

FOIA MARKER

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

OA/ID Number:	9002
FolderID:	

Folder Title:
Element Drafts [1]

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	10	2

HCFRA

What is the constituency involvement?
Unmet Needs?

HHS

Check the \$ FY 95, FY 96 \$s.
What are the unmet needs?

General - do
the individual
PHS add up to HHS?

Office of Population Affairs

- Where does their funding fit in? Overall of PHS?

ACPR

- \$ how does it fit in overall. → within HHS

Agency for Healthy Children & Families

Take out overall \$s. Unmet needs?
Constit. Involvement?

FDA

How does funding fit in overall within PHS?
Unmet needs.
Constit. Involvement?

Q2

How much test?

Reformatted Reviewed by JL

Agency

Comments

Stakeholder 10/17/95

Agency	Reformatted	JL Review	Comments
Health & Human Services			
NIH		10/16 ■	questions to go back to W, needs reformatting
CDC		????	
HRSA		10/16 ■	needs 1's reformatting
SAMHSA		■	
AHCPR		Pending 10/13	
IHS		Pending 10/13	
FDA		Pending 10/13	
ACF		Pending 10/13	
OPA		Pending 10/13	
HCFA		Pending 10/13	
OIH		????	
Defense			
Social Security Administration	Justin		handwritten list of questions
Housing and Urban Development			
Treasury			
Education			
Commerce			
Labor	Justin		
Veterans Affairs	Justin		
Energy			
Office of Management & Budget	Justin		
Office of Personnel Management	Justin		
Office of Drug Control Policy			
Corporation for National Service	10/18 10/25/95		
Justice			
EEOC	10/18 10/25		
State	Justin		
Agency for International Development	Justin		
US Information Agency	Justin		
Peace Corps	Justin		

Printing Office →

- Template that would be easier to use
- how to get in agency?

Area:

Goal:

Ideas for reatability

- Toc } Outline

CARE AND SERVICES

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: Through the First Lady's National Service Forum on Children's Health, support efforts to coordinate national service organizations, including HIV-related organizations.

Action Steps: Facilitate communication between the programs through tele-conferences, state and regional conferences and a newsletter.

Coordinate national service organizations and develop plans for creating a permanent linkages groups among groups.

Program Description: The First Lady's National Service Forum on Children's Health.

FY 95: ???

FY 96: ???

Populations Served: Children, including those living with HIV and AIDS.

Constituency Involved: Children's advocacy groups. ?

Unmet Needs: ???

Objective 2: To improve 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.

Maintain AmeriCorps programs which focus exclusively on providing HIV/AIDS-related services.

Program Description: Examples of AmeriCorps programs focusing on AIDS: The National Community AIDS Partnership, the Birmingham AIDS Outreach, AIDS Coalition Pinellas, the Triangle AIDS Network.

FY 95: Part of overall operating cost.

FY 96: Part of overall operating cost.

Populations Served: Persons living with HIV and AIDS and AmeriCorps volunteers.

Constituency Involved: AmeriCorps services and volunteers.

Unmet Needs: Funding for the future is in jeopardy.

Objective 3: 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 grandparents program, provide foster and respite care, as well as counseling and living assistance for children with HIV/AIDS in three cities -- Newark, N.J., New York City and San Antonio, Tex.

Trough 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: Examples of programs provided by senior volunteers include a meal delivery project for homebound AIDS patients in Los Angeles and a day center for children with AIDS in St. Petersburg, Fl.

FY 95: Part of overall operating cost.

FY 96: Part of overall operating cost.

Populations Served: Persons living with HIV and AIDS.

Constituency Involved: National Senior Service Corps. Any PLWAs?

Unmet Needs: Current projects are only available in selective cities. Expanded programs are needed. Funds are being cut for all National Senior Service Corps programs.

PREVENTION

Agency: Corporation for National Service

Goal: To offer HIV/AIDS education programs and other services with volunteers from the Learn and Serve America project. ✓

Objective 1: Support HIV-related Learn and Serve America projects.

Action Steps: Continue programs for children in grade school or secondary education to volunteer in community service activities, such as peer education in HIV/AIDS prevention, first aid and safety precaution training for senior citizens and school-based health and safety education training.

Continue to award higher education grants directly to colleges and universities which provide prevention and service activities in which students can participate.

Program Description: Examples of higher education programs include Robert Wood Johnson Medical School students providing health workshops on AIDS and other issues to the homeless in New Brunswick, N.J. and students at the University of San Diego serving people with AIDS.

FY 95: Part of overall operating budget.

FY 96: No funds appropriated.

Populations Served: Persons living with HIV and AIDS and others who could benefit from HIV/AIDS education.

Constituency Involved: The Learn and Serve America program and students across the country.

Unmet Needs: Budget cuts.

CIVIL RIGHTS

Agency: Department of Justice

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

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

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

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

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

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

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

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

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

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

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

CIVIL RIGHTS

Agency: Department of Justice

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

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

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

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

Descriptions: Provide grants and operate cooperative agreements.

FY 95: \$133,900

FY 96: Unknown

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

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

Unmet Need: Additional resources to provide more regional training.

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

PREVENTION

Agency: Department of Justice

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

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

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

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

- annual training and limited testing;
- annual HIV information update and infectious disease training to all staff;
- produce inmate and staff HIV educational videos;
- participate at least quarterly with HRSA in audio conferences on HIV issues; and
- conduct random HIV testing on inmates upon admission.

For employees of the DEA, FBI, INS, JMD, and USMS provide:

- general training and field office training;
- annual bloodborne pathogen training to all personnel as mandated by OSHA (discussion of HIV/AIDS is included in this training); and
- an annual update on the bloodborne pathogens training as necessary to discuss new information or changes in the use of safety equipment, etc. Supplement update with periodic memos on use of personal health equipment.???

Descriptions: DOJ staff prevention training programs.

FY 95: Part of overall operating budget.

FY 96: Part of overall operating budget.

Populations Served: DOJ employees and BOP inmates.

Constituent Involvement: ???

Unmet Need: Funding for testing of all inmates -- currently

approximately 10 percent are tested upon entry? during length of incarceration?. Additional resources for field office training for USMS and FBI.

PREVENTION

Agency: Department of Justice

Goal: Reduce risk of infection to at risk detainees.

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

Action Steps: Test detainees suspected of or diagnosed with HIV/AIDS or test upon detainee request and provide pre- and post-test counseling to detainees deemed at risk.

Descriptions: Provide limited testing and counseling.

FY 95: Part of overall operating budget.

FY 96: Part of overall operating budget.

Populations Served: Detainees

Constituent Involvement: ???

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

CARE AND SERVICES

Agency: Department of Justice

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

Objective: Data collection and publication of periodic reports.

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

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

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

1996 Survey of HIV/AIDS in Correctional Facilities.

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

Is prevalence data used allocate resources for care and treatment for inmates?

FY 95: Part of overall operating budget.

FY 96: Part of overall operating budget.

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

Constituent Involvement: NA.

Unmet Need: Funding for research into special segregation of inmates, treatment -- does this mean health care? , extent of risk and contact while under supervision.

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.

RESEARCH

Agency: Department of Commerce

Goal: To foster, serve and promote the Nation's economic development and technological advancement, including HIV-related advances.

Objective: Support activities which can assist in forwarding AIDS research.

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

Support the Patent and Trademark Office's 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

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

Constituency Involvement: ???

Unmet Need: ???

CARE AND SERVICES

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

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.

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.

RESEARCH

Agency: Department of Energy

Goal: Provide support for molecularly and mathematically oriented research, including HIV-related research. ✓

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

Action Steps: In partnership with National Institutes of Health, support the HIV Sequence and Analysis Project at the Los Alamos National Laboratory (LANL);

Through the LANL, serve as the secondary laboratory for the World Health Organization's AIDS efforts;

At Brookhaven National Laboratory, support synchrotron light sources and neutron beam facilities to assist researchers characterize the structural configuration of HIV in order to aid in the development of novel therapies; and

Using mathematical biology, model how HIV spreads within an individual (in contrast to spread through populations) in order to provide fast, safe avenues for pursuing new theories about HIV and developing clinical and other experimental studies.

Descriptions: The HIV Sequence and Analysis Project, WHO secondary laboratory, Brookhaven National Laboratory resources.

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

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

Populations Served: Scientific community.

Constituency Involvement: ???

Unmet Need: ???

RESEARCH

Agency: Department of the Treasury

Goal: Through tax code policies, provide incentives for privately-sponsored research, including HIV-related research.

Objective: Encourage private sector investment in medical research, including HIV-related research.

Action Steps: Support permanent extension of the Research and Experimentation Tax Credit and the Orphan Drug Tax Credit.

Descriptions: Research and Experimentation (R&E) Tax Credit and Orphan Drug Tax Credit.

FY 95: Not applicable.

FY 96: Not applicable.

Populations Served: Private sector entities supporting research.

Constituency Involvement: The National AIDS Drug Development Task Force, comprised of industry and government representatives and patient advocates, supported these policies.

Unmet Need: ???

INTERNATIONAL ACTIVITIES

Agency: Department of the Treasury

Goal: Support developing world programs, including HIV-related programs.

Objective: Work with the World Bank and MDBs?? to provide large-scale assistance for health projects, including HIV-related projects.

Action Steps: Through the Department's oversight authority over the World Bank, assist in the provision of external financing for AIDS programs in the developing world.

Descriptions: World Bank funding.

FY 95: Not applicable.

FY 96: Not applicable.

Populations Served: Developing countries.

Constituent Involvement: ??? -- Are any of the recipient countries involved in any of the decision-making processes?

Unmet Need: ???

CIVIL RIGHTS

Agency: U.S. Equal Opportunity Commission

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

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

Action Steps: Receive, investigate, and settle ADA discrimination complaints from job applicants and employees with HIV disease;

Litigate meritorious cases involving employment discrimination against persons with HIV disease; and

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

Descriptions: Enforcement of Title I of the ADA.

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

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

Populations Served: Job applicants and employees with HIV disease.

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

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

PREVENTION

Agency: Department of Defense

Goal: Preservation of an effective fighting force through prevention of HIV infection. ✓

Objective 1: Prevent HIV infection in service members.

Reduce the number of new active duty HIV infection by 20 percent by 1997.

Action Steps: Provide basic information on HIV transmission and risk reduction for new recruits, civilian work force members, and officers;

Require education and general military training on methods of transmission and approaches for avoiding transmission, including barrier methods, avoidance of intravenous drug use, and use of universal precautions;

Provide training for personnel, instructors, and peer educators; and

Support train the trainer courses to develop multidisciplinary teams from medical, dental, nursing, and public health corps for promoting HIV and AIDS education.

Objective 2: Ensure safety of the Armed Services Blood Program Office (ASBPO)

Action Steps: Advise service personnel with serologic evidence of HIV infection or repeated ELISA reactivity, but Western Blot negative or indeterminate, to refrain from donating blood.

Employ ASBPO "Look Back Program" to trace contacts of identified positive donors who seroconvert after blood donation -- trace and contact blood recipients.

FY 95: 245,000

FY 96: 245,000

Populations Served: Active duty service members and their eligible family members, health care providers and those at risk of exposure to body fluids, and recipients of ASBPO blood products.

Constituent Involvement: Active duty force, affiliated civilian workforce, and the health care and public health communities.

Unmet Need: None?

RESEARCH

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.

FY 95: 28,500,000

FY 96: 31,560,000

Populations Served: Active duty personnel.

Constituent Involvement: Clinicians, researchers, and active duty personnel.

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

CARE AND SERVICES

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: 2,680,000

FY 96: 2,680,000

Populations Served: HIV positive active duty personnel.

Constituent Involvement: ???

Unmet Need: ???

INTERNATIONAL ACTIVITIES

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.

FY 95: ???

FY 96: ???

Populations Served: ???

Constituent Involvement: ???

Unmet Need: ???

CIVIL RIGHTS

Agency: Department of Defense

Goal: Protect patient's rights to information and non-discrimination in receiving treatment for HIV and AIDS. ✓

Objective: Eliminate fear of untimely separation, stigma, or discrimination based on HIV status.

Action Steps: Results of laboratory tests may not be used as the sole basis for separation of a service member;

Laboratory test results confirming HIV infection may not be used as a independent basis for any adverse administrative action or any disciplinary action, including punitive sections un the Uniform Code of Military Justice;

Information obtained from a service member during or as a result of an epidemiological assessment may not be used against the service member;

Communicable disease reporting procedures of civil authorities shalt be followed through liaison between military public health authorities and the local, State, territorial, Federal, or host-nation jurisdiction;

All individuals with serologic evidence of HIV infection who are military health care beneficiaries shall be counseled by a physician or a designated health care provider regarding the significance of the antibody test;

Service members identified to be a risk shall be counseled and tested for serologic evidence of HIV infection;

Other DoD beneficiaries, such as retirees and family members identified to be at risk shall be informed of their risk and offered serologic testing, clinical evaluation, and counseling; and

Anonymity of HIV index case shall be maintained unless reporting is required by civil authorities.

Descriptions: Protection of patient's rights.

FY 95: ???

FY 96: ???

Populations Served: Active duty personnel.

Constituent Involvement: ???

Unmet Need: ???

CIVIL RIGHTS

Agency: Department of Labor

Goal: To provide protection for people living with HIV and AIDS from discrimination.

Objective: To provide protection for persons living with HIV and AIDS from discrimination in the workplace.

Action Steps: Establish policies under Section 503 of the Rehabilitation Act of 1973 providing for processing and investigating complaints filed by persons living with HIV.

Descriptions: Protection from discrimination in workplace.

FY 95: ???

FY 96: ???

Populations Served: Persons living with HIV and AIDS.

Constituency Involvement: Persons living with HIV and AIDS and Department of Labor staff.

Unmet Need: None.

CARE AND SERVICES

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

Populations Served: People living with HIV eligible for disability or social security insurance.

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.

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

Descriptions: Public information campaign.

FY 95: NA

FY 96: NA

Populations Served: PWAs 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.

INTERNATIONAL ACTIVITIES

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

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 to provide courses for in-country Medical Staff every other year.

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

Populations Served: Communities in developing countries, women and youth.

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.

INTERNATIONAL ACTIVITIES

Agency: U.S. Department of State

Goal: Promote more active involvement on HIV/AIDS issues by foreign governments. ✓

Objective: Persuade foreign governments to increase national and global activities to stem the spread of HIV/AIDS and to mitigate its impact.

Action Steps: Overseas posts will communicate the major objectives of the U.S. International Strategy on HIV/AIDS to host country officials.

Description: Initiative to increase commitment of foreign leaders.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involved: U.S. State Department, foreign governments, NGOs and business groups.

Unmet Needs: Staffing issues?

Agency: U.S. Department of State

Goal: Enhance U.S. participation on HIV/AIDS issues internationally.

Objective 1: Address HIV/AIDS in all appropriate international fora.

Action Steps: Ensure that the U.S. International Strategy is promoted at relevant international meetings of the U.N. and other bodies. Convene interagency meetings to discuss the international calendar and to develop cohesive approaches to AIDS issues.

Description: Implementation of the U.S. International Strategy on HIV/AIDS.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs globally and populations threatened by HIV/AIDS.

Constituency Involved: U.S. State Department and other federal agencies.

Unmet Needs: Staffing issues?

Objective 2: Assist U.S. agencies in improving responsiveness to a range of HIV/AIDS-related issues.

Action Steps: Address the issue of the spread of AIDS in international peacekeeping and humanitarian missions. Explore possibilities for closer collaboration with MDBs to stem the spread of AIDS.

Description: Improving U.S. responsiveness.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs around the world and populations threatened by HIV/AIDS.

Constituency Involved: U.S. State Department and MDBs.

Unmet Needs: Staffing issues?

Agency: U.S. Department of State

Goal: Enhance awareness of implications of HIV/AIDS worldwide. ✓

Objective 1: Heighten awareness of Congress as to implications of global HIV/AIDS on U.S. foreign policy.

Action Steps: Communicate to Congress the implications of global HIV/AIDS for foreign policy initiatives. Support biomedical research and international prevention efforts as means of reducing potential impact.

Description: Communicate implications of U.S. International Strategy on HIV/AIDS to Congress.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and the U.S. Congress.

Constituency Involved: U.S. State Department.

Unmet Needs: Staffing issues?

Objective 2: Heighten awareness within the U.S. foreign service community and other U.S. agencies of the foreign policy implications of global HIV/AIDS.

Action Steps: Distribute International Strategy on HIV/AIDS to embassy personnel;

Use training sessions and individual briefings of foreign service personnel to discuss HIV/AIDS as a foreign policy concern;

Work with U.S.-based international businesses to gain a better understanding of the economic impact of global HIV/AIDS on U.S. business; and

Continue to include HIV/AIDS-related discrimination and human rights abuses in regular embassy reporting.

Description: Inform and educate U.S. foreign service personnel.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS and State Department foreign service personnel.

Constituency Involved: U.S. State Department.

Unmet Needs: Staffing issues?

Agency: U.S. Department of State

Goal: Support U.S. technical agencies.

Objective: Support U.S. technical agencies in fulfilling the international HIV/AIDS objectives as appropriate to their individual agency mandates.

Action Steps: Assist USG agencies in strengthening or establishing international research and training collaborations and in gaining approval for HIV/AIDS vaccine trials and other research efforts.

Description: Support for international research.

FY 95: NA

FY 96: NA

Population Served: Nations affected by HIV/AIDS, PWAs globally, populations threatened by HIV/AIDS, researchers and USG agencies.

Constituency Involved: U.S. State Department, USG agencies and researchers.

Unmet Needs: Staffing issues?

INTERNATIONAL ACTIVITIES

Agency: U.S. Agency for International Development

Goal: Reduce STD Transmission with a focus on HIV in USAID emphasis countries.

Objective: Promote increased use of effective interventions to reduce sexual transmission of HIV/AIDS that are identified, strengthened, tested, and evaluated in HIV emphasis countries.

Action Steps: Test a female-controlled barrier method to prevent sexual transmission;

Start Phase III trials of a vaginal microbicide;

Develop and pilot at least two intervention models to reduce high risk behaviors;

Transfer, adapt and evaluate an effective protocol for HIV risk reduction counseling;

Develop and test three intervention models to reduce underlying social, economic and political determinants of HIV/STD;

Develop, field test and refine global methods for evaluating HIV/STD prevention interventions;

Complete population coverage and costing of proven intervention models;

Develop and test an improved model for STD diagnosis and case management in women;

Field test a rapid, non-invasive test for chlamydia and gonorrhea; and

Evaluate programs.

Description: Development and improvement of woman-controlled technologies. Improvement of STD/HIV prevention interventions and of technologies for STD management.

FY 95: Not available

FY 96: Not available

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involvement: USAID agency employees, developing country representatives, community representatives, 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.

Agency: U.S. Agency for International Development

Goal: Reduce perinatal and parenteral HIV transmission in USAID emphasis countries. ✓

Objective: Increased use of improved methods for reducing perinatal and parenteral HIV transmission available for program use in emphasis countries.

Action Steps: Disseminate information on options to reduce perinatal transmission of HIV in low-resource settings;

Provide technical assistance on low-cost, simple blood screening methodologies;

Make available protocols and models for reducing parenteral transmission of HIV in health care settings and in non-health care settings (i.e. injecting drug use).

Program Description: Increasing the use of methods aimed at reducing perinatal and parenteral HIV transmission.

FY 95: Not available

FY 96: Not available

Population Served: Persons living in USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, 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.

Agency: U.S. Agency for International Development

Goal: Improve social and cultural commitment to HIV/AIDS prevention worldwide. ✓

Objective: Enhance capacity of public, private, NGO and community-based organizations to design, implement and evaluate effective HIV/STD prevention and care programs.

Action Steps: Increase the number of HIV/AIDS emphasis countries whose national-level policy environments encourage and sustain participation of PLWH, indigenous NGOs and the private sector in HIV/STD prevention, care and advocacy;

Enhance the technical and managerial capability of indigenous NGOs and PVOs to design, implement and evaluate projects;

Strengthen local and regional networks of NGOS involved in HIV prevention, care and advocacy;

Assess and strengthen host country capacity for HIV/STD prevention research through training in under-represented skill areas;

Complete assessment of the availability of national information about drugs and reagents and their selection and pricing;

Develop and implement a participatory strategy to produce an approved strategic objective plan and results framework for the ATSP follow-on;

Maintain and disseminate a global HIV/AIDS surveillance database;

Disseminate two models of home- and community-based delivery of HIV/STD care;

Conduct socio-economic impact assessments, which include projections for AIDS orphans;

Complete situation assessments of the potential role of the private sector in meeting national health objectives, including HIV/STD prevention and care, as well as identifying major barriers to NGO and private sector involvement; and

Initiate work with donors and selected national governments at the global level to create transparent, standardized national health accounts which permit monitoring of types of expenditures, such as support of services mandated in the National AIDS Control Program.

Description: Improvement of social and cultural commitment to HIV/AIDS prevention.

FY 95: Not available

FY 96: Not available

Population Served: USAID HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, 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.

Agency: U.S. Agency for International Development

Goal: Improve multilateral coordination. ✓

Objective: Achieve better coordinated action by UNESCO, UNICEF, UNDP, UNFPA, WHO and the World Bank on HIV/AIDS prevention, control and mitigation.

Promote development of sustainable country-level institutions for HIV/STD service delivery, monitoring, surveillance, research and policy development through UNAIDS' training.

Support and analyze an international database on HIV/STD programs, maintain a global forum to incorporate experiences into programming and disseminate consensus to non-USAID countries.

Maximize country-level impact on prevention by supporting USAID complimentary activities and projects assumed in USAID strategic planning/logframes (i.e. blood screening and banking projects, advocacy and support for local appropriate care for PLWH.)

Action Steps: Provide strong support for UNAIDS.

Description: Increased support for UNAIDS' expanded response to HIV/AIDS in developing countries.

FY 95: Not available

FY 96: Not available

Population Served: All countries receiving UNAIDS funding and support.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, 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.

Agency: U.S. Agency for International Development

Goal: Improve services for HIV/STD prevention and care in emphasis countries. ✓

Objective: To increase knowledge, availability and quality of HIV/STD services in emphasis countries.

Action Steps: Increase knowledge to over 90 percent and 60 percent respectively in rural and urban general population adults.

Implement BCC programs and services to reach general population women in urban settings;

Use training protocols for promoting gender-, culture- and class-sensitive HIV/STD program design and implementation; and

Implement participatory community-based risk analysis and normative change interventions.

Description: Increased and improved implementation of behavior change communication interventions.

FY 95: Not available

FY 96: Not available

Population Served: USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, 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.

Agency: U.S. Agency for International Development

Goal: Increase availability of HIV/STD services in emphasis countries.

Objective: To increase knowledge, availability and quality of HIV/STD services in emphasis countries.

Action Steps: Provide 25 percent more technically-sound condom marketing and logistics management programs;

Implement improved national-level strategies to provide STD services;

Perform global and regional analyses of STD data to assess trends and efficacy of interventions;

Increase demand for technically-sound STD services among urban adults in all USAID project areas;

Use approaches for the integrated and coordinated delivery of HIV/STD, FP and other RH services.

Description: Increased and improved services for HIV/STD prevention and care.

FY 95: Not available

FY 96: Not available

Population Served: USAID's HIV/AIDS emphasis countries.

Constituency Involved: USAID agency employees, developing country representatives, community representatives, 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.

INTERNATIONAL ACTIVITIES

Agency: United States Information Agency

Goal: To increase understanding of and support for 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

Population Served: Policy makers, academics, journalists, researchers and 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.

Descriptions : International Visitors Program

FY 95: 240,000

FY 96: 200,000

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 U.S.

CARE AND SERVICES

Agency: Agency for Children and Families

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

Objective 1: Stabilize crisis situation and provide needed services.

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

Descriptions: Runaway and Homeless Youth Program.

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

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

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

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

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

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

Descriptions: Child Welfare Services Program.

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

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

Populations Served: Children in foster care.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

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

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

Descriptions: Abandoned Infants Assistance Program.

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

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

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

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

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

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

Descriptions: Head Start Program.

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

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

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

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

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

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

Descriptions: University Affiliated Program

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

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

Populations Served: Developmentally disabled persons.

Constituency Involvement: Advocacy Groups? Service Organizations?

Unmet Need: ???

PREVENTION

Agency: Office of Population Affairs

Goal: Reduce the number of new infections. ✓

Objective: Provide counselling, education, and HIV testing as needed to Title X program clinics.

Action Steps: Include HIV/AIDS education in all clinic education programs.

Include HIV/AIDS prevention in STD screening programs.

Provide HIV testing or referral for testing to all Title X clients who request testing.

Descriptions: Title X Program

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

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

Populations Served: The Title X program provides family planning and related reproductive health services to approx. 4.5 million clients annually through a network of 4,500 clinics. Clients are predominantly young women; most are members of low-income families, and 30 percent are adolescents and 2/3 are below age 25.

Constituency Involvement: For non-profit grantees, clients participate on boards of directors. For all grantees, clients participate on committees approving all information and education materials.

Unmet Need: The Title X program reaches an estimated 50 percent of potential clients. Expansion of program would provide a concomitant expansion in HIV/AIDS prevention activities, since these are provided as an integral part of the reproductive health services in Title X programs.

PREVENTION

Agency: Indian Health Service

Goal: Reduce the number of new infections among Federally recognized American Indians and Alaska Natives. ✓

Objective 1: Maintain surveillance of HIV infection in American Indians and Alaska Natives.

Action Steps: Maintain timely and complete case reporting to appropriate local, state and national entities and the Indian Health Service (IHS) AIDS Prevention Activities Office.

Descriptions: Area AIDS Coordinators will be responsible for reporting.

FY 95: 912,000

FY 96: 912,000

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: ???

Objective 2: Maintain training and information activities to provide health education and risk reduction messages.

Action Steps: Teach empowerment skills at the individual and community level that will enhance the individual's ability to actualize assimilated knowledge as behavior change.

Descriptions: The changed behavior includes adjustments of beliefs and the formation of AIDS community-based task forces at the local level.

FY 95: 2,321,000

FY 96: 2,321,000

Populations Served: American Indians and Alaska Natives population, tribal leaders, women, youth, individuals practicing high risk behavior, and IHS/tribal health care workers

Constituent Involvement: Local and National Indian Health Advisory Boards

Unmet Need: ???

INTERNATIONAL ACTIVITIES

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

Goal: Support U.S. interests globally by serving as a policy and coordinating body for international activities supported by HHS, a liaison with other U.S. departments and agencies supporting international activities, and a liaison with foreign governments working with U.S. ✓

Objective: Improve coordination among HHS and other Federally-supported international activities.

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

Develop mechanism for tracking HHS-related international activities.

Descriptions: International activities mapping project.

FY 95: NA

FY 96: NA

Populations Served: Program planners and policy makers.

Constituency Involvement: NA

Unmet Need: Staff to initiate and complete project.

RESEARCH

Agency: Agency for Health Care Policy and Research

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

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

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

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

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

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

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

Descriptions: HIV Costs and Service Utilization Study (HCSUS) ✓

FY 95: \$4,000,000

FY 96: \$4,000,000

Populations Served: HIV-infected individuals receiving treatment.

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

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

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

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

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

Descriptions: Women's Interagency HIV Study (WIHS)

FY 95: 55,000

FY 96: 75,000

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

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

Unmet Need: None.

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

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

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

Descriptions: Multicenter AIDS Cohort Study (MACS)

FY 95: 75,000

FY 96: 0

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

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

Unmet Need: None

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

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

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

Descriptions: HIV Epidemiological Research Study (HERS)

FY 95: 50,000

FY 96: 50,000

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

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

Unmet Need: None.

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

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

To examine any substitutions of formal for informal home care.

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

Abstract data from Medicaid claims.

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

FY 95: 394,557

FY 96: 0

Populations Served: Medicaid recipients with AIDS in New Jersey.

Constituency Involvement: NA

Unmet Need: None.

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

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

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

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

FY 96: 0

Populations Served: New York State Medicaid recipients.

Constituency Involvement: NA

Unmet Need: None.

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

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

Descriptions: Outcomes of Pharmaceutical Therapy in HIV Disease.

FY 95: 527,287

FY 96: 420,000

Populations Served: HIV-infected population in Maryland.

Constituency Involvement: NA

Unmet Need: None.

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

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

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

FY 95: 110,704 (from 1994 funds)

FY 96: 0

Populations Served: New Jersey Medicaid recipients.

Constituency Involvement: NA

Unmet Need: None.

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

Action Steps: Formulate statistical models and associated computer software.

Descriptions: Developing Econometric Models to Estimate AIDS Costs.

FY 95: 188,136

FY 96: 80,000

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

Constituency Involvement: NA

Unmet Need: None.

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

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

Descriptions: Determinants of Physicians' AIDS-Related Practice Behavior

FY 95: 216,054 (from 1994 funds)

FY 96: 0

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

Constituency Involvement: NA

Unmet Need: None.

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

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

Descriptions: Outcomes of Hospital Dedicated AIDS Units

FY 95: 137,538 (from 1994 funds)

FY 96: 0

Populations Served: 1500 patients receiving services in study hospitals.

Constituency Involvement: NA

Unmet Need: None.

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

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

Descriptions: Hospital Cost and Utilization Project

FY 95: 500,000

FY 96: 500,000

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

Constituency Involvement: NA

Unmet Need: None.

PREVENTION

Agency: Agency for Health Care Policy and Research

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

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

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

Descriptions: Demonstrating Computer Support Impact on AIDS Patients

FY 95: 430,440

FY 96: 390,000

Populations Served: Study volunteers.

Constituency Involvement: NA

Unmet Need: None.

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

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

Descriptions: Cost-Effectiveness of Preventing AIDS Complications.

FY 95: 198,541

FY 96: 225,000

Populations Served: Study volunteers.

Constituency Involvement: NA

Unmet Need: None.

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: Agency for Health Care Policy and Research

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

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

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

Descriptions: AIDS Treatment Information Service

FY 95: 41,300

FY 96: 53,326

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

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

Unmet Need: [REDACTED]

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

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

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

FY 95: 30,000 (to AIDS clearinghouse)

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

Populations Served: Clinical practitioners and individuals with HIV infection.

Constituency Involvement: NA

Unmet Need: NA

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

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

Descriptions: Effective Strategies of AIDS Programs in San Francisco.

FY 95: 198,883 (from 1994 funds)

FY 96: 0

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

Constituency Involvement: NA

Unmet Need: NA

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

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

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

FY 95: 75,000

FY 96: 0

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

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

Unmet Need: NA

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

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

Develop and coordinate distribution of HIV provider materials.

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

FY 95: 16,300,000

FY 96: 16,300,000

Populations Served: Health care providers and people living with HIV disease. 49

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

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

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

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

FY 95: 6,937,000

FY 96: 6,937,000

Populations Served: Children and Adults Living with HIV.

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

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

Increase patient access to clinical research.

Establish quality guidelines and evaluate program effectiveness.

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

Support consortia to improve the quality and availability of health care, including home and community-based services, continuation of health insurance, 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);

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

Evaluate program effectiveness.

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

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

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

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

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

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

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

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

Moreover, 24 states lack comprehensive care systems for children, youth, women; funding of approximately \$1.8 million would support

new planning and initial development projects in these states.

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

Descriptions: Special Projects of National Significance (SPNS).

FY 95: 2,092,302

FY 96: 4,000,000 ✓

Populations Served: Persons living with HIV and their families.

Constituentcy 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 more effective linkages among community providers and financially stable medical sites.

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

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

Action Steps: Increase emphasis on evaluation;

Increase the representation of evaluation researchers on review groups; and

Provide technical support for evaluation activities.

Descriptions: Evaluation of Special Projects of National Significance

FY 95: 2,000,000

FY 96: 4,000,000

Are there separate funds for the SPNS evaluation? ✓

Populations Served: SPNS grantees.

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

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

PREVENTION

Agency: Health Resources and Services Administration

Goal: Reduce the perinatal transmission of HIV.

Objective: Enhance provider capacity to provide appropriate services for women at the community level.

Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women.

Enhance providers' abilities to provide AZT for HIV positive pregnant women.

Action Steps: Establish the Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission (WIN);

Establish ongoing WIN Steering Committee;

Provide technical assistance to grantees;

Conduct centralized training for all WIN sites with follow-up local training;

Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop local guidelines;

Establish MCHB working group to coordinate HIV risk reduction related efforts across programs;

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

Evaluate sites.

Descriptions: Enhance outreach for HIV counseling and testing.

Improve service linkages for women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission.

PHS 076 Implementation Plan.

FY 95: 1,520,000

FY 96: 1,800,000

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

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

Constituency Involvement: Consumer participation in WIN steering committee and projects' advisory board. Linkage with other HRSA grantees including those from RWCA and SPNS programs.

Unmet Need: Funds needed to provide more services in order to reach more women and enhance evaluation efforts and improve technical assistance and training.

RESEARCH

Agency: Food and Drug Administration

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

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

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

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

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

FY 95: 25,235,000

FY 96: 25,536,000

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

Constituency Involvement: Advisory committees have representatives from academia, government, in addition to patient advocates. The pharmaceutical and biotechnology industries.

Unmet Need: More staff and resources would permit even greater responsiveness to industry and expedite more applications.

RESEARCH

Agency: Food and Drug Administration

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

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

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

Descriptions: Encourage early consultation with sponsoring companies, develop guidance documents, exchange information, and work with other agencies and international organizations.

Facilitate scientific review by FDA advisory committees.

FY 95: 11,863,000

FY 96: 12,005,000

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

Constituency Involvement: Advisory committees have representatives from academia, government, in addition to patient advocates. The pharmaceutical and biotechnology industries.

Unmet Need: More staff and resources would permit even greater responsiveness to industry and expedite more applications.

RESEARCH

Agency: Food and Drug Administration

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

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

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

Descriptions: Encourage early consultation with sponsor and develop guidance documents.

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

FY 95: 8,732,000

FY 96: 8,836,000

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

Constituency Involvement: Advisory committees have representatives from academia, government, in addition to patient advocates. The pharmaceutical and biotechnology industries.

Unmet Need: More staff and resources would permit even greater responsiveness to industry and expedite more applications.

PREVENTION

Agency: Food and Drug Administration

Goal: Reduce transfusion-transmitted HIV infection.

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

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

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

FY 95: 17,458,000

FY 96: 17,667,000 ✓

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

Constituency Involvement: Patient advocate and representatives from the blood-banking industry.

Unmet Need: More staff and resources would permit even greater responsiveness and oversight.

RESEARCH

Agency: Food and Drug Administration

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

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

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

Descriptions: Conduct meetings with sponsors on study design; produce guidance documents.

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

FY 95: 9,457,000

FY 96: 9,570,000

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

Constituency Involvement: Advisory committees have representatives from academia, government, in addition to patient advocates. The pharmaceutical and biotechnology industries.

Unmet Need: More staff and resources would permit even greater responsiveness to industry and expedite even more applications.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

Collect additional data on persons reported through HIV/AIDS surveillance which may be important for the planning and evaluation of prevention and care programs, such as social/economic status, levels of disabilities, drug use

history, sex behavior history, utilization of HIV testing and medical care services, and reproductive history in women;

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

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

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

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

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

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

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

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

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

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

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

Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS --- [relevance to goal?];

Share with prevention partners information on the need for and benefits of HIV reporting;

Develop methods to integrate various sources of data and to describe progress in HIV prevention; and

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

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

FY 95: 141,076,000

FY 96: 140,917,000

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

Constituency Involvement: There is regular consultation with national, state, and local public health officials and many other relevant organizations. Community-based organizations?

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives: Provide leadership in HIV and STD prevention by (1) establishing a national agenda through the media -- does this mean communicating a national agenda or message through the media?; (2) promoting credible messages based on science through credible channels; and (3) encouraging and supporting prevention efforts at the local level.

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

Develop methodologies to measure community mobilization or

changes in institutional behavior in relation to mass media public information and education programs;

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

Descriptions: Many of the activities cited above are carried out at local demonstration sites and in coordination with community planning efforts. In addition, specialized projects and studies also serve to focus attention on these activities, these include projects entitled: National Health Communications, Prevention Collaborative Partners, the CDC National AIDS Clearinghouse, and the CDC National AIDS Hotline. Prevention Marketing Initiative?

Also, linkage efforts with business, labor, and community groups

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

FY 95: \$45,970,000

FY 96: \$46,869,000

Populations Served: All segments of the population including 11 major racial and ethnic groups, young persons (18-25), persons engaging in behaviors that place them at risk for HIV infection, and business & labor leaders, their employees and families.

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of colleges and universities to provide HIV

education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

Conduct evaluations of the effectiveness of existing school-based interventions to reduce behaviors that result in HIV infection and related health problems;

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000



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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

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

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

Unmet Need: There is currently a lack of behavioral risk surveillance data for program planning and evaluation purposes. There is also a need to develop a more effective application of behavioral science findings to HIV prevention programs. And there is a special need to develop and maintain prevention efforts that target high risk women, youth and gay men of color.

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

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

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

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

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

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

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

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

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

Disseminate information about successful service models;

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

Increase productive work capacity as result of receiving services.

Descriptions: HIV/AIDS Mental Health Services Demonstration Program.

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

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

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

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

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

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

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

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

Facilitate entry into substance abuse treatment;

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

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

Evaluate program effectiveness.

Descriptions: HIV/AIDS Community Outreach Program.

FY 95: \$7,500,000

FY 96: \$7,500,000

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

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

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the transmission of HIV through improved training of health and mental health professionals. ✓

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

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

Establish linkages with health care providers;

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

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

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

Address managed care and training issues; and

Evaluate the effectiveness of training techniques.

Descriptions: AIDS Health Care Worker Training.

FY 95: \$2,930,000

FY 96: \$2,930,000 ✓

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

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

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

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

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

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

Descriptions: AIDS Training Grants.

FY 95: \$2,800,000

FY 96: \$0

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

Constituency Involvement: Health professionals and consumers.

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

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

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

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

Evaluate the efficiency and effectiveness of linked, integrated services.

Descriptions: The Linkage Initiative. ✓

FY 95: \$7,700,000

FY 96: \$0 (Funds are subsumed under the new Consolidated Demonstration Program.)

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

Constituency Involvement: ??

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

PREVENTION

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the number of new infections.

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

Demonstrate the differential effectiveness of incorporating HIV/AIDS prevention curricula into ongoing substance prevention programs.

Action Steps: Supplementation of high risk youth grants for alcohol, tobacco and other drugs (ATOD) prevention for the purpose of including HIV/AIDS prevention strategies in their present activities;

Develop program to empower youth with skills, knowledge, and beliefs for HIV prevention;

Demonstrate effective strategies to prevent ATOD use and abuse among high risk youth; and

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

Descriptions: High Risk Youth Demonstration Program.

FY 95: \$1,000,000

FY 96: \$3,000,000

Populations Served: High risk youth or youth at risk for ATOD, adolescent females, and youth at risk for AOD-related violent behavior.

Constituency Involvement: Families of youth, youth service workers, and the communities that support youth at risk for ATOD abuse.

Unmet Need: Presently this initiative reaches only 25 percent of high risk youth grantees. Supplementing all grantees would provide greater opportunity for services integration and evaluation.

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

Reduce ATOD use.

Action Steps: Supplementation of all community partnerships and

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

Solicit neighboring communities in program implementation.

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

FY 95: \$0

FY 96: \$5,000,000

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

Constituency Involvement: All community members.

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

Objective 3: Improve prevention training skills of FDP grantees.

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

Improve training regarding professional/client interaction.

Descriptions: Supplementation of FDP grantees.

FY 95: \$0

FY 96: \$650,000

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

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

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

PREVENTION

Agency: Health Care Financing Administration

Goal: Reduce perinatal transmission among Medicaid-eligible women.

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

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

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

FY 95: Federal resources to be determined.

FY 96: Federal resources to be determined.

Populations Served: HIV positive women eligible for Medicaid coverage.

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

Unmet Need: The pilot project? will not include women of unknown or negative HIV serostatus.

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

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

Develop directives in implementation of developed guidelines.

FY 95: Federal resources to be determined.

FY 96: Federal resources to be determined.

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

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

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

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

Description: Medicaid primary health care services.

Need: (1) more information on services covered by Medicaid;
(2) more information on waiver evaluation activities;
(3) more information on how HCFA will encourage compliance with changes in standard-of-care.

FY 95: 1,640 (Federal share)

FY 96: 1,800 (Federal share)

Populations Served: HIV positive Medicaid-eligible persons.

Constituency Involvement: More information

Unmet Need: More information

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: 15,400

FY 96: 16,115

Populations Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

Expand both predoctoral and postdoctoral training in structural biology; and

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

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

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

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

Foster animal models to study HIV-related malignancies;

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

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

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

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

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

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

Provide additional laboratory and biocontainment facilities for primate research;

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

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

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

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

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

Provide further support for the development of SPF macaque

colonies.

FY 95: 40,836

FY 96: 42,558

Populations Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

Action Steps: Support research on protective immune responses.

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

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

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

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

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

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

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

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

Objective 2: Identify strategies for eliciting protective immune responses.

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

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

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

Evaluate vaccine strategies in AIDS animal models;

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

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

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

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

Objective 3: Evaluate efficacy of vaccine candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Accelerate studies of maternal-infant transmission;

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

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

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

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

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

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

Objective 5: Identify promising vaccine candidates for efficacy trials.

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

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

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

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

Support and maintain the AIDS Vaccine Evaluation Groups;

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

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

Conduct behavioral research pertinent to preparation for Phase III trials.

Objective 6: Conduct vaccine efficacy studies.

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

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

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

Evaluate HIV vaccine candidate efficacy;

Evaluate multiple scientific hypotheses; and

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

FY 95: 111,831

FY 96: 118,128

Pops. Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

Action Steps: Support research on protective immune responses.

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

Determine the correlates of immune protection against, and immunologically mediated control of (1) HIV;

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

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

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

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

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

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

Objective 2: Identify strategies for eliciting protective immune responses.

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

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

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

Evaluate vaccine strategies in AIDS animal models;

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

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

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

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

Objective 3: Evaluate efficacy of vaccine candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Accelerate studies of maternal-infant transmission;

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

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

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

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

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

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

Objective 5: Identify promising vaccine candidates for efficacy trials.

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

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

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

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

Support and maintain the AIDS Vaccine Evaluation Groups;

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

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

Conduct behavioral research pertinent to preparation for Phase III trials.

Objective 6: Conduct vaccine efficacy studies.

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

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

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

Evaluate HIV vaccine candidate efficacy;

Evaluate multiple scientific hypotheses; and

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

FY 95: 111,831

FY 96: 118,128

Pops. Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

Objective 2: Develop and evaluate anti-retroviral therapies.

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

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

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

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

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

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

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

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

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

therapies, or drugs of abuse;

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

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

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

Objective 3: Develop and evaluate immune-restoring therapies.

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

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

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

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

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

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

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

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

Enhance collaboration among ICDs to facilitate the conduct

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

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

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

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

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

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

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

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

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

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

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

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

Descriptions: Support the rapid translation of basic

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: 473,262

FY 96: 495,839

Populations Served: All populations

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

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

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

RESEARCH

Agency: National Institutes of Health

Goal: Develop ^{Evaluative}therapeutics for HIV infection and its sequelae.

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

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

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

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

Continue and accelerate ^{active against novel targets} 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, ~~on an understanding of the molecular basis of bioavailability and pharmacokinetics, and on ability to follow up on lead compounds for the development of analogues;~~ develop and screen combinatorial libraries; emphasize central nervous system penetration; develop formulations that would be suitable for infants and children;

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

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

Increase understanding of the mechanisms and limitations of drug resistance; study the effect of various agents on HIV replication and viral variation; evaluate early markers of

resistance; evaluate the activity of anti-HIV drugs in various cell types (including macrophages) and in various stages of the cell cycle; and

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

Develop and
Objective 2: Evaluate anti-retroviral therapies.

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

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

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

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

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

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

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

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

Investigate possible interactions between therapies for HIV-related disease and other substances that HIV-infected

individuals might use, such as drug abuse treatment medications, oral contraceptives or other prescription drugs, nonprescription drugs, alternative or complementary therapies, or drugs of abuse;

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

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

Develop and
Objective 3: Evaluate immune-restoring therapies.

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

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

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

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

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

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

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

system;

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

Enhance collaboration among ICDs to facilitate the conduct of immune-based therapeutic trials and to enhance pathogenesis-related research in HIV-infected individuals.

Objective 4: ^{Develop and} Evaluate therapies for HIV-related opportunistic infections.

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

Descriptions: ~~Support 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, such as wasting syndrome. 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, CMV, 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*;~~

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

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

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

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

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

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

Develop +
Objective 5: Evaluate therapeutic interventions to block perinatal transmission.

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

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

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

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

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

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

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

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

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

Evaluate factors that contribute to or protect against vertical transmission; develop effective strategies that could more easily be afforded globally to help reduce

vertical transmission and perhaps decrease transmission via breast milk.

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

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

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

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

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

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

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

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

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

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

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

Improve collaboration between various adult and pediatric cooperative groups conducting clinical trials of HIV-

associated malignancies and ICDs and industry to accelerate trials completion and approval of active agents.

Objective 7: Develop and evaluate therapeutics^{ies} for HIV-related neurologic disease.

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

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

Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop strategies directed at the prevention and treatment of this complication of HIV infection;

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

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

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

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

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

Objective 8: Develop and evaluate therapeutics^{ies} for HIV-related complications.

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

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

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

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

FY 95: 473,262

FY 96: 495,839

Populations Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$49,566 over the FY 96 figure.

~~Populations Served:~~

~~Constituency Involvement:~~

~~Unmet Need:~~

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Determine the mechanisms of vertical HIV transmission; and

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

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

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

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

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

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

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

Action Steps: Elucidate the pathogenic mechanisms involved

in HIV-associated neurological diseases.

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

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

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

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

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

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

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

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

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

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

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

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

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

Study the effects of OIs on immune dysfunction; and

Elucidate immunologic markers that are correlative with

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

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

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

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

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

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

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

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

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

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

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

FY 95: 345,663

FY 96: 374,767

Pops. Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

Action Steps: Delineate the cellular and molecular mechanisms associated with ~~the~~ viral immunopathogenesis, of ~~HIV-related immune dysfunction.~~ 02

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Determine the mechanisms of vertical HIV transmission; and

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

Objective 3: Support research to enhance understanding ^{of} ~~about~~ HIV-related malignancies. ✓

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

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

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

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

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

Action Steps: Elucidate the pathogenic mechanisms involved in HIV-associated neurological diseases.

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

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

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

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

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

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

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

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

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

Descriptions: ^{Investigate} ~~Elucidate~~ the mechanisms of immune function that mediate protection against the OIs;

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

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

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

Study the effects of OIs on immune dysfunction; and

Elucidate immunologic markers that are correlative with disease progression for HIV-associated OIs and develop assays to accurately monitor these markers as a function of therapy.

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

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

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

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

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

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

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

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

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

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

FY 95: 345,663

FY 96: 374,767

Pops. Served: All populations

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

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