HIV/AIDS training of clinicians.

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

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

Establish linkages with health care providers;

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

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

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

Address managed care and training issues; and

Evaluate the effectiveness of training techniques.

**Descriptions:** AIDS Health Care Worker Training.

**FY 95:** \$2,930,000

**FY 96:** \$2,930,000

**FY 97:**

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

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

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

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

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

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

**Descriptions:** AIDS Training Grants.

**FY 95:** \$2,800,000

**FY 96:** \$0

**FY 97:**

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

**Constituency Involvement:** Health professionals and consumers.

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

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

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

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

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

Evaluate the efficiency and effectiveness of linked, integrated services.

**Descriptions:** The Linkage Initiative.

**FY 95:** \$7,700,000

**FY 96:**

**FY 97:**

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

**Constituency Involvement:** Service providers and consumers

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

**Agency:** Social Security Administration

**Goal:** Provide access to benefits payable under the Social Security Act.

**Objective:** Expedite and facilitate the processing of all disability claims, including those filed based on an allegation of HIV disease.

**Action Steps:** Process HIV claims under high priority status using procedures for processing claims where there is an indication of terminal illness.

Revise as necessary SSA's adjudicative policies based on dynamic nature of HIV disease.

Expedite claims processing by streamlining disability claims procedures and help AIDS service providers assist clients applying for SSI.

**Descriptions:** Disability and Social Insurance Programs and Outreach Demonstration Program (ODP).

**FY 95:** 1,005,000 plus 433,000 for ODP

**FY 96:** 1,200,000

**FY 97:** Use OMB figure

**Populations Served:** People living with HIV eligible for Title II and/or Title XVI social security benefits.

**Constituency Involvement:** People living with HIV and AIDS and their caregivers and advocates, the medical community, national AIDS organizations, SSA employees, coordinating federal agencies.

**Unmet Need:** Outreach programs now reach only four states. Additional funding would expand outreach project.

**Agency:** Social Security Administration

**Goal:** Provide information regarding benefits payable under the Social Security Act.

**Objective:** Provide information to people living with AIDS (PWAs) and to the medical community regarding eligibility requirements and changes in SSA programs as they apply to PWAs.

**Action Steps:** Inform PWAs about disability programs and eligibility requirements through mass mailings, electronic bulletin boards and community based organizations.

Participate and exhibit at national conventions.

Train on disability programs.

Coordinate public information campaigns among Federal agencies and non-governmental organizations to disseminate information to more people more rapidly.

**Descriptions:** Public information campaigns.

**FY 95:** NA

**FY 96:** NA

**FY 97:** NA

**Populations Served:** Persons living with HIV and their caregivers and advocates, the medical community and federal agencies.

**Constituent Involvement:** PLAs, their caregivers and advocates; the medical community; national- and community-based AIDS organizations; coordinating federal agencies and SSA employees.

**Unmet Need:** Additional technical, clerical support to disseminate information to more people.

**Agency:** Department of Housing and Urban Development

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

**Objective:** Provide states and localities with resources to provide housing and related services under long-term comprehensive strategies for meeting the needs of persons living with HIV/AIDS.

**Action Steps:** Award grants, both formula-based and competitively-selected grants to support a broad range of housing and services to prevent homelessness of persons living with HIV/AIDS. Unmet need, see above.

**Descriptions:** Housing Opportunities for Persons with AIDS (HOPWA) Program, in coordination with other HUD resources (see other HUD

goals).

**FY 95:** \$171,000,000

**FY 96:** \$171,000,000

**FY 97:** \$171,000,000

**Populations Served:** Low income persons living with HIV and their families.

**Constituency Involvement:** Communities participating in the Consolidated Planning Process will involve HIV/AIDS housing and services providers, advocates, and persons living with HIV.

**Unmet Need:** The HOPWA program can be estimated to serve about 50,000 persons living with HIV and their families. This includes about 35,000 units of housing assistance, mostly in the form of short-term payments and rental assistance. Up to 50 percent of persons living with HIV/AIDS are expected to need housing assistance of some kind during their lifetime; given that over 300,000 persons are living with AIDS, approximately 150,000 persons are expected to require housing assistance.

**Agency:** Department of Veterans Affairs

**Goal:** Provide high quality, comprehensive care across the spectrum of HIV disease to all eligible veterans.

**Objective 1:** Assess and evaluate claims and, if in order, make disability compensation or pension payments to eligible veterans with HIV-related illnesses.

**Action Steps:** Implement published final regulatory criteria effective March 24, 1992, for evaluating manifestations of HIV-related illnesses.

Publish amendment to portion of Schedule for Rating Disabilities.

**Objective 2:** Assist Departmental training programs to ensure widespread awareness of VA policies related to HIV/AIDS.

**Action Steps:** Coordinate with other Departmental offices to facilitate HIV/AIDS training at all Veterans Benefits Administration facilities.

Conduct follow-up training on HIV/AIDS as new information becomes available.

**Objective 3:** Expand outreach efforts to increase awareness of VA's HIV/AIDS programs.

**Action Steps:** Include information on VA's HIV/AIDS-related policies and accomplishments at external presentations, i.e., service organization meetings, town meetings.

**Objective 4:** Provide HIV testing and counseling to high risk groups of patients and/or patients who request testing.

**Action Steps:** Provide HIV testing and counseling services available at every VA medical center and/or VA outpatient clinic throughout the system;

Train professional health-care staff to serve as HIV counselors and patient educators on HIV prevention and transmission;

Establish quality laboratory standards for HIV testing, including ELISA and Western Blot; and

Ensure implementation of policy prohibiting routine involuntary screening.

**Objective 5:** Protect patients rights to information and self-determination in HIV testing process.

**Action Steps:** Ensure that HIV testing is performed only with written informed consent, utilizing standardized written informed consent form, by law and policy.

Provide counseling and patient education on prevention and transmission performed by trained health-care professionals.

Provide patient education pamphlet explaining HIV testing in VA available.

**Objective 6:** Protect patients rights to confidentiality in HIV testing and/or infection.

**Action Steps:** Ensure that medical records of veteran tested for or infected with HIV subject to additional confidentiality (beyond Privacy Act), by law, regulation and policy.

Implement safeguards to assure that: veteran HIV testing or status is released only with patient's written authorization with exceptions to disclosure (public health agencies, spouse, sexual partners) only under specified conditions; VA staff's access to medical records only on "need to know" basis; and legal, clinical and administrative staff trained in confidentiality regulations and policy.

**Objective 7:** Protect patient's rights to non-discrimination in admission to or treatment in VA health-care facilities.

**Action Steps:** Ensure non-discrimination in admission and treatment on the basis of HIV status, established by law and policy.

Implement safeguards to assure that: access to medical treatment based on clinical judgment, not HIV status; legal, clinical and administrative staff trained in regulations and policy with periodic updates and consultation available; and patient representatives and clinical staff are available in all facilities for patient grievances.

**Objective 8:** Provide state-of-the-art medical treatment for patients with HIV infection or AIDS through professional health-care staff educated and current in state-of-the-art HIV/AIDS treatment and the availability of appropriate pharmaceuticals and therapeutics at health-care facilities.

**Action Steps:** Provide FDA approved pharmaceuticals and therapies at local medical centers, outpatient clinics or health-care facilities or referral medical centers in VHA networks.

Provide compassionate use and therapies under research protocols at referral or other medical centers and facilities throughout system.

Promote integration of clinical treatment and research in HIV/AIDS.

Establish and maintain "Centers of Excellence" for the care of HIV/AIDS patients utilizing multidisciplinary models of care.

Facilitate physician and other clinician participation in local and national educational programs, professional societies, local, state and national advisory groups.

Support on-going education and training of health-care and support staff throughout system.

Encourage establishment of formal and informal physician and clinician networks for treatment advice.

**Objective 9:** Provide full range of medical and psycho-social services to meet comprehensive care needs.

**Action Steps:** Provide specialty and subspecialty care in medicine, surgery, psychiatry, psychology, rehabilitation in medical centers and/or networks.

At medical center level, provide comprehensive social services and counseling including family, housing and community referrals.

**Objective 10:** Provide consultation on legal, clinical and policy issues related to the care of HIV-infected patients.

**Action Steps:** Address and or refer to the appropriate individuals, questions and inquiries from external agencies, field staff, and veterans on issues related to HIV infection and AIDS.

Maintain and establish, as needed, special advisory groups of interdisciplinary field experts to address problems or issues requiring national focus. Include veterans in deliberations, as appropriate.

Implement, through policy, guidelines and recommendations of CDC, PHS, OSHA and other Federal agencies specific to HIV/AIDS and bloodborne pathogens.

**Objective 11:** Assess the impact of the HIV/AIDS epidemic on VA health-care system for resource utilization and planning purposes.

**Action Steps:** Maintain confidential HIV/AIDS Registry of all patients treated in VA health-care facilities.

Evaluate workload distribution by medical center to determine geographical distribution.

Utilize workload information as validation tool in resource allocation process.

In conjunction with the resource allocation group, estimate future workload based on past and present figures.

Include special field advisory group in resource planning and management in the allocation process for HIV/AIDS care.

**Objective 12:** Participate in interagency planning on issues related to HIV/AIDS. Provide expertise, when requested, on special issues.

**Action Steps:** Cooperate and collaborate with other agencies such as CDC on special issues such HIV-infected health-care workers, when requested. Provide expertise from field.

Involve other agencies, as appropriate, on special issues in HIV/AIDS.

Utilize OSHA, HHS, CDC, FDA expertise on specific issues, as necessary.

**Objective 13:** Ensure that Federal, State, County and local officials are aware of Department policies, procedures, treatment of personnel and veterans with HIV/AIDS.

**Action Steps:** Monitor status of pending legislation for State, County and local officials.

Serve on committees that develop and review Department policies when requested.

**Objective 14:** Ensure Department policies and procedures comply with Federal law.

**Action Steps:** Interpret Federal laws that impact on VA's HIV/AIDS program.

Provide legal advice and counsel to program officials.

Serve on committees that develop and review Department policies when requested.

Review new and updated policy directive on HIV/AIDS.

**Descriptions:** Medical care and services.

**FY 95:** \$281,000,000 \*

**FY 96:** \$300,000,000 \*

**FY 97:** \$310,000,000 \*

\* Resources for HIV/AIDS care are derived from the general Medical Care Budget. FY 1995 figures are reported expenditures. FY 1996 and FY 1997 are based on the projected number of patients by category or stage of disease and estimated resources required. The estimates are those contained in the President's budget.

**Populations Served:** Eligible HIV positive veterans.

**Constituency Involvement:** Eligible veterans through local medical centers and facilities.

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

**Agency:** Department of Housing and Urban Development

**Goal:** Increase the housing supply for persons with disabilities, including persons living with HIV and their families.

**Objective 1:** Increase the supply of permanent housing units for persons living with HIV.

**Action Steps:** Encourage HIV housing and program sponsors to apply for funds for projects for persons living with HIV.

**Descriptions:** Section 811 Supportive Housing Program for Persons with Disabilities.

**FY 95:** \$376,000,000 (Represents the full program appropriation; no set aside for persons with HIV is made.)

**FY 96:** \$258,000,000 (Represents the full program appropriation; no set aside for persons with HIV is made. \$25 million for increased contract terms only)

**FY 97:** \$174,000,000 (Part of Housing for Special Populations fund of \$769 million, i.e. elderly and disabled.)

**Populations Served:** Disabled person 18 years of age and older.

**Constituency Involvement:** Input received through local planning groups.

**Unmet Need:** Program can serve PWAs in project which may include persons with other disabilities; however, with the increasing number of persons living with HIV/AIDS, further housing resources will need to be sought.

**Objective 2:** Assist communities in providing local comprehensive systems of housing assistance and related services for persons who are homeless by increasing the supply, accessibility and appropriateness of housing and related supportive service options to address the needs of persons who are homeless and living with HIV/AIDS.

**Action Steps:** Ensure the availability of funds to support community-wide efforts to comprehensively address the needs for emergency, transitional and permanent supportive housing for person with HIV/AIDS.

**Descriptions:** Continuum of Care Homeless Assistance, including the Supportive Housing Program, Shelter Plus Care program, and the Section 8 Moderate Rehabilitation for Single Room Occupancy Dwellings for Homeless Individuals program.

**FY 95:** \$1,100,000,000

**FY 96:** \$823,000,000

**FY 97:** \$1,120,000,000

**Populations Served:** Homeless persons and families, including persons with disabilities, such as persons living with HIV/AIDS.

**Constituency Involvement:** Communities participating in the development of coordinated and comprehensive systems of housing and care for persons who are homeless, include government agencies, nonprofit organizations, advocates, and consumers.

**Unmet Need:** In 1995, HUD made the largest ever award of Federal funds to address the needs of persons who are homeless to communities and projects which are part of comprehensive and coordinated systems of housing and care. Although 881 projects were funded with the \$904 million available in the competition, another 1,900 projects were not selected or funded due to the amount of funds available. These additional 1,500 projects requested about \$2 billion in assistance. No measure of the unmet needs of HUD's other programs are made, although programs which support community economic development, the availability of affordable housing and reduce the rent burdens on clients through rental assistance may have considerable amounts of unmet needs for persons living with HIV/AIDS.

**Agency:** Department of Housing and Urban Development

**Goal:** Increase the capacity of AIDS housing and service providers to develop, operate, and evaluate housing programs for persons living with HIV.

**Objective:** Increase the capacity of AIDS housing and service providers to develop, operate, and evaluate housing programs for persons living with HIV.

**Action Steps:** Ensure the availability of technical assistance and other support for nonprofit providers.

Authorize technical assistance activities in HUD programs for HIV-related nonprofit providers and grantees.

**Descriptions:** Technical assistance or other support for the development of program capacity.

**FY 95:** \$0

**FY 96:** \$0 (Some funding within homeless assistance grants and HOPWA funding.)

**FY 97:** \$0 (Some funding within homeless assistance grants and HOPWA funding.)

**Populations Served:** Homeless persons, including those living with HIV.

**Constituency Involvement:** HUD program grantees, including State and local governments, housing authorities and finance agencies and non-profit organizations that develop, provide or coordinate services for person receiving housing assistance, as well as advocates and consumers.

**Unmet Need:** There is a need to broaden and deepen the ability of AIDS housing and service providers and AIDS program grantees to expand the range of housing options, ensure quality and responsive programs and undertake evaluation efforts. This will become increasingly important as additional demands will be made on programs as the epidemic increases the number of persons living with HIV. No additional funds are requested as these activities are part of the functions of existing offices, such as the Office of HIV/AIDS Housing, Fair Housing and Equal Opportunities and other program offices.

**Agency:** Department of Housing and Urban Development

**Goal:** Increase the awareness of staff in public and private organizations to the general and unique needs of persons living with HIV.

**Objective:** Increase awareness regarding HIV among agency and other staff.

**Action Steps:** Authorize training activities in HUD programs for HUD staff, HIV-related nonprofit providers and grantees.

**Descriptions:** Training and support for HIV awareness.

**FY 95:** \$0

**FY 96:** \$0

**FY 97:** \$0

**Populations Served:** Public and private staff and persons at risk for HIV infection.

**Constituency Involvement:** HUD program grantees, including State and local governments, housing authorities and finance agencies and non-profit organizations that develop, provide or coordinate services for person receiving housing assistance, as well as advocates and consumers.

**Unmet Need:** Misinformation, prejudice and non-responsiveness continue in the operation of public and private housing programs and the general awareness of individuals in preventing the spread of HIV. The increasing numbers of persons living with HIV requiring housing assistance, will increase the challenges on service programs to be vigilant in ensuring that information is accurately communicated and efforts are in no manner prejudicial. No additional funds are requested as these activities are part of the functions of existing offices, such as the Office of HIV/AIDS Housing, Fair Housing and Equal Opportunities and other program offices.

**Agency:** Department of Housing and Urban Development

**Goal:** Increase the awareness and responsiveness of HUD programs that may target or incidentally assist persons living with HIV.

**Objective:** Ensure that the needs of persons living with HIV are addressed in HUD programs.

**Action Steps:** Designate an office with direct responsibility for programs and advocacy on AIDS issues.

**Descriptions:** Office on HIV/AIDS Housing

**FY 95:** \$0 (within current efforts)

**FY 96:** \$0 (within current efforts)

**FY 97:** \$0 (within current efforts)

**Populations Served:** Homeless persons, nonprofit organizations, government agencies, and HUD staff.

**Constituency Involvement:** HUD program grantees, including State and local governments, housing authorities and finance agencies and non-profit organizations that develop, provide or coordinate services for person receiving housing assistance, as well as advocates and consumers.

**Unmet Need:** Maintaining office functions that promote understanding of AIDS and the needs of persons living with HIV as well as support for programs that support these clients. More staff would allow even greater impact on HUD programs. No additional funds are requested as these activities are part of the functions of existing offices, such as the Office of HIV/AIDS Housing, Fair Housing and Equal Opportunities and other program offices.

**Agency:** Department of Defense

**Goal:** Provide state-of-the-art patient-centered comprehensive care for all eligible service members throughout the asymptomatic and symptomatic phases of HIV and AIDS.

**Objective:** Provide immediate evaluation and continuity of care for service members who become HIV positive.

Through contact tracing, identify persons at risk and provide consultation and evaluation. Refer to care as appropriate.

Provide continuation of employment until no longer physically fit for duty.

**Action Steps:** Conduct periodic screening of active duty personnel;

For HIV positive personnel, provide comprehensive evaluation, treatment, and care;

Restrict assignment to continental U.S., Alaska, Hawaii, or Puerto Rico to assure continuity of medical care; and

Educate health care staff on best clinical practice for persons living with HIV.

**Descriptions:** Comprehensive state-of-the-art clinical care.

**FY 95:** \$2,000,000 to \$3,000,000

**FY 96:** \$2,000,000 to \$3,000,000

**FY 97:** \$2,000,000 to \$3,000,000

**Populations Served:** HIV positive active duty personnel.

**Constituency Involvement:** Clinicians, active duty personnel, military health providers, manpower and personnel administration staff.

**Unmet Need:** None.

**Agency:** Office of Personnel Management

**Goal:** Implement and improve workplace policies and employee benefits.

**Objective 1:** Implement and improve workplace guidelines.

**Action Steps:** Publish and distribute OPM's "HIV/AIDS Policy Guidelines".

Publish and distribute OPM personnel manuals on related HIV/AIDS issues, such as information on accommodations for employees who are HIV positive and on educational resources.

**Descriptions:** Policy development.

**FY 95:** \$20,000

**FY 96:** \$15,000

**FY 97:** \$0 (Goal achieved)

**Populations Served:** Federal agencies and employees, including labor organizations.

**Constituency Involvement:** Federal agencies and employees, including labor organizations.

**Unmet Need:** None.

**Objective 2:** Improve life insurance benefits programs.

**Action Steps:** Distribute guidance on "living benefits" insurance benefits.

Develop and distribute guidance on viatical settlements.

**Descriptions:** Insurance programs.

**FY 95:** None.

**FY 96:** None.

**FY 97:** None.

**Populations Served:** Federal agencies and employees and retirees covered by the Federal Employees Group Life Insurance Program.

**Constituent Involvement:** Federal agencies and employees and retirees covered by the Federal Employees Group Life Insurance Program.

**Unmet Need:** None.

**Agency:** Department of Justice

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

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

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

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

**Descriptions:** Provide grants and operate cooperative agreements.

**FY 95:** \$133,900

**FY 96:** Although no funds have been budgeted, the training for law enforcement and social services personnel was covered by the FY 95 budget and will continue.

**FY 97:** The department anticipates allocating additional funds for training.

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

**Constituent Involvement:** Victims rights groups were consulted regarding the curriculum development for the training program.

**Unmet Need:** Additional resources to provide more regional training.

**Agency:** Department of Justice

**Goal:** Provide health care for prisoners with HIV/AIDS. Educate and counsel the inmate population about the transmission of HIV/AIDS and for the purpose of reducing the incidence of HIV transmission.

**Objective:** Provide counseling, education and treatment for prisoners.

**Action Steps:** Conduct random HIV testing on 10% of newly incarcerated inmates;

Provide pre- and post-test counseling for inmates;

Conduct HIV tests on new inmates where clinically indicated, provide HIV training and education for all newly committed inmates during their admission and orientation;

Provide additional HIV and infectious disease-related training annually to each incarcerated inmate who has a job-related potential exposure to bloodborne pathogens; and

Provide health care for inmates.

**Descriptions:** Provide testing, counseling, education, and health care for inmates.

**FY 95:** \$1,000,000 for prevention and \$500,000,000 for medical care

**FY 96:** \$1,000,000 for prevention and \$500,000,000 for medical care

**FY 97:** \$1,000,000 for prevention and \$600,000,000 for medical care

**Population Served:** Bureau of Prisons inmates.

**Constituency Involvement:** None.

**Unmet Need:** Funding for counseling and testing of all inmates.

**Agency:** Corporation for National Service

**Goal:** To promote HIV/AIDS awareness and to provide respite care and other services to persons living with HIV and AIDS.

**Objective 1:** To promote HIV/AIDS awareness through training and other service activities.

**Action Steps:** Encourage all AmeriCorps programs to provide training in HIV/AIDS to AmeriCorps members and encourage them to become involved in HIV/AIDS service activities.

**Program Description:** Examples of AmeriCorps programs focusing on AIDS: The National AIDS Fund and the Birmingham AIDS Outreach Program.

**FY 95:** Part of overall operating cost.

**FY 96:** Part of overall operating cost.

**FY 97:** Part of overall operating cost.

**Populations Served:** Persons living with HIV and AIDS and AmeriCorps Members.

**Constituency Involved:** AmeriCorps Members and the public at large.

**Unmet Needs:** Without these programs, HIV/AIDS service providers would not be able to deliver services to as many people with HIV/AIDS.

**Objective 2:** To match volunteers from the National Senior Service Corps with persons living with HIV and AIDS for respite care and other services.

**Action Steps:** Through the Foster Grandparent program, provide foster and respite care, as well as counseling and living assistance for children with HIV/AIDS.

Through the Senior Companion Program, provide some persons living with HIV and AIDS with volunteers for respite care and living assistance.

Continue to provide some persons living with HIV and AIDS with health and nutrition services and respite care from the Retired and Senior Volunteer Program.

**Program Description:** An example of a program provided by senior volunteers include a program in Indianapolis where seniors visit people living with AIDS that are confined to a hospice.

**FY 95:** Part of overall operating cost.

**FY 96:** Part of overall operating cost.

**FY 97:** Part of overall operating cost.

**Populations Served:** Persons living with HIV and AIDS.

**Constituency Involved:** National Senior Service Corps and people living with HIV and AIDS.

**Unmet Needs:** Without these programs, respite services to persons living with AIDS would be unavailable.

GOALS..

- ✓ DHHS, ACF      To meet the social and support service needs of children, youth, and families with or at risk for HIV/AIDS.
- ✓ DHHS, HCFA      Provide primary health care to Medicaid-eligible HIV positive persons.
- Provide quality home health care for HIV positive Medicaid and Medicare beneficiaries.
- ✓ DHHS, HRSA      Increase the number of competent primary care providers willing to care for HIV positive persons.
- Reduce barriers to obtaining dental care for HIV positive persons.
- Increase access to care and improve quality of life for persons living with HIV and AIDS.
- Develop and evaluate innovative models of comprehensive managed care for persons living with HIV.
- ✓ DHHS, SAMSHA    To provide a range of high quality mental health services to people affected by or living with HIV and AIDS.
- Improve HIV/AIDS training of clinicians.
- Improve the integration of substance treatment and primary medical care.
- ✓ SSA              Provide access to benefits payable under the Social Security Act.
- Provide information regarding benefits payable under the Social Security Act.
- ✓ VA                Provide high quality, comprehensive care across the spectrum of HIV disease to all eligible veterans.
- ✓ HUD              Provide support and encourage the development of local programs that provide a comprehensive range of housing and related services for persons living with HIV.
- Increase the housing supply for persons with disabilities, including persons living with HIV and

their families.

Increase the capacity of AIDS housing and service providers to develop, operate, and evaluate housing programs for persons living with HIV.

Increase the awareness of staff in public and private organizations to the general and unique needs of persons living with HIV.

Increase the awareness and responsiveness of HUD programs that may target or incidentally assist persons living with HIV.

✓OPM

Implement and improve workplace policies and employee benefits.

✓DOD

Provide state-of-the-art patient-centered comprehensive care for all eligible service members throughout the asymptomatic and symptomatic phases of HIV and AIDS.

✓DOJ

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

Provide health care for prisoners with HIV/AIDS. Educate and counsel the inmate population about the transmission of HIV/AIDS and for the purpose of reducing the incidence of HIV transmission.

✓CorpNS

To promote HIV/AIDS awareness and to provide respite care and other services to persons living with HIV and AIDS.

***The National Strategy for HIV and AIDS, Appendix E: Translation of Research into Practice***  
***Draft for Office of Management and Budget Review: 6.28.96***

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**Agency:** Department of Health and Human Services, the 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:** \$0

**FY 97:** \$0

**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:** \$60,000

**FY 96:** \$0

**FY 97:** \$0

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*Draft for Office of Management and Budget Review: 6.28.96*

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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:** \$0

**FY 96:** \$0

**FY 97:** \$0

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

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

**Unmet Need:** N/A

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

**Action Steps:** Developed guide and related materials which 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

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**FY 96:** \$0

**FY 97:** \$0

**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

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Agency: National Institutes of Health

**Goal:** To support the dissemination and transfer of HIV-related research information to researchers, health care providers, HIV-related service providers, and HIV-infected individuals and their advocates.

**Objective 1:** Support the effective dissemination and utilization of HIV/AIDS information to all constituent communities of NIH.

**Description:** Effective Communication: Exchange of information about basic, clinical, and behavioral HIV/AIDS research finds is essential to progress in research and ultimately to improved care and treatment for HIV-infected people. The traditional methods of reporting ongoing studies and research results in peer-reviewed journals and at scientific meetings may be slow and may reach only limited audience. Health educators, health care providers, and patients, particularly those in underserved communities, need to know the results of clinical and prevention intervention studies, state-of-the-art recommendations, and the most up-to-date standards of health care. This information should be timely, include discussion of the potential implications of research findings for patient care, and should be in a form that audiences can use. The latest computer and information technologies should be exploited whenever appropriate. The findings resulting from communications research should be incorporated into the strategies to carry out this objective.

**Objective 1:** Rapidly disseminate new research findings with information on their potential implications on prevention, care, and treatment of HIV-infected individuals.

Expand access to current treatment and patient management guidelines including state-of-the-art care and information on clinical trials using multiple technologies such as, but not limited to, on-line access AIDSTRIALS and AIDSDRUGS data bases) and voice access (HIV/AIDS Treatment Information Service and the AIDS Clinical Trials Information Service).

Improve current and develop and evaluate new techniques for the two-way communication of information to scientific and lay audiences, particularly to hard-to-reach populations.

Support community groups to access HIV/AIDS information resources in their development of educational materials.

Develop and disseminate educational information. Enhance understanding of HIV and basic and clinical research processes by health care providers, community-based HIV/AIDS service organizations, and persons with HIV/AIDS.

*The National Strategy for HIV and AIDS, Appendix E: Translation of Research into Practice*  
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Develop mechanisms for rapidly disseminating information on research in progress to the research community in order to increase collaboration, reduce duplication of effort, and enhance the discovery process.

Enhance communication with the pharmaceutical industry concerning research on the development of therapeutics and vaccines.

Communicate and exchange information internationally on topics such as prevention and treatment information, patient management guidelines, and research results that impact on the care of HIV-infected individuals, particularly in developing countries.

Support the exchange of basic, clinical, and behavioral research information at community, regional, national, and international conferences and workshops.

Provide on-line, in advance when possible, the full text of abstracts and other information from scientific meetings.

Collect, archive, and make available existing data from NIH-supported basic and applied research for secondary data analysis.

Disseminate widely information concerning specimen repositories, including existing repositories, specimens available and relevant information concerning cohorts, contact people, and the process for obtaining access to samples.

Evaluate the effectiveness of communication efforts by appropriate means, including obtaining feedback from target audience members and information dissemination intermediaries.

**Objective 2:** Support research to identify existing gaps in communications approaches, identify existing strategies that are effective, and develop and test new and innovative communication strategies that will improve access to and use of state-of-the-art HIV information by all relevant audiences.

**Description:** Research: Past assessments have identified important information needs and barriers for relevant target audiences such as health care providers, service providers, people with HIV and their advocates, at-risk populations, basic and applied researchers, and the general public, and although significant communications efforts have been initiated, some communities still may not be (1) receiving needed information, (2) receiving information in a context appropriate for the audience, (3) comprehending the information, or (4) translating the information into action. New approaches are needed to ensure that the communication of

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information resulting from research is optimally effective.

**Action Steps:** Develop, test and evaluate innovative strategies for effectively reaching scientific audiences with relevant HIV information.

Investigate how and under what circumstances different communication and dissemination strategies influence the adoption of scientifically based HIV behavior change interventions and clinical practice activities in various populations.

Identify obstacles to information dissemination and develop and test possible ways to overcome these obstacles.

Assess the information needs of, and sources of information used by, various audiences, including biomedical and behavioral research communities, health care providers, service providers, people with HIV and their advocates, at-risk populations, and the general public.

Investigate the adoption of new technologies for disseminating basic and applied research findings.

Develop, improve, and evaluate the interface between human factors and emerging technologies for information exchange in HIV/AIDS.

**Objective 3:** Develop, implement, and evaluate mechanisms that promote coordination and collaboration on all current HIV/AIDS communication activities among NIH ICDs and with other Federal and non-Federal groups.

**Description:** Coordination: The scientific and lay communities look to the NIH as a central source of information on HIV/AIDS. Since multiple NIH ICDs disseminate HIV/AIDS information to these communities, coordination of efforts is essential. In order to make more effective use of limited Federal dollars, increase efficiency, make better use of new technologies, and ensure credibility with the scientific and lay communities, there must be more collaboration and better coordination of communication activities within the NIH and between the NIH and other Federal Agencies, community groups, universities, and the private sector.

**Action Steps:** Build ongoing partnerships between community-based organizations and basic, clinical, and behavioral researchers through both the intramural and extramural research programs to encourage exchange of information and experience throughout the research process to enhance research, treatment, and prevention efforts. For example, this could be accomplished through requirements in appropriate funding proposals to establish appropriate communication

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and coordination.

Promote closer interagency collaboration within PHS on information dissemination programs.

Coordinate collaboration among all ICDs in the provision of information about their clinical trials for HIV/AIDS to the AIDS Clinical Trial Information Service.

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

Expand the development and use of HIV/AIDS resource on the Internet to facilitate domestic (NIH and non-NIH) and international research collaboration and data sharing.

Continue collaborations with the United Nations/World Health Organization (WHO) AIDS program, the Pan American Health Organization (PAHO), and international AIDS agencies or societies to obtain and disseminate information about international clinical trials.

Collaborate with public and health sciences libraries to facilitate community group access to needed information.

Work within HHS, including HCFA, and with the private sector in the development of medical standards of care for determining guidelines for reimbursement.

**FY 95:** \$16,153,000

**FY 96:** \$17,912,000

**FY 97:** \$17,694,000

**Populations Served:** All populations.

**Constituency Involvement:** Researchers, clinicians, community and patient representatives, and NIH-affiliated advisory councils and committees.

**Unmet Needs:** The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$833,000 over the FY 97 figure.

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**Goals**

**DHHS, AHCPR**      To expedite the dissemination of data from research.

**DHHS, NIH**        To support the dissemination and transfer of HIV-related research information to researchers, health care providers, HIV-related service providers, and HIV-infected individuals and their advocates.

*International*

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

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

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

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

Develop mechanism for tracking HHS-related international activities.

**Descriptions:** International activities mapping project.

**FY 95:** NA - HIV activities integrated into overall budget

**FY 96:** NA - HIV activities integrated into overall budget

**FY 97:** NA - HIV activities integrated into overall budget

**Populations Served:** Program planners and policy makers.

**Constituency Involvement:** ????

**Unmet Need:** Staff to initiate and complete project.

*International*  
DOD  
DHHS, OIA  
Department of State  
Dept. Treasury  
Peace Corps  
AID  
USIA

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**Agency:** U.S. Agency for International Development

**Goal:** Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Population Served:** Persons living with AIDS in USAID HIV/AIDS emphasis countries.

**Constituency Involved:** USAID agency employees, developing country representatives,

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community representatives, PVO/NGO partners, multilateral donors and other bilateral donors.

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

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

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

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

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

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

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

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

**FY 95:** \$119,000

**FY 96:** \$114,000

**FY 97:** \$114,000

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

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

donors.

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

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**Agency:** United States Information Agency

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

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

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

**Description:** Information on USG policy and programs.

**FY 95:** \$350,000

**FY 96:** \$325,000

**FY 97:** \$325,000

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

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

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

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

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

**Description:** International Visitors Program.

**FY 95:** \$240,000

**FY 96:** \$200,000

**FY 97:** \$200,000

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**Population Served:** Health policy makers and NGO leaders.

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

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

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**Agency:** Department of Defense

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

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

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

Coordinate with Department of State.

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

**FY 95:** \$1,500,000

**FY 96:** \$1,500,000

**FY 97:** \$1,200,000

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

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

**Unmet Need:** None.

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**Agency:** Peace Corps

**Goal:** Prevent transmission of HIV infection for Peace Corps Trainees and Volunteers.

**Objective 1:** Provide all trainees with comprehensive HIV/AIDS training during the preservice training period.

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

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

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

**Action Steps:** Train OMS staff on communication and counseling skills;

Continue to educate volunteers about HIV/AIDS during inservice trainings and conferences;

Develop and distribute health newsletters;

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

Disseminate videos, pamphlets, education material on HIV/AIDS prevention; and

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

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

**FY 95:** \$300,000

**FY 96:** \$100,000

**FY 97:** \$100,000

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

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

**Unmet Need:** Due to budget constraints, Office of Medical Services (OMS) will only be able

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to provide courses for in-country Medical Staff every other year.

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**Agency:** Peace Corps

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

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

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

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

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

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

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

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

Support the development of projects and training curriculum;

Support workshops for APCDs in three regions;

Provide expert consultants for the development of projects and training; and

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

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

**FY 95:** \$4,500,000

**FY 96:** \$5,000,000

**FY 97:** \$5,000,000

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

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**Constituency Involvement:** Peace Corps designs all programs in conjunction with the beneficiary population.

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

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GOALS .....

- ✓ ~~D~~HHS, OIH Support U.S. interests globally by serving as a policy and coordinating body for international activities supported by HHS, a liaison with other U.S. departments and agencies supporting international activities, and a liaison with foreign governments working with U.S.
- ✓ USAID Sustainable reduction in sexually transmitted infections (STIs)/HIV transmission among key populations.
- ✓ ~~S~~IA To increase understanding of and support for U.S. Government (USG) policies and programs on HIV/AIDS among foreign publics.
- ✓ ~~D~~OD Support leadership in the international community by sharing research methodologies and findings, observing host nation requirements for HIV testing and reporting, and supporting research at international sites with high prevalence or incidence of HIV and AIDS.
- ✓ ~~P~~ace Corps Prevent transmission of HIV infection for Peace Corps Trainees and Volunteers.

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

✓ *State*

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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 Strategy for HIV and AIDS 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 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.

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 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.

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This document is a snapshot of where we are and where we think we need to go. Collaboration is one of the hallmarks of this 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.

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.

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.

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

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

## ***Preface***

### **The Need for a National Strategy for HIV and AIDS**

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

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

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

### **The Strategy as a Catalyst for Change**

The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS. The 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.

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***Executive Summary***

== Place Holder ==

## **I. INTRODUCTION**

### ***Scope of the HIV/AIDS Pandemic***

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

### **An Expanding Public Health Threat**

As of October 1995, the Centers for Disease Control and Prevention (CDC) reported 501,310 cases of AIDS among persons in the U.S.; 311,381 of these persons have been reported to have died as a result of complications related to HIV. Since 1987, AIDS has gone from being the 15th ranked cause of death among all Americans to the 8th. It is now the leading cause of death among Americans aged 25 to 44. (See

Figure 1.) In 1994 alone, approximately 81,000 new cases of AIDS and more than 45,000 AIDS-related deaths were reported to the CDC in 1994. The CDC estimates that between 40,000 and 60,000 Americans are becoming newly infected with HIV each year, and that between 800,000 and one million Americans are currently living with HIV.

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users. Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1994, more than 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1994 — alone, more than 1,000 new pediatric AIDS cases were reported. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among people

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under the age of 21. Under current trends, between 27 and 54 young people in the United States under the age of 21 are infected by HIV each day, or more than two young people every hour. Moreover, a significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

Communities of color have been more severely and disproportionately affected by the epidemic. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 18 percent of new cases through October 1995, although this group represents only 9 percent of the general population. In 1982, Blacks and Hispanics represented 31 percent of all AIDS cases; however, as of October 1995 these groups comprised 51 percent of cumulative AIDS cases. ~~Say men of color in certain regions of the country account for approximately 39 percent of new AIDS cases.~~

AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to non-urban areas, including dramatic increases in certain regions of the South and Midwest. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462)

were reported from the South.<sup>1</sup> While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, and each of the American Territories. (See Figure 2.) B

Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

### **The Social Impact**

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

AIDS is a disease that most often affects people in the prime of life. It

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disproportionately kills people during their most productive years. That it is the leading cause of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.<sup>2</sup> Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of potential life lost before age 65.

The human toll has been staggering and is likely to continue.

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 disease<sup>3</sup>, \$25,000 to 84,000 for Cancer<sup>4</sup>, and \$119,000 for HIV/AIDS<sup>5</sup> Overall HHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS. In FY 1995 DHHS spent approximately: \$38.0 billion for heart disease, \$17.5 billion for cancer, and \$6.0 billion for AIDS. [DHHS -- update figures.]

In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000.

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***The Evolving Challenge of the HIV/AIDS Epidemic***

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

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

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

now face new scientific challenges in developing a vaccine and the new generation of therapeutics for primary and opportunistic infections.

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

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. [Awaiting additional language from NIH.] Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy. The recent approval of a new class of therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier in their infection so they can receive the

new treatments and we need, as well, to ensure that health care professionals are well-trained and know the best way to provide that care.

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

From a societal perspective, while we have made tremendous progress in overcoming fear and discrimination, we still have a long way to go. There are no grounds for discriminating against persons with HIV infection and yet 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.

## ***Goal of the National Strategy***

The goal of the National Strategy for HIV and AIDS is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To 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 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. To date, planning has been focused primarily in the Public Health Service (PHS)<sup>6</sup>, Department of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome<sup>7</sup>, the "Coolfont"<sup>8</sup> and "Charlottesville"<sup>9</sup> reports, and the PHS Strategic Plan to Combat HIV and AIDS in

the United States<sup>10</sup>. Recommendations have also been issued by a number of groups, including the National Commission on AIDS<sup>11</sup> and the Presidential Advisory Council for HIV and AIDS. There have also been significant planning efforts on the part of individual Agencies. However, until now there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

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

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

There has also been a reliance on groups outside of government -- the same groups that have been 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. The advice and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by 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 strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;
- To provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections; and,
- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress -- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international

activities, translation of research into clinical practice, and civil rights) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

### **Implementation**

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 handful of people, while others will require extensive thoughtful effort on the part of many players in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

## **Organization of the Strategy**

The National Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities can be found in three locations within the document. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet needs. And third, funding tables can be found in Appendix G.

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

The type of information provided in the appendices varies depending upon the type of efforts Departments and Agencies

sponsor. Support for HIV/AIDS activities falls into two general categories: in the first, HIV/AIDS activities are an essential part of the mission; in the second category, HIV-related activities are not an explicit part of the mission but are indirectly supported or receive collateral benefit from Agency supported work and/or policies. There are a number of Agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA)), while other Agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Data are presented, therefore, in a manner consistent with an Agency's level of involvement.

## **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 \$6,848 million. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally sponsored activities include direct support for research, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for State and local governments, academic institutions, private foundations, health care

institutions and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

## **PREVENTION**

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

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.<sup>12</sup> The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 American will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, the long period of time when people may not be aware they are infected, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted

primarily as a result of personal and private individual behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a diversity of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention efforts are funded by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with States, local governments, and community-based organizations. Other Agencies focus on specific aspects of prevention. For example, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages

broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

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

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

## **Opportunities for Progress**

### **Modes of Transmission**

An important part of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use and their sexual partners, young and minority men having sex with men, heterosexual transmission, and through perinatal transmission. Moreover, the youth of our country are becoming infected at an alarming rate -- 50 percent of new infections in the United States are in persons under 25 years of age. HIV is the leading cause of death in Americans aged 25 to 44 and it is likely that many of these people were infected while they were adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases and Hispanics represented 18 percent of new cases. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

SAMSHA

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A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. As previously

noted, the CDC is the Federal Agency with primary responsibility for monitoring the epidemic. Seroprevalence surveys provide information on the level of HIV infections in "sentinel" populations. The CDC AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. (These data must be collected with the appropriate confidentiality protections.)

The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs coupled with fiscal 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

strategies<sup>13</sup>, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

### **Prevention Research<sup>14</sup>**

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

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

To capitalize on what is known and improve

HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV-associated sexual and drug-using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.<sup>15</sup> And although we have some information on relevant risk-taking behaviors, more information about knowledge, attitudes, decision-making processes, and beliefs about AIDS and other sexually transmitted diseases (STDs) is much needed. Such data enable scientists to establish theories of behavioral change, which then provide researchers with tools for identifying what approaches may be most effective for an individual or a community.<sup>16</sup> [Awaiting revised language from NIH.]

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

In HIV and AIDS, this intervention research

can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.<sup>17</sup> Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.<sup>18</sup> 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.<sup>19</sup>

However, despite this evidence of success, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and

behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related 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 be incorporated into prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, the CDC must consider providing broader technical assistance and training to community organizations. Moreover, a community-based effort that would test prevention models in a real-world setting should be carefully considered. [Awaiting additional language from NIH.]

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There *are* good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations,

which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

### **Prevention Programs**

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

**Community Involvement.** For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal-local partnership. Through this effort, it is possible to establish joint goals for the

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prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for good priority setting and decision making.

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

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

A second avenue for controlling the spread of HIV among addicted persons is enrollment into drug treatment programs. Substance abuse treatment is 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 substantial evidence that use of alcohol and other substances can adversely influence risk-taking behavior. In addition,

it is estimated that x percent of the population is affected by alcohol abuse and other non-injectable drugs.

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for 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 issue has begun and will continue. The CDC has initiated State-by-State discussion, including meetings with State Legislators, regarding HIV prevention issues. The CDC is also working with the National Conference of State Legislatures to provide a forum for a broad spectrum of views on this important issues.

**Treatment for Sexually Transmitted Diseases and Tuberculosis.** Studies have shown that the presence of sexually transmitted diseases (STDs) can significantly increase the efficiency of HIV transmission, even by as much as 20 times. Studies have also shown that widespread treatment of STDs in certain communities has led to a 40 percent reduction in new HIV infections in these groups.<sup>20, 21</sup> These data suggest treating STDs can be an effective HIV prevention strategy and points to a need for all clinicians to be vigilant in efforts to prevent and treat STDs.

Persons who are HIV positive are at significant risk for developing of *M. tuberculosis* (TB) disease. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.<sup>22</sup> In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

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

**Integration Into Primary Care.** To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at risk

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

Incorporating a patient's sexual and drug using history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

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

## **RESEARCH**

One of the Federal government's goals is to provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research.

Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms, and other parts of the private sector. It will also require an ongoing dialogue between the public and private sectors.

At present, a number of Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports a significant portion of these efforts. NIH funds research on HIV-related natural history and epidemiology, etiology and pathogenesis, therapeutics, vaccines, and behavior. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR)

funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The Agency also supports facilities employing sophisticated methods for identifying viral variants.

### **Contributions of Research**

[Awaiting revised language from NIH.] The Nation has already reaped some of the benefits of supporting research in general, and HIV-related research specifically. AIDS research has provided advances for treatment of other diseases. For example, HIV-related research has contributed to progress in treating breast cancer. Research revealed that by blocking cytokine receptors, tumor cell growth could be inhibited; this finding led to the development of new treatments for breast cancer.

Advances in treating conditions resulting from immunosuppression have come from HIV-targeted research. One of the most promising experimental therapies for advanced breast cancer is high-dose chemotherapy followed by bone marrow transplantation, but the treatment causes

profound immunosuppression; AIDS-related research has provided valuable insights regarding the management of these patients.

HIV-related research has also accelerated study of the human immune system which has in turn improved our ability to understand and treat other conditions such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis.

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

Research investments made before the advent of the AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research previously conducted on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses yielded invaluable information for identifying HIV as the etiologic agent of the emerging epidemic,

and advances in molecular biology provided researchers with the tools to understand HIV's structure and develop drugs based on that information.

Due in great part to Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. Clinicians now have a growing array of medication to treat and in some cases prevent a variety of HIV-associated opportunistic infections. An NIH-sponsored study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Data from federally-sponsored prospective epidemiological studies are helping scientists understand the factors that enable long-term non-progressors to live many years after infection without presenting clinical signs of progression to AIDS. [Awaiting revised language from NIH.] Understanding what happens in these non-progressors may help researchers develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus. Combination therapies are offer great potential promise in this area and in preventing perinatal transmission. 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, will require a considered and coordinated effort.

### **Opportunities for Progress**

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

Within the NIH, the Agency with the largest portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. As part of fulfilling the requirements of the law, the OAR develops a yearly NIH plan and budget for AIDS research and receives directly from the President and the Office of Management and Budget (OMB) a 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 it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

It is also clear that while NIH supports a significant portion of HIV-related research, other Agencies and Departments support a broad spectrum of research related to HIV and AIDS. Multiple Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths. For the government to effectively support a diversity of promising approaches, these research efforts must also be well-planned and coordinated. To achieve this the Director of the Office of National AIDS Policy coordinated an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge it was to develop a coordinated plan and budget specifically for HIV and AIDS research across all Agencies Departments. [Awaiting additional language from NIH.]

The first Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS was completed in April 1996. The development of this plan brought together

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representatives from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Energy, and the Department of Veterans Affairs. This plan provides an initial blueprint to focus and coordinate existing Federal HIV/AIDS research initiatives and thereby utilize available resources more efficiently and effectively. It also serves as a foundation for continued planning and evaluation.

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

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

The issues driving this debate are scientific

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

Both approaches face significant obstacles and it is clear that the developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue. [Awaiting revised language from NIH.]

In addition to effective collaboration with private sector partners, it is also vital that the Federal effort be well-coordinated. The Federal linkages that were strengthened

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during the development of the Federal Biomedical and Behavioral Research Plan and Budget for HIV and AIDS should be utilized in furthering coordination. [Awaiting additional language from NIH.]

**Microbicides.** Many scientists believe that the prevention of sexually transmitted HIV infection will depend on the development of a safe, effective, female-controlled mechanical and chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections. [Awaiting revised language from NIH.] Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs<sup>23</sup>. Microbicides could provide an easily available and inexpensive protection option for millions of women worldwide.

The barrier methods that are currently available have limitations. Most require consent, if not active participation of the male partner, and therefore cannot be independently used at the discretion of the female partner. Although epidemiological studies have demonstrated that the correct and consistent use of condoms will reduce the risk of acquiring HIV and other STDs there are many situations in which interpersonal, social, or cultural barriers interfere with a woman's ability to successfully negotiate condom use. The need for a method that can be employed by

women is based on the prevalence of non-consensual sex, sex without condom use, and risky behaviors that occur without partner knowledge. [Awaiting revised language from NIH.]

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

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

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

that play a key factor in treatment and prevention have also not been sufficiently studied.

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

There is also need for adolescent-relevant information on the part of clinicians and researchers. Models of collaboration have 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 program<sup>24</sup>, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based

on surrogate markers and/or laboratory tests, data regarding clinical effectiveness are increasingly unavailable. For example, we do not know the optimal stage in the course of HIV 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. [Awaiting additional language from NIH.]

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted; these are important efforts

that should continue. [Awaiting additional language from NIH.]

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

#### **Research: An Investment for the Future.**

And finally, research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to improving lives and the Nation must continue this investment. [Awaiting additional language from NIH.]

## **CARE & SERVICES**

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.<sup>25</sup>

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 care and services to have the most beneficial impact they should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal Agencies. For example, Creating a community program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

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

**Evaluation.** Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those on the frontlines of the epidemic. It can assist us in providing better care to persons living with HIV. In an era of limited resources coupled with a demand for cost effective services of high quality, we must use all the tools available to us if we are to help those persons living with HIV.

**Quality of Care.** Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success

in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

## **INTERNATIONAL ACTIVITIES**

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

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.<sup>26</sup> 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; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several Agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). The DOD is conducting clinical trials of candidate HIV vaccines in Thailand and NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. [Awaiting additional language from NIH.] The results of the studies ultimately will be used to develop

interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

### **Opportunities for Progress**

**International Leadership.** The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS).<sup>27</sup> 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 Vice President's "Lessons without Borders Project" initiative to bring

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. [Awaiting additional language from NIH.]

These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the Agencies supporting international activities 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 teleconferencing. NIH also supports publicly

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

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**

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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.<sup>28</sup> Other research indicates that a disturbing number of clinicians do not use universal precautions in the course of routine patient care.<sup>29</sup>

We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study 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 breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

**State of the Art Guidelines.** One of the most difficult tasks for clinicians and patients is interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. It is essential that

practical information for practicing clinicians and their patients be provided in a timely manner.

The Federal government must develop a mechanism for ensuring periodic assessment of the state of the art, ensuring that essential information can be found easily, and disseminating that information widely. This will require collaboration with industry, government, and professional groups.

**Coordination of Federal Activities.** Enhancing coordination of information dissemination activities among Public Health Service Agencies is an important priority. Within the DHHS, the Office of HIV/AIDS Policy has the lead responsibility for coordinating the HIV-related activities of the Public Health Service Agencies. Ensuring that information about a research breakthrough is easily available, reaches the appropriate persons and organizations, and that policies and standard-of-care practices for Federally-sponsored programs are modified to reflect the new standard, will require a 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, good models of effective prevention interventions have been developed, but often this valuable information is not reaching those persons developing, implementing, and evaluating prevention programs. Here again, the Public Health Service must take the lead in

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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 treatment of persons living with HIV is caring, ethical, and in accordance with legal standards. Discrimination based on HIV status is illegal and morally wrong.

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

The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by State law.

The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990 (ADA). (Federal Agencies are prohibited from discriminating against people with disabilities under the Rehabilitation Act of 1973.) Title I of the ADA prohibits discrimination against qualified disabled

individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

### **Opportunities for Progress**

**Enforcement of Federal Laws.** The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including clinicians who have refused to care for HIV-positive 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

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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.

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***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.
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 (SAMSHA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Food and Drug Administration (FDA), and the Indian Health Service (IHS). Information regarding these agencies can be found in the Appendices.
7. Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome (AIDS), Public Health Reports 100:453-455, September-October, 1985.
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.

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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.

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

24. 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.

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

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

27. 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.

28. 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.

29. 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)