

FOIA MARKER

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Veterans Health Administration

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

<i>Objectives</i>	<i>Action Steps</i>
<u>National AIDS Program</u> Veteran Services - Medical Centers, Outpatient Clinics, Health Care facilities	
1. Provide HIV testing and counseling to high risk groups of patients and/or patients who request testing.	1. a. HIV testing and counseling services available at every VA medical center and/or VA outpatient clinic throughout the system. b. Trained professional health-care staff to serve as HIV counselors and patient educators on HIV prevention and transmission. c. Established quality laboratory standards for HIV testing, including ELISA and Western Blot. d. Widespread routine involuntary screening of any patient group prohibited.
2. Protect patients rights to information and self-determination in HIV testing process.	2. a. HIV testing performed only with written informed consent, utilizing standardized written informed consent form, by law and policy. b. Pre- and post-test counseling mandated as part of HIV testing process. c. Elements of counseling and documentation defined. d. Counseling and patient education on prevention and transmission performed by trained health-care professionals. e. Patient education pamphlet explaining HIV testing in VA available.
3. Protect patients rights to confidentiality in HIV testing and/or infection.	3. a. Medical records of veteran tested for or infected with HIV subject to additional confidentiality (beyond Privacy Act), by law, regulation and policy. b. Veteran HIV testing or status released only with patient's written authorization. Exceptions to disclosure (public health agencies, spouse, sexual partners) only under

	specified conditions. c. VA staff's access to medical records only on "need to know" basis. d. Legal, clinical and administrative staff trained in confidentiality regulations and policy; periodic updates and consultation available.
4. Protect patient's rights to non-discrimination in admission to or treatment in VA health-care facilities.	4. a. Non-discrimination in admission and treatment on the basis of HIV status, established by law and policy. b. Access to medical treatment based on clinical judgment, not HIV status. c. Legal, clinical and administrative staff trained in regulations and policy; periodic updates and consultation available. d. Patient representative, clinical staff available in all facilities for patient grievances.
5. Provide state-of-the-art medical treatment for patients with HIV infection or AIDS through: i. professional health-care staff educated and current in state-of-the-art HIV/AIDS treatment.	5. i.a. Physician and other clinician participation in local and national educational programs, professional societies, local, state and national advisory groups i.b. National HIV/AIDS advisory group on treatment issues related to HIV/AIDS. i.c. Publication of VA HIV/AIDS clinical advisory group information letters, guidelines on specific treatment issues. i.d. Dissemination of AHCPR clinical practice guidelines, HHS, CDC recommendations, FDA and other Federal or national professional society guidelines, as appropriate. i.e. National VA educational programs for physicians on clinical updates in treatment of HIV/AIDS. National educational program for nurses, nurse practitioners, physician assistants and other clinicians on therapeutic issues. i.f. Quarterly VA national teleconference calls on treatment issues available to all clinicians.

5. <i>ii.</i> availability of appropriate pharmaceuticals and therapeutics at health-care facilities.	5. <i>i.g.</i> Formal and informal physician and clinician networks for treatment advice established. 5. <i>ii.a.</i> FDA approved pharmaceuticals and therapies available at local medical centers, outpatient clinics or health-care facilities or referral medical centers in VHA networks. <i>ii.b.</i> Compassionate use and therapies under research protocols available at referral or other medical centers and facilities throughout system. <i>ii.c.</i> Integration of clinical treatment and research in HIV/AIDS.
6. Provide full range of medical and psycho-social services to meet comprehensive care needs.	6. a. Specialty and subspecialty care in medicine, surgery, psychiatry, psychology, rehabilitation available in medical centers or networks. b. At medical center level, comprehensive social services and counseling including family, housing and community referral available.
7. Establish and maintain "Centers of Excellence" for the care of HIV/AIDS patients utilizing multidisciplinary models of care.	7. a. Four AIDS clinical units established at New York, Miami, West Los Angeles and San Francisco VAMCs. b. Expertise in outpatient clinic development, coordination of care, integration of research and clinical care exported throughout system via conference calls, national education conferences, one-on-one referrals.
8. Prevent transmission of HIV in health-care setting.	8. a. On-going implementation of CDC recommendations on universal precautions, via policy. b. Continuing implementation of OSHA rule on protection of health-care workers against bloodborne pathogens via policy. c. National training program on interdisciplinary team training for staff from infection control, employee health, safety in all VAMCs to implement OSHA rule. (Completed)

National Office of Academic Affairs (Education)	
9. Support on-going education and training of health-care and support staff throughout system.	9. a. Individual participation in professional societies at local, state and national levels. b. National training programs, teleconferences. c. Disseminate/develop videos, printed materials, training books, publications, posters and all forms of educational materials to support professional and technical staff in issues related to HIV/AIDS. d. Quarterly satellite teleconference calls on timely issues related to patient care utilizing expert faculty. e. National electronic news service and newsletters to disseminate current information from wide variety of sources.
National AIDS Service Office- Washington, DC	
10. Provide consultation on legal, clinical and policy issues related to the care of HIV-infected and AIDS patients.	10. a. Address and or refer to the appropriate individuals, questions and inquiries from external agencies, field staff, veterans on issues related to HIV infection and AIDS.
11. Assess the impact of the HIV/AIDS epidemic on VA health-care system for resource utilization and planning purposes.	11. a. Maintain confidential HIV/AIDS Registry of all patients treated in VA health-care facilities. b. Evaluate workload distribution by medical center to determine geographical distribution. c. Utilize workload information as validation tool in resource allocation process. d. In conjunction with the resource allocation group, estimate future workload based on past and present figures. e. Include special field advisory group in resource planning and management in the allocation process for HIV/AIDS care.
12. Participate in interagency planning on issues related to HIV/AIDS. Provide expertise, when requested, on special issues.	12. a. Cooperate and collaborate with other agencies such as CDC on special issues such HIV-infected health-care workers, when requested. Provide expertise from field.
13. Involve other agencies, as appropriate, on	13. a. Utilize OSHA, HHS, CDC, FDA expertise on specific

special issues in HIV/AIDS.	issues, as necessary.
14. Provide policy and guidance on issues pertinent to the care of HIV/AIDS patients.	14. a. Maintain and establish, as needed, special advisory groups of interdisciplinary field experts to address problems or issues requiring national focus. Include veterans in deliberations, as appropriate. b. Implement, through policy, guidelines and recommendations of CDC, PHS, OSHA and other Federal agencies specific to HIV/AIDS and bloodborne pathogens.

Veterans Health Administration

GOAL: Prevent transmission of HIV infection through education of employees and patients.

<i>Objectives</i>	<i>Action Steps</i>
Office of Academic Affairs/AIDS Service	
1. Educate and maintain cadre of knowledgeable staff to teach all staff in VA health-care facilities on prevention and transmission of HIV infection.	1. a. National "train the trainer" education program to educate selected staff from every VA Medical Center on how to organize and conduct staff educational activities on HIV transmission and prevention. (Completed) b. Update training materials/revise strategies to maintain knowledgeable base of trainers for every facility.
2. Train and maintain cadre of professional staff to conduct HIV transmission and prevention education for patients and conduct pre- and post-test HIV antibody test counseling.	2. a. National training program to educate 2 professional staff from every VA medical center to conduct patient education and pre- and post-test counseling. (Completed) b. Maintain on-going training program on limited basis to address turnover of staff and maintain cadre of counselors/patient educators.
3. Integrate HIV prevention education in addiction treatment programs.	3. a. National training program for professional staff in addiction treatment programs and Vet Centers on how to integrate HIV prevention education for patients in their treatment areas. (Completed)
4. Stimulate innovative approaches to HIV/AIDS education at the local level (VA medical center and	4. a. Educational demonstration grants to HIV/AIDS education proposals on competitive basis. (Completed)

community).	b. Systemwide dissemination of completed projects through annual publication and national quarterly newsletters.
5. Maintain education and information support systems.	5. a. Continue AIDS awareness and education programs through national system of regional education centers and individual facility programs b. Through library system, continue purchase of appropriate private and Federal sector videos, publications, posters, and other materials.

Veterans Health Administration

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

Research and Development	
1. Support AIDS-related research as a high priority area within the VA-served patient population utilizing the unique resources.	1. a. Fund research with high technical and scientific merit. b. Continue to fund AIDS-related research through existing funding mechanisms, i.e., investigator-initiated studies, cooperative studies, and research centers. c. Collaborate with other federal departments and agencies in initiating and conducting AIDS relevant research (including joint funding of projects), thereby making the unique resources of VA available to collaborating investigators. d. Provide applicants for research support with feedback on the technical and scientific quality of their proposals.
2. Develop and maintain AIDS Research Centers to stimulate and emphasize importance of HIV/AIDS research in VA's unique population.	2. a. AIDS Research Centers established based on competitive proposal basis. b. Current Research Center locations at New York, Durham, Atlanta and San Diego VA Medical Centers.

3. Encourage collaboration with other Federal departments and agencies in initiating and conducting AIDS-related research.	3. a. Investigator requested funding by NIH, other Federal agencies. b. VA, other agency joint funding also available. c. Participation in community trials on individual investigator and medical center basis.
4. Publish and present findings of research in peer reviewed journals, and at national and international conferences.	4. a. Listing of publications, presentations at international and national conferences available upon request.

Other Departmental Offices

Intergovernmental Affairs	
1. Ensure that Federal, State, County and local officials are aware of Department policies, procedures, treatment of personnel and veterans with HIV/AIDS.	1. a. Monitor status of pending legislation for State, County and local officials. b. Serve on committees that develop and review Department policies when requested.
General Counsel	
1. Ensure Department policies and procedures comply with Federal law.	1. a. Interpret Federal laws that impact on VA's HIV/AIDS program. b. Provide legal advice and counsel to program officials. c. Serve on committees that develop and review Department policies when requested. d. Review new and updated policy directive on HIV/AIDS.
Human Resources Management	
1. Provide framework for nondiscrimination in the workplace for employees with HIV/AIDS.	1. a. Continue to implement established workplace policies on nondiscrimination for employees with HIV/AIDS as well as all employees with chronic disease or disability. b. Conduct national training of all employees on transmission and prevention of HIV, employee policies and benefits. "Like Any Other Employee: HIV/AIDS in the Workplace". (To be completed in fiscal year 1995) c. Provide continuing educational activities on HIV

	prevention and transmission for all employees in concert with other offices. d. Conduct on-going educational activities for employees, supervisors and managers on work-related issues such as confidentiality, leave, reasonable accommodation, health/life insurance, and disability retirement. e. Include education on above issues as part of routine orientation for all new employees. f. Provide employee assistance service and equal opportunity program counselors to address questions and/or grievances.
Office of Public Affairs	
1. Publicize VA's HIV/AIDS-related accomplishments to internal/external audiences.	1. a. Update AIDS fact sheet on yearly basis or more frequently as topic demands. b. Update AIDS Research fact sheet on yearly basis or more frequently as topic demands. c. Prepare annual national release for World AIDS Day. d. Promote VA AIDS research through Public Affair National Story Program. e. Prepare Secretary's Daily Messages as appropriate. f. Prepare Secretary's Pay Stub messages as appropriate. g. Develop appropriate topics for publication in VAnguard, VA's employee newsletter.

Veterans Benefits Administration

Goal: To evaluate and provide disability compensation or pension benefits to eligible veterans with HIV infection or AIDS.

Veterans Benefits Administration	
1. Assess and evaluate claims and, if in order, make disability compensation or pension payments to eligible veterans with HIV-related illnesses.	1. a. Published final regulatory criteria effective March 24, 1992, for evaluating manifestations of HIV-related illnesses. b. Publish amendment to portion of Schedule for Rating Disabilities currently entitled "Systemic Conditions." The title will be changed to "Infectious Diseases, Immune Disorders and Nutritional Deficiencies." This portion of the Schedule will be updated to use current medical terminology and unambiguous criteria for evaluating disabilities. The amendment will make no substantive change in the criteria for HIV-related illnesses.
2. Assist Departmental training programs to ensure widespread awareness of VA policies related to HIV/AIDS.	2. a. Coordinate with other Departmental offices to facilitate HIV/AIDS training at all Veterans Benefits Administration facilities. b. Conduct follow-up training on HIV/AIDS as new information becomes available.
3. Expand outreach efforts to increase awareness of VA's HIV/AIDS programs.	3. a. Include information on VA's HIV/AIDS-related policies and accomplishments at external presentations, i.e., service organization meetings, town meetings.

PROGRAMS

PROGRAMS					Unmet Needs
Description	Resources		Population Served	Constituency Served	
	FY 1995 (in \$ millions)	FY 1996 (in \$ millions)			
Medical care*	292	307	Eligible veterans	Eligible veterans through local medical centers and facilities.	

*FY 1995 budget figures based on the estimated number of patients by category or stage of HIV disease and past resource expenditures. Resources for HIV/AIDS patient care are derived from the general Medical Care Budget.

FY 1996 estimates are based upon the resource levels contained in the President's 1996 budget.

Programs					Unmet Needs
Description	Resources		Population Served	Constituency Served	
	FY 1995 (in \$ millions)	FY 1996 (in \$ millions)			
Prevention activities: Education Universal precautions (initiated in 1987)	31	31	VA health-care and support staff, veteran patients and families, general public	Local VA medical centers and health-care facilities, local communities	

* Figures are based on the estimated expenditures for universal precautions and education and are part of the general Medical Care budget. FY 1996 estimates are based upon the resource levels contained in the President's 1996 budget.

Programs					Unmet Needs
Description	Resources		Population Served	Constituency Served	
	FY 1995 (in \$ millions)	FY 1996 (in \$ millions)			
Research activities*	6	7	Veteran patients, general public	Veteran patients, scientific community, general public at large	

*Estimated expenditures for HIV/AIDS research within the general Medical and Prosthetics Research budgets. FY 1996 estimates are based upon the resource levels contained in the President's 1996 budget.

TREATMENT

Agency: Office of National Drug Control Policy

Goal: Reduce the number of current hardcore drug addicts.

Objective: Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

What the base figure the 20 percent reduction is based on?

Action Steps: Encourage private sector drug treatment organizations to share information and work together to heighten treatment efforts nationwide, including efforts aimed and HIV/AIDS treatment.

Encourage community-based treatment services in all communities to include services for drug use and HIV/AIDS.

Support state organizations in providing a statewide network of community treatment partnerships.

Convene a forum to address national treatment policy matters, including the connection between HIV/AIDS and drug use.

Provide guidelines on ??? to communities receiving Substance Abuse Performance Partnership funds.

Descriptions: Substance Abuse Performance Partnership Program. In addition, ONDCP's annual National Drug Control Strategy includes treatment of illicit drug use related to co-morbid disorders such as HIV/AIDS.

FY 95: \$1,600,000

FY 96: \$1,600,000

Does the \$1.6 million cover both treatment and prevention? Or is the total for both treatment and prevention \$3.2 million? Is this program co-funded with any other departments or agencies?

Populations Served: 2.7 million, at risk. Are these persons enrolled in ONDCP-sponsored programs?

Constituency Involvement: Community partnerships. Any examples of groups involved?

Unmet Need: Reduction plan targets approximately 20 percent of the population during the coming fiscal year. Twenty percent of which population?

PREVENTION

Agency: Office of National Drug Control Policy

Goal: Reduce the number of new hardcore drug addicts.

Objective: Reduce the number of injection drug use and cocaine addicts with high risk sex practices 20 percent by 1997.

What the base figure the 20 percent reduction is based on?

Action Steps: Encourage private sector drug treatment organizations to share information and work together to heighten treatment efforts nationwide, including efforts aimed and HIV/AIDS treatment.

Encourage community-based treatment services in all communities to include services for drug use and HIV/AIDS.

Support state organizations in providing a statewide network of community treatment partnerships.

Convene a forum to address national treatment policy matters, including the connection between HIV/AIDS and drug use.

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Unmet Need: Reduction plan targets approximately 20 percent of the population during the coming fiscal year. Twenty percent of which population?

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.

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 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;

Trough 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: ???

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: ???

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: ???

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. (What is the baseline figure for this reduction?)

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 serconvert 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.

Constituency 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.

Constituency 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.

Constituency 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: ???

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.

Through the Senior Companion Program, provide some persons living with HIV and AIDS with volunteers for respite care and living assistance.

Continue to provide some persons living with HIV and AIDS with health and nutrition services and respite care from the Retired and Senior Volunteer Program.

Program Description: 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.

PREVENTION

Agency: Department of Education

Goal: Disseminate information on Department of Education (ED) Programs in coordination with other Federal agencies.

Objective 1: Coordinate with HHS to provide information and points of contact for existing ED programs.

Action Steps: Coordinate and share information with CDC-sponsored National AIDS Clearing House;

Include information related to school-based programs are include in the Comprehensive Health Information Database. Is this a CDC or ED database?

Descriptions: Names of programs that would be shared are _____?

FY 95: ???

FY 96: ???

Populations Served: ???

Constituency Involvement: ???

Unmet Need: Groups are currently unaware of available resources, or unable to access them easily.

Objective 2: Identify informational needs of schools regarding HIV/AIDS and disseminate information that addresses those needs.

Action Steps: Using existing survey data, identify informational gaps;

Coordinate with the CDC on the School Health Information Planning Program (SHIP);

Identify public and private agencies and groups that have developed HIV-related materials appropriate for school-based programs;

Catalog and distribute information on these resources;

Establish process to inform schools about resources available to address HIV/AIDS education and prevention;

Provide schools with information on Federal resources;

Prepare publication on the relationship between HIV/AIDS to drug use;

Meet with the National Coordinating Committee and the Interagency Committee on School Health to assist in

identifying areas of need and publicizing the availability of resources.

Descriptions: Names of publications would be _____?

FY 95: ???

FY 96: ???

Populations Served: School administrators, planners, and teachers. Accurate?

Constituent Involvement: ???

Unmet Need: Many groups are unaware that resources are available to assist them. Increased funding would assist in improved information dissemination?

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

Constituency 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.

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 and AIDS.

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.

INTERNATIONAL ACTIVITIES

Agency: United States Information Agency

Goal: To increase understanding of and support for U.S. Government 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 Non-governmental Organizations (NGO) leaders.

Constituency Involvement: USG officials, academics/researchers and NGO leaders.

Unmet Needs: Lack of technology in many underdeveloped countries may prohibit information from reaching key audiences.

Objective 2: To give foreign decision makers a first-hand experience with U.S. policy and programs - public and private, national and local - to address the HIV/AIDS pandemic and encourage exchange with their U.S. counterparts.

Action Steps: Sponsor multi-regional, regional and individual International Visitor Programs, focusing specifically on HIV/AIDS issues and as part of programs on substance abuse, civil society, human rights and community health.

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.

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 prevention tools 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. 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 AIEEP 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 966: 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 PLWHA.)

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

Does USAID provide the U.S. funding for UNAIDS?

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.

Objectives: 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: 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.

Does the State Department provide the U.S. contribution to UNAIDS?

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: N/A

FY 96: N/A

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: N/A

FY 96: N/A

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?

Janelle's Comments.

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

Budget Tables (Will be developed after confirmation of individual budget figures.)

Acronym List

Letter from the Director of the Office of National AIDS Policy

The national epidemic and international pandemic of HIV and AIDS is a public health crisis of unprecedented proportions, it is the health crisis of this century. The HIV/AIDS epidemic poses a continuing public health crisis that requires solid support for multiple approaches to finding a cure and a vaccine. We must also persevere in our efforts to promote prevention, care, and the ethical treatment of persons with AIDS.

This is the first time a government-wide national plan for the United States has been developed for fighting HIV. It links programs to national objectives. Such a plan was one of the recommendations put forth in 1993 by the National Commission on AIDS. The President, as part of his strong commitment to assuring an efficient coordinated effort, requested that the Office of National AIDS Policy develop a comprehensive plan to guide the federal response to this epidemic.

The Office of National AIDS Policy (ONAP) was created by President Clinton in 1993 to provide greater national focus and direction for the Federal government's response to HIV and AIDS. ONAP is an integral participant in the development of Federal AIDS policies, including annual budget requests and legislative initiatives. As Director of ONAP, I also serve as the head of the U.S. delegation to the United Nations Joint Programme on HIV/AIDS and other international forums.

True government-wide planning requires a commitment from all departments, agencies, and all levels of government to work together toward clearly defined goals. Therefore, this strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF) a request went out for the executive branch agencies to identify their activities, goals, and objectives. With leadership from the President and in partnership with the departments and agencies that are members of the IDTF, we have taken unprecedented steps to prospectively assess and map out future action. As presented here, the national strategy establishes a baseline of current efforts government-wide, links goals to budget objectives, and guides us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. It is intended to be a living document that will require regular updating as goals are reached and replaced with new challenges.

The purpose of this comprehensive national strategy is to set

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forth overarching national goals and priorities for 1996 in charting our course for combatting the epidemic of HIV and AIDS. It also includes an accounting of current Federal activities in the areas of prevention, research, services, translation of science into practice, international activities, and civil rights. This document is meant to build on other planning documents such as the legislatively mandated NIH plan and the U.S. International Strategy on HIV/AIDS developed by the U.S. Department of State. I would like to thank and credit the agencies for the time and attention given by their staffs in developing the individual portions of the comprehensive plan.

This epidemic challenges our Nation on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged the people of this country to look at things they would prefer to not confront. ~~There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected.~~ *fear -- of --* Fifteen years into this epidemic, persons living with HIV still endure daily prejudice and discrimination based on their HIV status. We are challenged by the inadequacy of a social and health care infrastructure -- a system that is in many places, woefully unprepared to address the needs of the HIV-infected. Moreover, the safety net provided by programs such as Medicare and Medicaid is being threatened by funding changes. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

But despite the difficulties, AIDS has also brought forth the compassion and caring found throughout this Nation. In my many meetings around the country with persons living with HIV I have been inspired by their personal courage. I have been impressed by the compassion and the dedication with which many communities and individuals have risen to the challenge of preventing infections and caring for those who are sick, demonstrating how this Nation can rise to meet the most difficult challenges placed in its path. And those Americans living with HIV, and others who are at risk of infection, their families, and their communities deserve a thoughtful, effective, and aggressive plan to combat this epidemic.

strategy
The epidemic of HIV and AIDS threatens the economic progress of many countries around the world. In the United States HIV is now the leading cause of death among Americans aged 25 to 44. Now is when we must move forward and build upon our efforts -- the future of our Nation and of our children and our world depend on it.

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This is a time of great challenges and great ^{opportunities} opportunity. And while AIDS is a terrifying tragedy that has already affected far, far too many people around the world, I believe it is a disease that we can defeat -- just as we have defeated polio, smallpox, many forms of cancer, and other ^{health} scourges in the history of our planet. We will be able to win our battle with HIV and AIDS with commitment, courage, and leadership.

Scope of the HIV/AIDS Pandemic

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

An Expanding Public Health Threat

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

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

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cases have been on the rise¹ and in 1994 alone, more than 1,000 new pediatric AIDS cases were reported -- an 8 percent increase in just one year.

Communities of color are more severely and disproportionately affected. As of October 1995, African-Americans accounted for 38 percent of newly reported AIDS cases, while representing approximately 12 percent of the general population. Hispanics represented 18 percent of new cases through October 1995, although this group represents only 9 percent of the general population. In 1981 persons of color represented only x percent of AIDS cases, as of October 1995 this group now comprises x percent of new AIDS cases. Moreover, in certain regions of the country gay men of color account for approximately 39 percent of new AIDS cases. Young gay men of color aged 10 to 24 are especially hard hit, representing 53 percent of new AIDS cases nationwide.

The proportion of cases due to the common modes of transmission are also changing. The CDC estimates that in the United States approximately 50 percent of all new cases are now related directly or indirectly to substance abuse, particularly the use of injectable drugs. As a result, the incidence and prevalence of HIV infection in injecting drug users (IDUs) and their sexual partners and their children is rising.

Moreover, AIDS is no longer just an urban problem. The HIV/AIDS pandemic is spreading to rural areas, including dramatic increases in certain regions of the south. In fact, between 1993 and 1995 the largest numbers of AIDS cases (86,462) were reported from the south, which also accounted for the largest proportionate increase in cases (31%).² While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing faster than in urban areas. AIDS cases have now been reported in all 50 states, the District of Columbia, Puerto Rico, and each of the American territories. (See Figure 2.)

Internationally, the toll of the epidemic is even greater. The World Health Organization (WHO) estimates that since 1981, 2.4 million cases of AIDS have occurred worldwide. It has estimated

¹ It is anticipated that this trend could be reversed with the implementation of the PHS recommendations for the administration of AZT to women during pregnancy and to their infants after birth.

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that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 at least 25 million people will become infected with HIV, or an average of 10,000 people a day.

The Social Impact

Sadly, prejudice and discrimination are still encountered by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical services, emergency medical treatment, dental services, and medical insurance. They have been discharged from their jobs and evicted from their homes. And unlike other persons with infectious diseases, many persons living with HIV to have been the target of violence, rejected by their families, and suffered discrimination based on their HIV status.

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

Goal of the National Strategy

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

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

The national strategy for HIV and AIDS presented here is broader in scope than prior planning efforts. To date, planning has been primarily focused in the Public Health Service as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome⁴, the "Coolfont"⁵ and "Charlottesville"⁶ reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States⁷. Recommendations have also been issued from a number of groups, including the National Commission on AIDS⁸ in addition to significant planning efforts on the part of individual agencies. However, there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also incorporates issues such as housing, health care, and civil rights. This strategy addresses this important need. Moreover, realizing the goals of the strategy will require continued consultation and planning with Federal departments and agencies, and with the infected and affected communities.

Common Goals and Opportunities for Progress

This national strategy for HIV and AIDS has been developed from the bottom up. Through the Interdepartmental Task Force on HIV and AIDS (IDTF), a group that consists of representatives from executive branch departments and agencies that conduct AIDS-

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relevant work, a request went out for the agencies to identify their activities in relation to national goals and objectives. The IDTF member agencies developed their individual portions of the strategy, linking their goals, objectives, to budget levels and identifying areas for progress and collaboration. IDTF members, with their specialized knowledge on a broad range of HIV-related issues, have been crucial in identifying opportunities for progress and areas requiring special attention. In developing these areas for progress the Office of National AIDS Policy has also consulted members of the President's Advisory Council on HIV and AIDS, the activist community, participants in the White House Conference on HIV and AIDS, people on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and caregivers. The insights provided by a number of groups including the National Commission on AIDS, the Institute of Medicine and National Research Council, the General Accounting Office, and the Office of Technology Assessment have also been helpful. Therefore, the expertise and experience of those who work closely with communities, clinicians, researchers, service and research organizations, and infected persons is reflected in these goals and opportunities for progress.

Based on these consultations, the following national goals are established.

- Provide strong support for research in order to find a cure for those currently infected and a preventive vaccine to protect the uninfected.
- Provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections.
- Ensure appropriate care for and ethical treatment of persons with AIDS.

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

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- Strengthening HIV prevention activities;
- Supporting diversified research approaches;
- Strengthening approaches to substance abuse treatment and prevention;
- Strengthening the health care and services safety net;
- Improving translation of research results into medical practice; and,
- Improving evaluation and priority setting.

Within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of this strategy, there is specific discussion about opportunities for progress that are relevant to that substantive area.

Challenge of the HIV Epidemic

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. But, the challenges we face today are very different than challenges we have faced so far. It is a growing epidemic in which more persons are infected every year, in every geographic area, every ethnic and racial group, and every age range. [We now know how it is transmitted, the etiological agent, and we have a test to diagnose infected persons and protect the blood supply.] And thanks to behavioral researchers and the innovative outreach and prevention strategies developed by community groups, we have prevention models that work. The challenge before us now is to build on these successes and develop prevention interventions that reach even more Americans at risk for infection. Thanks to clinical research, significant progress has been made in drug development and clinical care. As a result, people with AIDS now live twice as long as they did a decade ago. And with the results of the NIH-sponsored research we now have the ability to prevent perinatally acquired HIV infection in some newborns by treating women with AZT during pregnancy.

A significant challenge facing the country now is ensuring access to prevention services and medical care for the growing number of people who are currently disenfranchised from the health care system. We need to improve our efforts in providing people with care early in their infection so they can receive quality health care. We also need to train health care professionals so they know the best way to provide that care. Strengthening our prevention efforts has never been more important. Developing prevention messages that are specially targeted to the group or

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groups they are intended to reach is critical if we are to reduce the number of new infections. And, from a societal perspective, we still have a long way to go in overcoming fear and discrimination.

Moreover, HIV and AIDS is just one of many infections emerging world-wide that has the potential to devastate communities and nations. It is one of the most lethal epidemics to affect mankind, but it is probably not the last challenge of this kind that we will face. There are likely to be others for which there is no cure, treatment, or vaccine. Our efforts in combatting the pandemic of HIV and AIDS could well benefit us not only in ending this pandemic, but in preventing future ones as well.

Overview of Federal Efforts

Introduction

The scope and nature of the HIV/AIDS epidemic has brought state, local, and Federal involvement into many AIDS-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in Federal activities since the beginning of the epidemic. Currently, these activities include direct support for research, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and other nations. While Federal agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for state and local governments and community-based organizations, which often have substantial surveillance, prevention, and health care responsibilities.

The national strategy for HIV and AIDS has been organized around the substantive areas that reflect the major components of the Federal effort: prevention, research, care and services, international activities, translation of science into practice, and civil rights. Current agency activities have not been organized around administrative structures, but by substantive areas. In cases where a single agency may have responsibility for more than one component of a substantive area, such as prevention and research, documentation of their activities will be found in the respective substantive sections. In many cases there are cross-cutting issues that could fall in several categories, such as internationally-based treatment and prevention efforts. In this case, programs that are specifically targeted towards countries or regions, are included in the international section. Efforts that are part of an overall program that may include domestic and overseas endeavors, are included in their relevant sections, and not the international activities section.

*what does
this
mean?*

Agency support of HIV/AIDS activities falls into two general categories, where HIV/AIDS activities are a central part of their mission or, not an explicit part of their mission but AIDS-related activities are indirectly supported or receive collateral benefit from agency supported work and/or policies. There are a number of agencies for whom AIDS-specific activities are central to their mission (e.g., the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the

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Health Resources and Services Administration (HRSA)), while other agencies maintain programs and activities that support a broad range of activities, of which HIV-related activities are one among many (e.g., the U.S. Agency for International Development (USAID) and the Department of Justice (DOJ)). Agencies that support research and provide shared access to highly sophisticated and expensive technology, such as the Department of Energy and its support of sophisticated imaging equipment, can assist a wide range of researchers including those studying HIV. Data are therefore presented in a manner consistent with the level of involvement an agency may have.

This report is organized by the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights. Information and discussion of Federal activities can be found in two places. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has an associated appendix that provides information on individual agency goals, objectives, funding levels, constituency involvement, and unmet needs. Given that agencies and departments may have several areas of responsibility, listings of individual agency activities may be found in more than one appendix.

PREVENTION

The Nation's prevention goal is to provide solid support for effective prevention strategies so as to reduce the number of new infections each and every year until there are no new infections. Achieving this goal will require a dedicated alliance between the Federal government, states, local governments, communities, businesses, non-governmental organizations, families, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the prevention task faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.² The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 American will become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of the virus' virulence, long period of time/where people may not be aware of their HIV status, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted primarily as a result of personal and private individual behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a vast diversity of age, race, HIV status, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors. not
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Prevention activities are currently supported by several Federal agencies. (See Appendix A.) Most Federal prevention efforts are funded by the Public Health Service, although other departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These

² This section will address primary prevention activities. Other aspects of prevention, such as secondary prevention (i.e. preventing complications of HIV infection), development of topical microbicides, the behavioral components of vaccine research, and international prevention activities will be discussed in the following research, care and services, and international activities sections.

efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the agency with primary Federal HIV-prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with states, local governments, and community-based organizations. Other agencies focus on specific aspects of prevention. For example, the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income, medically underserved persons.

The efforts of Federal agencies have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both formal research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will prompt behavior change.

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

Opportunities for Progress

Modes of Transmission

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

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

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

There are, however, opportunities for refinement. Effective prevention intervention programs begin with sound information on who is at risk. Current CDC surveillance systems do not currently capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (These data must be collected with the appropriate confidentiality protections.) Collection of these data are needed as part of an enhanced effort to link surveillance and epidemiological data to priority setting, in addition to the design and evaluation of prevention programs. The CDC has recognized the value of this approach and has incorporated data collection design into its community planning process. These shifts in data needs also require that the CDC reevaluate and reconfigure its data collection efforts; such a change may require reconfiguring of currently collected data to address these needs. As part of the agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies⁹, the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Gaps in Scientific Knowledge

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

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

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

In HIV and AIDS, this intervention research can focus on both individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.¹³ Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.¹⁴ A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.¹⁴

However, despite these successes, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research regarding strategies that facilitate sustained adoption and maintenance of HIV preventive behaviors. Another area for investment is research on cultural barriers and strategies to reach populations resistant to behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism for reducing HIV risk behavior. Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related disciplines will invariably improve the development of effective prevention interventions.

Social Marketing Research. It is important that the findings from basic behavioral and intervention research be incorporated into prevention programs. Agencies supporting social marketing activities need to build on current knowledge in addition to strengthening efforts to understand barriers to the implementation and replication of promising prevention programs. Given the highly innovative nature of these endeavors, the CDC must give consider providing broader technical assistance and training to community organizations. Moreover, a community-based effort that would test prevention models in a real-world setting should be carefully considered.

We know from efforts in other countries that HIV related social

marketing efforts can be successful. However, in the United States, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the design and implementation of prevention interventions. There are good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

Current Gaps in Program Areas

In order to stop new infections, the results of basic behavioral, intervention and social marketing research must serve as the foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, the shifting demographics of the epidemic coupled with restricted resources has resulted in gaps in program areas that limit the Nation's ability to prevent new infections. It is therefore important that prevention planners carefully prioritize their efforts based on local epidemiology.

Community Involvement. For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

One of the most important innovations in the prevention area is community planning. The community planning process is an outstanding model of a Federal-local partnership. Through this effort, it is possible to establish joint goals for the prevention of HIV that will meet Federal standards while remaining responsive to local needs. However, this process is early in its development and requires significant, ongoing leadership and technical assistance from the CDC if it is to fulfill its potential for good priority setting and decision making.

Substance Abuse Treatment. Injection drug use is one of the major forces driving the epidemic with half of all new cases ^{being} directly or indirectly related to this mode of transmission. Limiting the impact of this mode of transmission will require efforts on several fronts. First, we need to improve the integration of HIV prevention activities and substance abuse

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

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

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

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

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

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

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Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these inter-dependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

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

There is scientific evidence that controversial harm reduction approaches, such as needle exchange programs, can be effective. Among the conclusions presented in a recent report by the Institute of Medicine was that there is no credible evidence that drug use is increased among participants as a result of needle exchange programs that provide legal access to sterile equipment. The IOM also concluded that the lower the fraction of needles in circulation that are contaminated, the lower the risk of new infections. They went on to recommend that needle exchange programs be regarded as an effective component of a comprehensive strategy to prevent infectious disease.¹⁸ There is also evidence that needle exchange programs provide an opportunity to get people into treatment, thereby further reducing their risk and the risk for their sexual partners.

While the data strongly support the effectiveness of needle exchange programs in preventing the spread of infection, we continue to believe that decisions regarding these approaches should be a community decision based on local epidemiology. We also believe that certain existing statutes restrict potential prevention efforts. The Federal government will work with state and local officials to provide the information they need to take advantage of this intervention.

³ Harm reduction efforts support people by reducing their risk of HIV transmission by teaching behaviors that do not transmit HIV. In the case of HIV and substance abuse this can include: needle exchange programs, decriminalization of needle and syringe possession, legalizing syringe purchases without prescription, increasing the availability of clean syringes, providing information on cleaning injection equipment ("cleaning works"), and reducing needle sharing behaviors.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. This includes incorporating a patient's sexual history when a medical history is taken, offering HIV-related counseling and voluntary testing, and working with HIV positive individuals so they do not infect others. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to local and Federal governments.

Evaluation. It is important to assess the effectiveness of the prevention interventions that have or will be implemented. Prospectively set performance measures can be used as a basis for evaluation and program improvement. Incorporating effectiveness measures must become a routine part of all Federally-funded programs. It is only through sound evaluations that we will be able to determine whether our efforts have been effective in slowing the epidemic. Achieving this will also require careful examination of what programs should be continued, what activities need to be initiated and a awareness that a reconfiguration of some program priorities may be required.

RESEARCH

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

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

Contributions of Research

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

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followed by bone marrow transplantation; this treatment that causes profound immunosuppression and only 1 in 20 women generally survive the transplant. Advances in treating diseases resulting from immunosuppression have come from HIV-targeted research. HIV-related research has also accelerated study of the human immune system which has in turn improved our ability to understand and treat other conditions such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. HIV research involving the blood/brain barrier has led to a better understanding of the mechanisms by which infectious agents spread into the nervous system. This research has valuable implications for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Moreover, before the AIDS epidemic, little investment was made in research to treat viral diseases. Studies to develop anti-HIV therapies have improved our understanding of other viral diseases and led to development of treatments for many other diseases.

In addition, research investments made before the advent of AIDS epidemic produced a body of scientific knowledge that enabled researchers to more quickly pursue theories and avenues of investigation. For example, research conducted previously on the immune system in general, and CD4+ cells in particular, provided early insights into the pathogenesis of HIV. Research investments in retroviruses provided valuable information for identifying HIV as the etiologic agent of the emerging epidemic, and advances in molecular biology provided researchers with the tools to understand HIV's structure and develop drugs based on that information.

Due in great part to this Federally-sponsored research, persons with AIDS now live twice as long as they did a decade ago. AIDS-related conditions that used to mean a quick and often painful death for people living with HIV can be treated and even prevented. An NIH study found that it is possible to dramatically reduce the chance of transmission of HIV from mother to infant. Thanks to our investment in prospective epidemiological studies we are beginning to understand the factors that enable long-term non-progressors to live many years after infection virtually disease free. Understanding what happens in these non-progressors may help us develop better therapies and a vaccine.

And there is further reason for hope. Scientists now believe that a vaccine is possible. New classes of anti-retroviral therapies appear to be powerful in controlling the virus.

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Combination therapies are also showing great promise in this area. In addition, the Food and Drug Administration, through its accelerated approval program, is now approving drugs faster than ever before and faster than any European nation. *interesting*

However, despite these advances there is more that needs to be done to reach the national goal of a vaccine and a cure. The epidemic of HIV and AIDS presents an unprecedented challenge. HIV is unique in that it attacks the very immune system that is supposed to protect us from disease -- mankind has never before encountered a virus such as this. Since the beginning of the epidemic, identifying the best approaches to pursue and support has been, and continues to be, a challenging task. Identifying the most promising scientific avenues and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities will require a considered and coordinated effort.

Opportunities for Progress

Coordinated Research Plan and Budget. Developing and implementing the Federal government's AIDS research agenda presents a number of challenges. Within the NIH, the agency with the largest HIV-related research portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, and fund the AIDS research activities of these ICDs, the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. As part of fulfilling the requirements of the law, the OAR develops a yearly NIH plan and budget for AIDS research and receives directly from the President and the Office of Management and Budget (OMB) a single appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgement and provides flexibility for pursuing the most promising research opportunities. It is crucial that the authority granted OAR in the revitalization legislation, including the single appropriation, be supported and maintained. With such a large research enterprise it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

It is also clear that while NIH supports a significant portion of HIV-related research, other agencies and departments also play a

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significant role in our search for a cure and a vaccine for HIV. If the government is to effectively support a diversity of promising approaches, these research efforts must also be well-planned, coordinated, and maintain accountability. To achieve this the Director of the Office of National AIDS Policy will coordinate an inter-departmental working group, chaired by the Director of the Office of AIDS Research, whose charge is to develop a coordinated plan and budget specifically for HIV and AIDS research across all departments.

Vaccine Development. Reaching the goal of developing a vaccine will require the joint commitment of government and the private sector. Several challenges currently face the U.S. and the world in continuing the vaccine development effort. The first is to meet the daunting scientific challenge and the second is to create an environment where the private sector can effectively join in partnership with the Federal government. The National AIDS Drug Development Task Force (ADDTF), which included representatives from government, the private sector, and the activist community, identified a range of approaches to accelerating the development of therapeutics for HIV infection. And while the ADDTF focused primarily on the development of HIV-related therapeutics and not vaccines, one of the areas identified by ADDTF and the Department of Health and Human Services members for further discussion was vaccine development. Further dialogue involving key players in this areas was deemed as essential in determining and overcoming critical problems and identifying opportunities for development. Therefore, in order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, President Clinton has asked the Vice President to convene a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents.

At present researchers hold two major views regarding the most promising approaches to vaccine development. Some scientists believe that we need to return to basic science to gather more information to guide us, while others believe that only efficacy trials will provide the answers that really matter and in the face of a global emergency we must empirically test candidate vaccines in people immediately. Both groups have valid arguments.

The issues driving this debate are both scientific and social, with different parts of the world experiencing the epidemic in different ways. Some regions of the world have already experienced the devastating consequences of the epidemic while,

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in some regions the epidemic is in its early stages. Some governments have shown a greater interest than others in pursuing vaccine trials as a method of slowing the growth of the epidemic in their countries. Both the social and scientific issues must be considered when planning trials. However, given the state of scientific knowledge, both the 'basic' and 'empirical' avenues can, should, and are being pursued.

It is also vital that this effort be well-coordinated and that all available data are shared and used by scientists as vaccine development moves forward. Therefore, a coordinated vaccine program that ensures support for promising avenues of vaccine research, will be one of the issues addressed in the aforementioned interdepartmental research plan to be developed under the direction of the Director of the Office of AIDS Research.

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

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

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

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

Due in part to the FDA's accelerated approval program⁴, the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether the treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding clinical effectiveness is increasingly unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that the post-marketing efficacy studies, currently mandated through regulation are carried out. Conducting these studies will require the efforts of clinicians who have demonstrated their ability to carry out the long-term follow-up of patients that such clinical effectiveness studies require. It is also essential that these studies, like all studies, include persons representing a diversity of race, ethnicity, gender, age, and drug using behaviors. If these studies are not done we will not know which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for these less effective treatments.

One of the most difficult tasks for clinicians and patients is

⁴ The accelerated approval program permits companies to seek approval of drugs for serious or life-threatening illnesses based on surrogate or laboratory markers, such as CD4+ cell count or viral burden measures. For drugs approved under this program, the sponsoring company is required to conduct follow-up studies that determine whether there is a clinical benefit for the patient. There is currently concern that these subsequent clinical effectiveness studies are not being^{done}. However, by law, if the subsequent studies do not prove a clinical benefit, approval may be withdrawn by the FDA.

interpreting the patchwork of data and articles regarding treatments and converting it into a therapeutic strategy. With every research breakthrough, this task becomes more difficult. It is essential that practical information for practicing clinicians and their patients is provided in a timely manner. The Federal government must develop a mechanism for ensuring periodic assessment of the state of the art, ensuring that essential information can be found easily, and disseminating that information widely. This will require collaboration with industry, government, and professional groups. [See Translation of Science into Practice section for further discussion.]

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

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

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

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Research: An Investment for the Future. And finally, research is an investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead them to a cure and a vaccine. At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other departments and agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to improving lives and the Nation must continue this investment.

CARE & SERVICES

One of the national goals is to ensure appropriate care for all persons living with HIV and AIDS. For many of these persons, maintaining adequate health insurance coverage can be extremely challenging. There are many who exhaust their personal resources and private sector options over the course of their illness and are left to rely on the nation's medical care safety. Achieving the goal of ensuring appropriate care of all Americans, including those living with HIV, will require a dedicated alliance among the Federal government, states, the private sector, local communities, community-based organizations, clinics, families, and individuals.

Background

Persons living with HIV finance needed health care services through a variety of mechanisms. Currently, nearly 50 percent of adult Americans living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care. For the remainder, their lives often depend on the Federal health care safety net. (See Appendix C.)

For those ^{who} that qualify, care and services are provided through a number of Federal agencies, many in cooperation with local organizations and the AIDS community who have admirably served those living with HIV. Taken together, these efforts form a valuable, if incomplete, safety net for some of the most vulnerable people in our Nation. By far the largest sources of care for persons living with HIV are Medicaid and Medicare. For Americans living with HIV, Medicaid is the single largest source of health care financing, providing coverage for nearly 50 percent of adults and more than 90 percent of children living with AIDS.

A second major source of care is provided through Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA); it was established to fill certain gaps in coverage for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and states primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title III of the Act provides early intervention services such as

counseling and testing, medical care, and educational services for medically underserved persons with the goal reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs. Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs.

Opportunities for Progress

The challenge before us today, especially in light of the restricted fiscal environment, is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. To achieve this, AIDS care and service programs must build upon past successes, continue to improve prioritization efforts, improve accountability, and increase the cost-effectiveness of services they provide.

The Health Care Safety Net. We must continue to adequately fund the program that is the cornerstone of care -- Medicaid. Medicaid is the lifeline of support to millions of Americans. It provides access to doctors, hospitals, treatments, and home care -- the services that allow people to live longer more productive lives. Present Congressional plans to cut the Medicaid program overall by \$169 billion and turn it into a block grant in effect reverses this Nation's 30-year National commitment to the poor and those in need. Cutting Medicaid to this level would cut the lifeline for millions of Americans, including those living with HIV and AIDS. Maintaining this program in a viable format must be a National priority.

With the potential cuts in Medicaid and welfare, the importance of the public health safety net increases for all vulnerable populations -- disproportionately so for people with AIDS. This will require several responses. First, no one Federal program will be able to absorb the unmet need that may be created by proposed changes to the Medicaid, Medicare and welfare programs. All Federal programs, along with state and local organizations, must share the responsibility for serving and caring for people with AIDS. This must include the full integration of HIV-related care into programs that serve the needy, such as community health centers. Second, it is important that programs such as those funded under the CARE Act receive sufficient funding so as to maintain the safety net. In addition, AIDS programs must do a better job of prioritizing what services they can provide -- and

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Federal agencies must assist grantees in this regard. Treatment and primary care must come before ancillary services. And finally, the shift to managed care will have implications for programs such as the Ryan White Care Act programs. As this approach becomes more common, HRSA will need to provide more technical assistance to prepare grantees to work within a managed care structure.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV positive persons, in addition to reducing the spread of infection, lies in providing people access to an integrated continuum of health care services. This includes counseling and testing, comprehensive health care, home health care, and access to substance abuse treatment and prevention services.

One of the most powerful methods of recruiting people into primary care is knowledge of serostatus -- persons who know they are HIV positive are more likely to seek health care. Counseling and testing services can serve as a gateway to this care. Unfortunately, the majority of Americans do not know whether or not they are HIV positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking an HIV positive person with care also provides an opportunity for education so they can adopt behaviors which may reduce their chances of infecting others. This in part means offering addiction treatment to assist persons in stopping risky behaviors. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. As noted in the Prevention Section of this plan, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to local and Federal governments.

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

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of their illness.²⁰ Persons living with HIV have an increased challenge in finding affordable housing on a limited income and finding appropriate housing with needed levels of support. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS. The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. It is estimated that the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital. The HOPWA program must be protected, but it must also be acknowledged that HOPWA cannot do it alone. Protecting this component of the safety net and providing housing for persons living with HIV will require integrating housing services into other programs and ensuring a shared responsibility between Federal, state, local governments and community organizations.

Prisoners. There are also groups of people, such as prisoners, who fall outside these traditional safety net programs. While most prisoners living with HIV are incarcerated in state and local prisons, medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Both identifying the HIV positive prisoners and ensuring access to quality care for incarcerated persons is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and access to research opportunities that do not face the non-incarcerated population.

Improving access to appropriate HIV-related care in prisons must be a priority. This effort can be accomplished by improving the knowledge and skill of the health care team in the prison in the management of HIV-related issues. In addition, efforts must be made to improve collaborative efforts to build linkages between prisons and outside public health departments and agencies who have experience in providing care for prisoners. These efforts can also serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.

Program Coordination. For care and services to have the most beneficial impact they must be coordinated and comprehensive.

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However, for organizations on the front lines of the epidemic, putting together a comprehensive integrated program requires applying to numerous Federal agencies. For example, creating a program that integrates primary care with substance abuse treatment and prevention, and sexually transmitted disease screening and prevention would require separate applications to SAMSHA, HRSA, and CDC. Adding housing assistance and a research component would require additional applications to HUD and the NIH. The Federal government needs to simplify its funding structures so that primary care, prevention, and treatment can be integrated in order to provide cost-effective, integrated services to HIV-infected persons and persons at risk for HIV, such as substance abusers and their partners. Through the Interdepartmental Task Force for HIV and AIDS (IDTF), key agencies must identify approaches for facilitating the development of integrated care and prevention programs at the implementation level.

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those on the frontlines of the epidemic. It can assist us in providing better care to persons living with HIV. In an era of limited resources coupled with a demand for cost effective services of high quality, we must use all the tools available to us if we are to help those persons living with HIV.

Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care. One Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection. However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal agencies, professional organizations, medical schools, and individual clinicians.

INTERNATIONAL ACTIVITIES

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

This pandemic presents a unique set of health, social, economic, and political challenges. It most often affects people aged 25 to 44 -- those who are in the most productive years of life. The period from initial infection to disease onset can be many years, during which time persons many unknowingly spread the infection. The WHO estimates that there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.²¹ Governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

Due to the global nature of the pandemic, its negative impact on both developed and developing countries cannot be overstated. It is clear that if we do not stop the pandemic globally, we will not be able to halt its spread in the United States.

At present several Federal agencies are working on slowing the AIDS epidemic worldwide. (See Appendix D.) The Department of State has worked with other departments, agencies, and non-governmental organizations to develop a framework to guide U.S. foreign policy in the global efforts against HIV and AIDS. The major areas identified for U.S. leadership are: preventing new infections; reducing the personal and social impact of the pandemic; and mobilizing and unify national and international efforts. The U.S. Agency for International Development (USAID) also has a leadership role in the global HIV effort through development assistance, research and policy formation. USAID focuses its strategy on developing prevention programs based on proven interventions, addressing social, cultural, regulatory and

economic issues related to HIV/AIDS and other sexually transmitted infections, and developing and testing new interventions and methods to prevent transmission and mitigate the impact of the epidemic. The U.S. Information Agency (USIA) supports programs that promote dissemination of U.S. policies and information related to HIV and AIDS; and the Peace Corps trains a portion of its volunteers to directly address HIV-related concerns in their countries of placement. In addition, several agencies support research overseas, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Defense (DOD). For example, DOD is conducting clinical trials of candidate HIV vaccines in Thailand. NIH (working in collaboration with USAID), supports basic scientific studies on social and behavioral aspects of AIDS in developing countries. The results of the studies ultimately will be used to develop interventions to reduce behaviors that place individuals at risk for contracting HIV infection.

Opportunities for Progress

International Leadership. The United States has established a global leadership role in combatting the epidemic. This leadership must continue. The U.S. strongly supports the newly established Joint and Co-sponsored United Nations Programme on AIDS (UNAIDS)⁵. Moreover, the U.S. is a member of the governing body of UNAIDS. Supporting UNAIDS demonstrates the continuing commitment of the U.S. to collaborate with other countries in lessening the impact of the epidemic. The U.S. also supports efforts to more effectively make use of available resources as well as to encourage non-traditional donor countries to provide much needed contributions. Supporting UNAIDS and its innovative programmatic efforts, and its goal of working to assure that therapeutics (and vaccines when developed) are made available to the residents of developing countries is not only morally correct, but also furthers U.S. interests by promoting economic and social stability worldwide.

⁵ Until recently, the United Nation's response to HIV/AIDS was focused primarily in WHO's Global Programme on AIDS. On January 1, 1996 the U.N. launched UNAIDS, combining the efforts of six U.N. agencies to strengthen coordination and focus support for HIV/AIDS activities at the country and global levels. UNAIDS has established three mutually reinforcing roles: to be a major source of policy development and research; provide technical support; and be an advocate for comprehensive, multisectoral responses to the pandemic.

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Sharing Technology and Bringing Lessons Home. In addition to financing the development of large scale, comprehensive AIDS prevention programs in many countries, USAID has gained valuable insights and lessons from experiences from these countries and is applying them to U.S. populations. Based on the Vice President's initiative to bring the lessons back home through the "Lesson without Borders Project" to inner city and rural areas with problems similar to those experienced overseas, the goal is to create linkages between U.S. community organizations and international projects in order to share solutions to problems that know no borders. The U.S., through its various agencies, will continue to build and strengthen networks that will facilitate leadership, coordination and transnational approaches to AIDS prevention and control programs and AIDS related research; exchange culturally and linguistically appropriate educational and training materials; and demonstrate the bidirectionality of USAID international programs and its potential impact on US based programs, U.S. based non-governmental organizations and indigenous groups.

Program Coordination. One of the most challenging aspects of the U.S. effort is effective coordination among a host of agencies with varied missions and activities. The State Department and agencies such as USAID and USIA are primarily focused on country-specific activities, that include many HIV-related objectives. Agencies which conduct research, such as NIH and CDC, plan their activities not around where they take place, but around scientific gaps and interests. These differences in focus present challenges in effectively planning, coordinating, and evaluating the overall U.S. international effort. Therefore, in order to improve this endeavor, the agencies supporting international activities on the Interdepartmental Task Force for HIV and AIDS must develop a mechanism for identifying and coordinating this effort.

TRANSLATION OF SCIENCE INTO PRACTICE

An important element in our fight against AIDS is ensuring that hard won research advances are translated into practice (i.e., ensuring that new knowledge is incorporated into standard medical practice of clinicians caring for persons living with HIV). The increasing presence of HIV in every community necessitates that all health care providers become knowledgeable about caring for persons with HIV. Improving the translation of research advances into daily clinical practice will require an ongoing collaborative effort on the part of the Federal government, individual health care providers, medical schools, professional organizations, international organizations, health centers and hospitals, and other parts of the private sector.

Information dissemination activities fall under the missions of several agencies. (See Appendix E.) The National Institutes of Health (NIH) supports a broad range of efforts including a "Clinical Alerts" mechanism for the dissemination of clinical trials results to health professionals, the media, and the general public. NIH also supports publicly available computerized databases such as AIDSDRUGS, AIDSTRIALS, and AIDSLINE in addition to a toll-free 1-800 TRIALS-A AIDS Clinical Trials Information Service (ACTIS). The Centers for Disease Control and Prevention (CDC) also disseminates information through hotlines such as its toll-free 1-800-HIV-0440 HIV/AIDS Treatment Information Service (ATIS) and the AIDS Information Clearinghouse. The CDC also issues guidelines for health professionals through its *Morbidity and Mortality Weekly Report*; such guidelines have included The U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women. The Agency for Health Care Policy and Research (AHCPR) has published a series of HIV-related clinical practice guidelines for clinicians and companion pamphlets for their patients; an example these materials are clinician guidelines for the evaluation and management of early HIV infection. The Health Resources and Services Administration has also developed guidances for its CARE Act grantees.

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

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

Opportunities for Progress

However, despite these successes, there are still areas for improvement. For example, an AHCPR-supported study indicated that primary care physicians miss significant HIV-related symptoms during patient examinations.²³ Other research indicates that a disturbing number of clinicians are not aware of or do not use universal precautions in the course of routine patient care.²⁴ We are also at a stage, unlike in the beginning of the epidemic, where research advances are coming more frequently. In the case of the NIH study which demonstrated it is possible to block perinatal transmission by administering a specific AZT regimen to the mother and baby, it became clear that this scientific breakthrough required a change in the standard-of-care. This change also required the development of new testing and counseling guidelines to reflect the new options available to women. And it meant that for patients enrolled in Medicaid and Medicare to receive access to this breakthrough, a policy change on the part of the Health Care Financing Administration (HCFA) was required.

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

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

CIVIL RIGHTS

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

Opportunities for Progress

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

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

The Federal government has aggressively and successfully prosecuted private sector violations of the ADA. These efforts will continue. Under this provision the government has been extremely successful in prosecuting a range of cases, including clinicians who have refused to care for HIV infected patients and employers who have dismissed persons based on their actual or

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perceived HIV status. In addition to ongoing efforts, a joint Department of Justice and Health and Human Services program will seek to combat nursing home discrimination against persons living with AIDS.

The Federal government must also actively work to remedy any of its own existing discriminatory policies. In order to identify areas of possible concern, the Director of the Office of National AIDS Policy will as soon as possible conduct a systematic review of agency and department testing programs. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

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■ **Budget Tables**

(Will be developed after confirmation of individual budget figures.)

■ **Acronyms**

ACTG	AIDS Clinical Trial Group
ADA	Americans with Disabilities Act of 1990
ADC	AIDS Dementia Complex
AHCPR	Agency for Health Care Policy and Research
AIDS	Acquired Immune Deficiency Syndrome
AOD	Alcohol and other drugs
ATOD	Alcohol, tobacco, and other drugs
BOP	Bureau of Prisons
CARE	Ryan White Comprehensive AIDS Resources Emergency Act
CDC	The Centers for Disease Control and Prevention
CMV	
CNS	Central Nervous System
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
DOJ	Department of Justice
DOL	Department of Labor
EEOC	Equal Employment Opportunity Commission
FDA	Food and Drug Administration
GCRC	General Clinical Research Centers Program
HCFA	Health Care Financing Administration
HIV	Human Immunodeficiency Virus
HOPWA	Housing Opportunities for Persons with AIDS
HRSA	Health Resources and Services Administration
HSV	Herpes Simplex Virus
HUD	Department of Housing and Urban Development
HTLV-1	
ICD	Institute(s), Center(s), Division(s)
IDTF	Interdepartmental Task Force on HIV and AIDS
IHS	Indian Health Service
IOM	Institute of Medicine
MAI	

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NCRR	National Center for Research Resources
NGO	Non-governmental Organization
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NREN	National Research and Education Network
OAR	Office of AIDS Research
OI	Opportunistic Infection
OMB	Office of Management and Budget
PCP	<i>Pneumocystis carinii</i> pneumonia
PHS	Public Health Service
PLWH	Persons living with HIV
PSA	Public Service Announcement
PVO	Private Voluntary Organization
PWA	Person with AIDS
RFIP	Research Facilities Infrastructure Program (NIH)
RPRC	Regional Primate Research Center (NIH)
RWCA	Ryan White Comprehensive AIDS Resources Emergency (CARE) Act
SAMHSA	Substance Abuse and Mental Health Services Administration
SPF	Specific Pathogen-Free
SSA	Social Security Administration
SSI	Supplemental Security Income
TA	Technical Assistance
TB	<i>Mycobacterium tuberculosis</i>
UNAIDS	United Nations Programme on AIDS
USAID	U.S. Agency for International Development
USIA	U.S. Information Agency
WHO	World Health Organization

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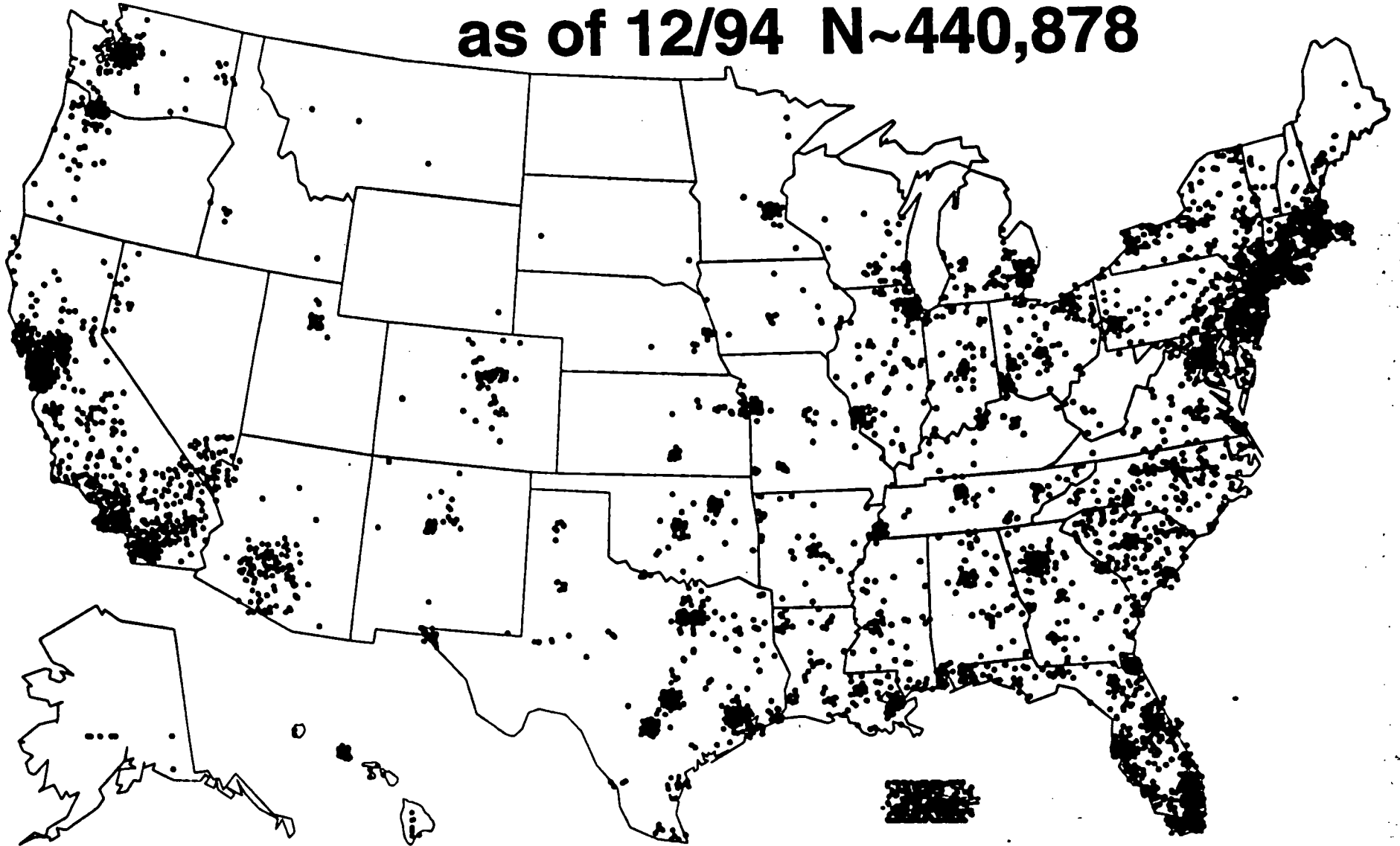
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22. Douglas S. Paauw, Marjorie D. Wenrich, J. Randall Curtis, Jan D. Carline, Paul G. Ramwey. Ability of Primary Care Physicians to Recognize Physical Finding Associated with HIV Infection. JAMA. 1995; 274:1380-1382.

23. AHCPR - confirm

CHART #2

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



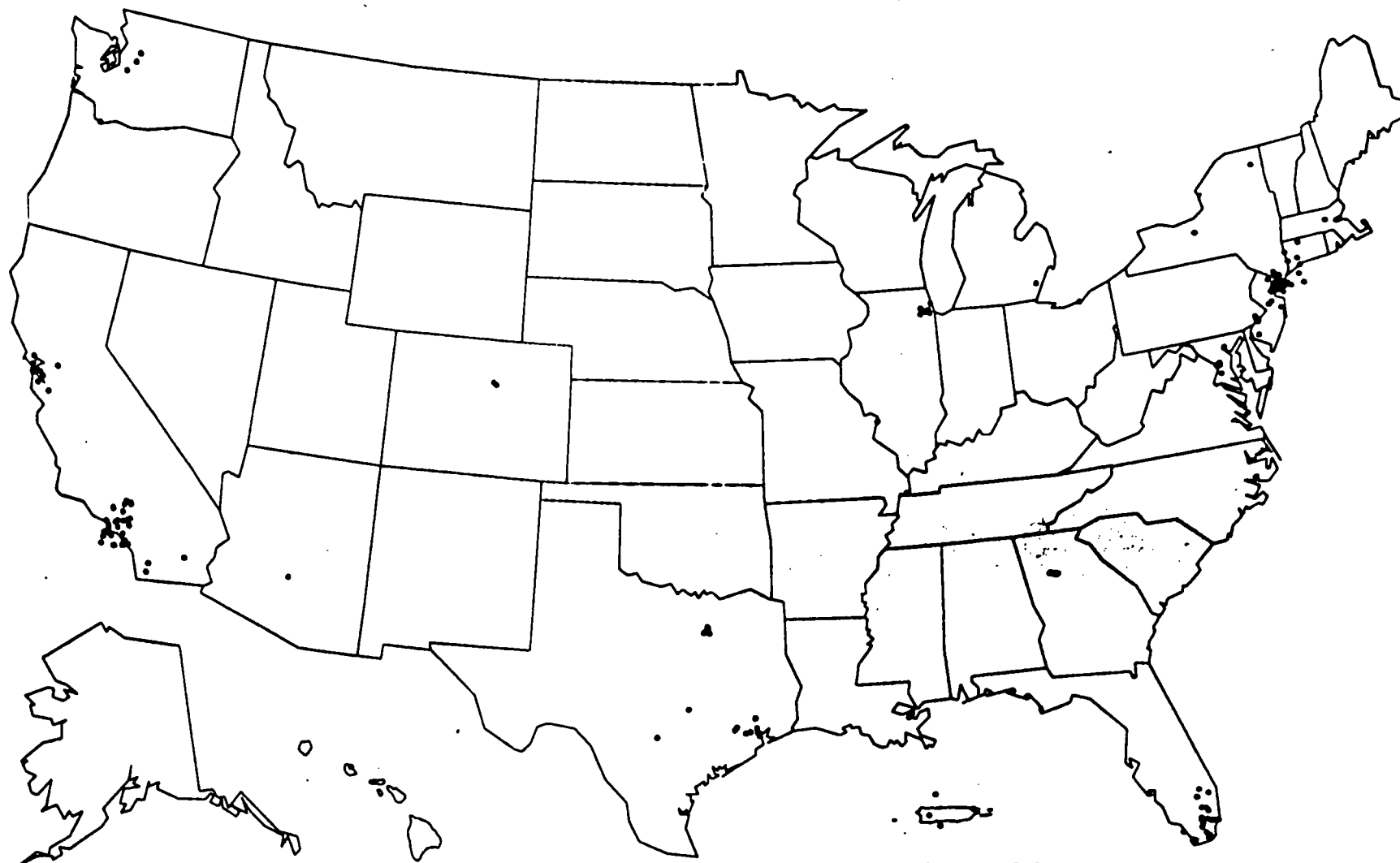
Each point = 30 cases

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



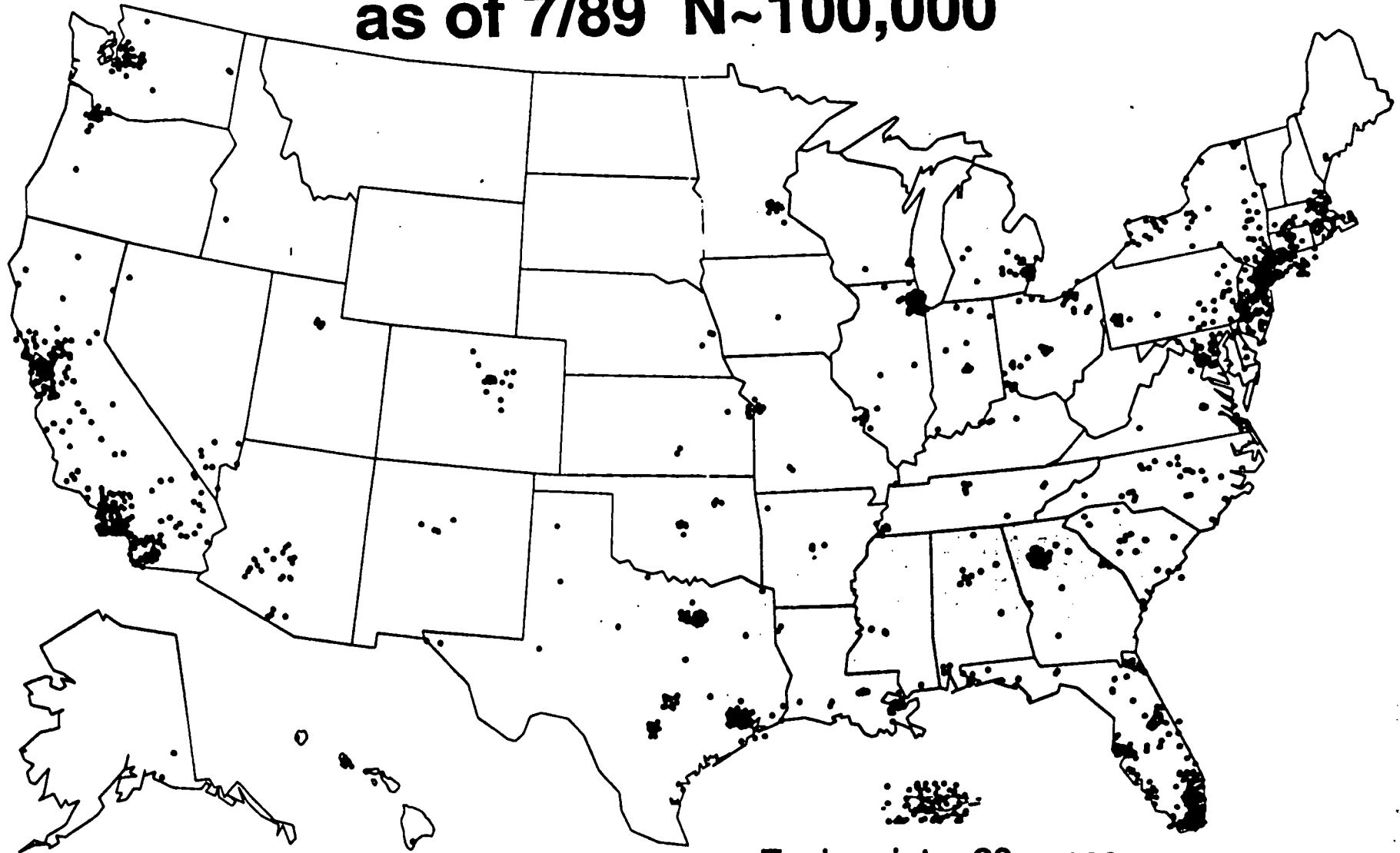
Each point = 30 cases

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



Each point = 30 cases

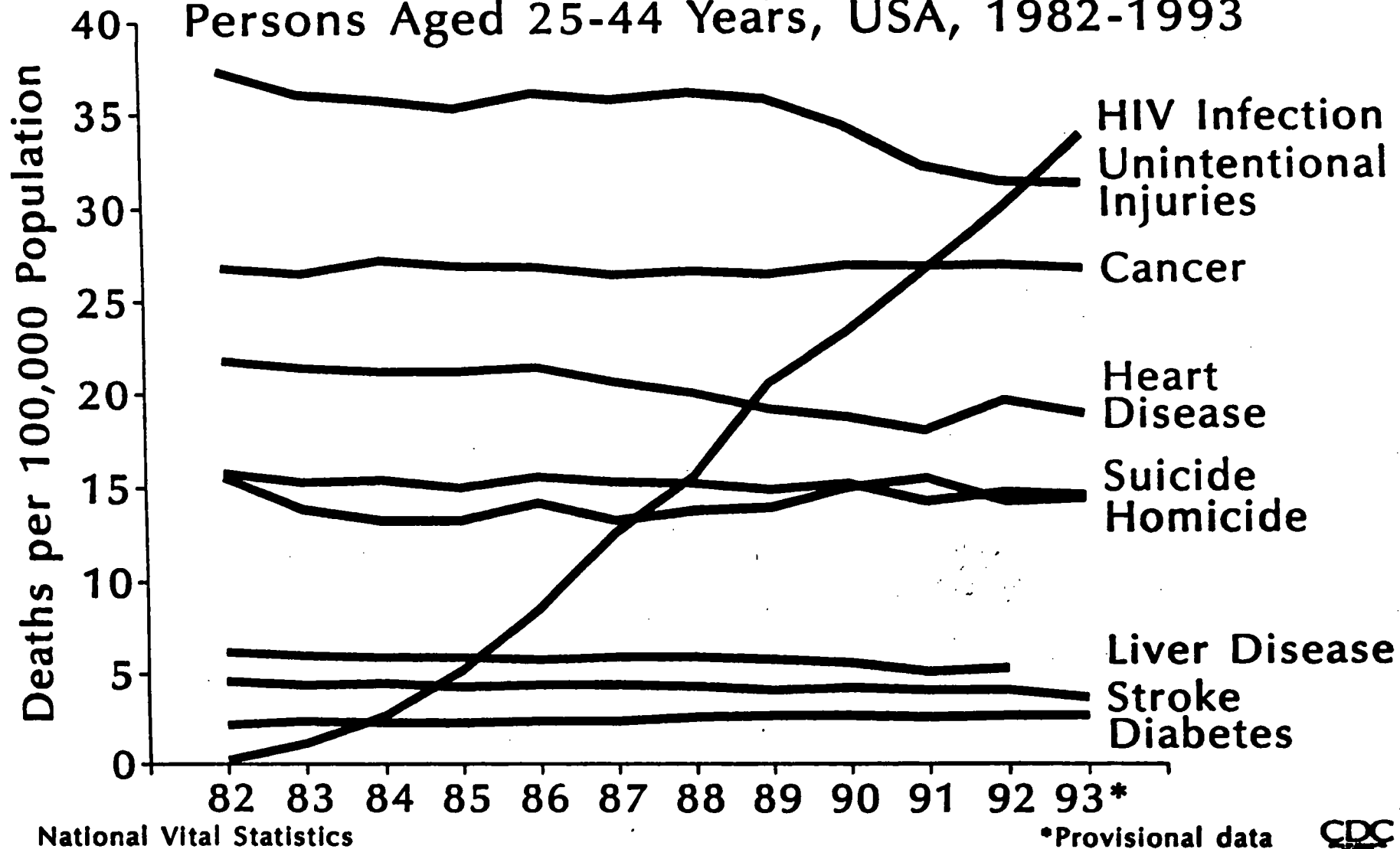
Cumulative U.S. AIDS Cases as of 7/89 N~100,000



Each point = 30 cases

CHART #1

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



• Part coding $\rightarrow$ W²re plan
need minimum to start

| call
| Jack

> Council meeting next week

> Bob Engler.

International stuff $\rightarrow$

National Institutes of Health

Area Research

Goal 1 Conduct and support research on the natural history and epidemiology of HIV infection and AIDS in all populations

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Develop and assess intervention strategies to reduce or prevent HIV transmission	Support development and evaluation of improved, acceptable, effective physical and non-irritating chemical barrier methods and conduct research on existing barrier methods to prevent sexual transmission of HIV and STDs; Develop strategies and conduct studies to evaluate vaccines, drugs, and other interventions, such as cesarean sections, vaginal cleansing, and breast-feeding practices that prevent perinatal transmission. These should include randomized trials where possible, cooperation between study groups, and re-analysis of data from existing studies, where appropriate; Assess the efficacy of combined strategies that decrease blood-borne transmission of HIV; for example, evaluating existing needle exchange programs, the use of bleach as a disinfectant, and drug abuse prevention and treatment on reducing HIV transmission and seroincidence;	48,656	48,137 PB 73,006 Bypass	All populations	Community, nter, Puts, On sec. advisory groups - (Council, ARAC, etc.) Any task, role for the boards?	24,929 Δ from the NIAH FY 1996 Comprehensive Plan + Estimate for Scientific Opportunities in AIDS Research.

gather data on the HHVLPV
Collect data to examine the transmission of HIV & progression of HIV-related disease to assist in the development of biologically based interventions.

Keep - but does it need to be p. 1?

Justin - Would you please make a copy Thanks - Julie

Put in? political problems vis-a-vis NRC report? should be in context of HHS/NIH statements.

Natural History/Epi - TOTAL

FY95 Approp	FY96 Pres. Bond	Bypass	Δ
17,014	188,822	237,271	48,449

for overall unmet need.

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Develop and assess intervention strategies to reduce or prevent HIV transmission (continued)	Develop domestic and international cohort-based infrastructures for testing HIV vaccines and other interventions (e.g., microbicides, behavioral) for preventing HIV transmission; Develop and evaluate interventions related to sexual behavior, including (1) STD treatment and prevention and their effects on HIV transmission, (2) interventions focused on influencing safe sexual behaviors, reproductive decision-making, and contraceptive choices for women, and (3) integration of health care delivery systems such as those that combine reproductive health and STD/HIV prevention and treatment services; Develop methods of outreach that would engage high-risk populations, enroll them in research to identify factors that contribute to high-risk behavior, and increase and maintain compliance with interventions as well as recruit and retain hard-to-reach populations in studies; Incorporate interdisciplinary evaluation research designs of HIV prevention strategies to ensure adequacy of findings regarding outcome, process, and descriptive analysis;					

Can these be
ordered diff?
STD/microb, et. together
Vaccine up front?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Develop and assess intervention strategies to reduce or prevent HIV transmission (continued)	Evaluate the social acceptability, the ease of compliance, and barriers to access and use of interventions (e.g., AZT for perinatal transmission, virucides); Develop and evaluate improved procedures for screening, monitoring, and inactivating HIV and other retroviruses in the blood supply; and develop and evaluate alternatives to allogeneic blood transfusion, including artificial blood substitutes and hematopoietic growth factors; and Assess the impact of drug and alcohol abuse on efficacy of behavior modification interventions directed at sexual transmission.					
Natural History and Epidemiology <i>Examine the role of risk factors + mechanisms of HIV transmission to assist in the development of biologically + behaviorally based interventions.</i>	Characterize the risk factors and mechanisms of HIV transmission in various populations <i>Objective #2, p. 42</i>	Evaluate HIV transmission in relationship to: - viral factors, virus load in the blood and at mucosal sites, characteristics of the HIV virus present (virus subtype and phenotype), and co-infection with other viruses (HTLV and HIV2); - host factors such as pregnancy, menstrual cycle, hormonal contraceptives, and HLA type;	24,271	26,257 PB 52,624 Bypass	All populations		<i>5 26,367 from...</i>

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Characterize the risk factors and mechanisms of HIV transmission in various populations (continued)	c. local factors including intercurrent STDs, oral and anogenital inflammation (ulceration), mucosal immunity, and anatomic factors such as ectopy; and d. behavioral risk factors, such as oral and anal sex; Further differentiate the timing and mechanism of perinatal transmission; Study susceptibility to HIV infection, especially in individuals who are at high risk for repeated exposure to HIV but who remain uninfected, in order to determine factors related to resistance, including mucosal immunity, viral, genetic, and other immunologic factors, endocrinologic factors, and other factors; Determine the role of breast-feeding in the transmission of HIV from infected mother to child; and Examine the extent to which drug use (including alcohol and tobacco) and drug-using behaviors affect susceptibility and/or transmission of HIV.	omit? —	26	Are there many like this? ☒ Stop on what <u>is</u> it.		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology <i>Enhance understanding of HIV-related disease progression to assist in the development of effective strategies for HIV-infected patients</i>	Elucidate the progression of HIV-related disease, from early infection through long-term consequences and sequelae, with the goal of understanding, preventing, and treating those factors that may lead to disease <i>(Objective #3, P. 44)</i>	Identify pathogenic mechanisms and cofactors for disease progression and disease-specific outcomes in well-defined subsets of individuals (e.g., high-CD4 long-term survivors, low-CD4 long-term survivors, rapid progressors). ~~Studies should include investigation of behavioral, genetic, virologic, immunologic, and host factors;~~ In diverse populations, describe the full spectrum of HIV-related disease, including OIs, HIV-related malignancies, wasting, and organ-specific complications; evaluate the impact of sociodemographic variables, gender, age, and route of transmission on HIV disease progression, time to AIDS, and specific outcomes; Study the natural history of early HIV infection; Evaluate issues specific to HIV-infected children, including: (1) mechanisms that contribute to impaired growth and neurodevelopment, (2) impact on childhood infectious diseases and the safety and efficacy of immunization, and (3) childhood-specific complications including lymphoid interstitial pneumonitis;	53,565	59,574 PB 54,983 Bypass	All populations		<i>Are we over-funding in this area?!</i>

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Natural History and Epidemiology	Elucidate the progression of HIV-related disease, from early infection through long-term consequences and sequelae, with the goal of understanding, preventing, and treating those factors that may lead to disease (continued)	Evaluate the interaction of hormonal factors (including pregnancy, contraceptives, and hormonal replacement therapy) and HIV disease progression; Maintain longitudinal cohorts and create linkage with clinical studies (e.g., ACTG, CPCRA) to (1) efficiently examine the full spectrum of disease, (2) assess the impact of therapies on the frequency and severity of HIV-related sequelae, disease progression, and survival, and (3) assess and validate laboratory and behavioral markers; Study the progression of HIV-related disease in adolescents ~~who have acquired their diseases as a result of injecting drug use and/or sexual activity;~~ Study the factors that predict, protect against, contribute to, or limit the progression of HIV infection in the nervous system including early cognitive impairment, dementia, and neuropathy;					

— as opposed to what else?

— as opposed to what else?!

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Elucidate the progression of HIV-related disease, from early infection through long-term consequences and sequelae, with the goal of understanding, preventing, and treating those factors that may lead to disease (continued)	Develop, maintain, and expand national repositories for the collection and banking of blood, other body fluids, and tissue specimens obtained from longitudinal cohort studies and other well-characterized populations of HIV-infected individuals as a resource for studies of HIV-mediated pathogenesis, correlates of immunity to HIV infection, and specific HIV-related outcomes; Study the nutritional and absorption factors that predict, protect against, contribute to, or limit the progression of HIV-related wasting and weight loss; Evaluate strategies of care delivery and case management to determine their impact on HIV disease progression and quality of life; Elucidate the mechanisms of HIV-associated carcinogenesis and improve strategies for early diagnosis and for effectively treating these malignancies; Study oral lesions in HIV disease and progression; and Study the long-term natural history of related retroviruses (e.g., HTLV and HIV-2) to elucidate retroviral pathogenesis and resistance mechanisms.					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology Enhance understanding of susceptibility to HIV infection at the biological level. <u>Review.</u>	Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease (Objective #4, p. 47) What does this mean? no behavior	Apply cutting-edge laboratory approaches and behavioral strategies to assess susceptibility to infection and transmission and monitor disease progression and response to intervention in population studies; Facilitate the transfer of novel laboratory and behavioral strategies from basic research to epidemiologic applications; Promote development and application of laboratory approaches to elucidate mechanisms, cofactors, and timing of maternal-fetal-infant transmission of HIV infection; Assess new virologic parameters (e.g., viral burden, genotype/phenotype) applicable to body fluids that correlate with infectiousness for evaluating interventions (e.g., spermicides/microbicides, vaccines); Identify laboratory parameters associated with HIV-related outcomes, such as intermediate end points preceding HIV-associated infections and malignancies, predictors of long-term survival or rapid progression, and markers of exposure to HIV without infection;	23,074	23,210 PB 28,395 Bypass	All populations		Δ 5,185

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease (continued)	Facilitate, develop, evaluate, and apply assays for assessment of mucosal immunity related to susceptibility to infection and impact of intervention; Identify, characterize, and evaluate reliable diagnostic markers, including markers in saliva, for the purpose of applying rapid and sensitive diagnostic technologies for detecting HIV infection; Promote development and assessment of assays to detect HIV infection in vaccinated populations; and Establish, maintain, and expand national repositories of biologic specimens (e.g., blood, body fluid, and tissue) obtained from well-characterized individuals in longitudinal studies to facilitate rapid evaluation of existing strategies and development of new strategies.					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Perform the epidemiologic studies of HIV infection, related conditions, and risk behaviors in domestic and international populations in which HIV is prevalent, emerging, and/or increasing	Identify emerging high-risk groups in the United States through seroincidence studies and identification of behavior risk factors in the population. Examples of groups that need particular attention and further evaluation include minorities, women, adolescents, children, young gay men, homeless mentally ill, drug users, and the incarcerated;	29,448	31,644	PB All populations		
Enhance understanding of HIV infection in populations in which HIV is prevalent, emerging, and/or increasing for the purpose of developing better Rx + Vxs.	(Objective #5 p. 49)	Develop infrastructure to define populations in the United States and throughout the world with high incidence and prevalence suitable for vaccine and other intervention trials;					
		Delineate the epidemiology of behavioral risk factors for HIV in defined population-based studies;					
		Measure the occurrence of other infectious agents, e.g., other viruses (HTLV-1, HSV-2, hepatitis B and C, etc.), sexually transmitted diseases, and mycobacterium (e.g., MTB, M. avium) in populations at risk for HIV;					
		Coordinate with the CDC, WHO, and other institutions to maintain a comprehensive view of the epidemic with as much detailed information about subpopulations as possible;					

include?

48

Are we overfunding this?

are they doing them? Is this CDC?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology	Perform the epidemiologic studies of HIV infection, related conditions, and risk behaviors in domestic and international populations in which HIV is prevalent, emerging, and/or increasing (continued)	Promote the development of new high-quality biometry programs for AIDS research evaluation, including new methodologies; Define the scope and role of HIV in the etiology of cancer and determine the impact of HIV-related malignancy on total cancer burden in the population; and Cooperate with health services agencies to determine why many individuals and groups continue to underutilize health services related to HIV that are already available (e.g., access to care, perceptions regarding efficacy, etc.).					

Who are they?
Cooperating?
AHCPR?

Who at NIH does this?

Area Research

Goal 2 Conduct and support research on the etiology and pathogenesis of HIV infection to define the mechanism by which the virus causes disease by ↓

Objectives	Action Steps	Descriptions	Programs										
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs						
			FY 1995 (apprpr.)	FY 1996 (proposed)									
Etiology and Pathogenesis Enhance understanding of HIV pathogenesis define	Delineate the cellular and molecular mechanisms associated with the viral immunopathogenesis of HIV-related immune dysfunction Objective #1, p. 61	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;	201,040 FY 95 est. 122,052	217,368 PB 168,661 Bypass	All populations	Basic Research overfunded. Refuse ->							
Etiology Pathogenesis TOTAL <table><tr><td>FY95 Approp.</td><td>FY96 Res Bud.</td><td>Bypass</td><td rowspan="2">} 46,716</td></tr><tr><td>345,663</td><td>374,767</td><td>420,983</td></tr></table> (unmet need)							FY95 Approp.	FY96 Res Bud.	Bypass	} 46,716	345,663	374,767	420,983
FY95 Approp.	FY96 Res Bud.	Bypass	} 46,716										
345,663	374,767	420,983											

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis	Delineate the cellular and molecular mechanisms associated with the viral immunopathogenesis of HIV-related immune dysfunction (continued)	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 <i>in vivo</i> 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.					
Etiology and Pathogenesis	Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression	Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection;	28,140	34,233 PB	All populations		
		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;					

Keep? Why not?

114,152 Bypass

highlight as major area of unmet need, esp. opportunity?

Perhaps combine Objectives #1 + 2 -> seem similar and apparent overfunding of #1 looks strange.

Cps

Enhance understanding of cellular + molecular mechanisms that underlie HIV-related immune dysfunction.

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis	Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression (continued)	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.					
Etiology and Pathogenesis Enhance knowledge about HIV-related cancers.	Elucidate the etiologic factors and cofactors in the pathogenesis of HIV-related malignancies (Objective 3a, P. 64)	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.	28,544	28,941 PB All populations 16,795 Bypass			

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Etiology and Pathogenesis Enhance understanding of HIV-related neuropathogenesis.	Elucidate the pathogenic mechanisms involved in HIV-associated neurological diseases (Objective 3.b, P.65)	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, using ~~neurological and appropriate neuropsychologic assessment tools;~~ 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	38,984	41,067 PB 47,363 B pass	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		Develop neuroimaging tools for correlative structural-functional studies of progressive HIV-associated neurological disorders.					
Etiology and Pathogenesis Enhance understanding of HIV-related OIs.	Elucidate the pathogenesis of HIV-related opportunistic infections (Objective 3C, P.67)	Elucidate the mechanisms of immune function that mediate protection against the OIs; Develop <i>in vitro</i> 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.	32,222	35,151 PB 46,775 Bypass	All populations		

Objectives	Action Steps	Programs				
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Etiology and Pathogenesis Enhance understanding of HIV-related pathology.	Elucidate the etiology and pathophysiology of HIV-related wasting, failure to thrive, and growth retardation (Objective 3d, P. 74)	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.	2,931	2,918 ^{FB} 6,638 ^{Bypass}	All populations	
Etiology and Pathogenesis Enhance understanding of HIV-related organ/tissue disorders.	Elucidate the etiology and pathogenesis of HIV-related organ/tissue-specific disorders, such as HIV-associated renal, gastrointestinal, endocrine, cardiopulmonary, autoimmune, and other diseases (Objective 3e, P. 75)	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.	13,802	15,089 ^{FB} 18,591 ^{Bypass} ▶ Objective 3 compressed 14,95 ^{FB} 102,681 108,077 119,571 ▶ Compress 1-3e FY 95 ^{FB} 345,663 371,767 420,983	All populations	

Area Research

Goal 3 ~~Conduct and support research to develop~~ therapeutics for HIV infection and its sequelae

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics . Identify & develop novel anti-HIV therapies.	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry (Objective 3.1, p. 83)	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;	154,833	162,200 ~~15~~ All populations 134,980 ~~Bypass~~			

Therapeutics

~~Total~~

FY95 Approp.	FY96 Res. Bud.	Bypass	Δ
473,262	495,839	545,405	47,566

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry (continued)	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 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;					

} Coord. E Energy ?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry (continued)	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.					
Therapeutics <i>Evaluate new AR therapies.</i>	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies <i>(Objective #2, p. 85.)</i>	Support and improve clinical trials of potential therapeutic agents and combinations of agents in studies to determine pharmacokinetics and bioavailability and evaluate anti-HIV combinations that are non-cross-resistant, synergistic, and toxicity-sparing and that may delay development of drug-resistant HIV strains; enhance collaboration between and within ICDs to facilitate opportunities for clinical trials; Increase the understanding of the pathogenesis of HIV disease based on the evaluation of antiretroviral agents in clinical trials;	145,105	151,627 ^{PB} <i>Bipase</i> 216,181	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies (continued)	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 <u>clinical trials methodology and study design</u> 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; Establish and expand appropriate career training programs for laboratory investigators, clinical investigators, and translational scientists; Develop and validate quality-of-life parameters included in patient assessments of clinical trials;					

(?)

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Therapeutics	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies (continued)	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					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		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.					
Therapeutics <i>Evaluate immune-restorative therapies</i>	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 <i>Objective #3, p.89</i>	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;	18,619	19,349 <i>PB</i> 21,779 <i>Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	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 (continued)	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.					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics <i>Evaluate OI therapies</i>	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 <i>(Objective #4, p. 89)</i>	<i>Use data from basic research</i> 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;	107,915	111,887 PB 97,787 Bypass <i>already in basic section.</i>	All populations		
Therapeutics	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 (continued)	~~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 <i>Pneumocystis carinii</i>;~~ <i>already in basic section.</i>					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics		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. ~~Important OIs include <i>Mycobacterium tuberculosis</i> infection (TB), <i>Mycobacterium avium</i> complex, cytomegalovirus infection, cryptosporidiosis, microsporidiosis, cryptococcal disease, azole-resistant fungal infection, toxoplasmosis, PCP, acyclovir-resistant herpes infections, progressive multifocal leukoencephalopathy (PML), bacterial infections, and other infections whose course is affected by HIV.~~ Evaluate immune-based therapies as adjuncts for treating OIs;					
	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 (continued)	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. Strategies need to focus on time of initiation, compliance, pharmacologic interactions, toxicities and adverse reactions (e.g., trimethoprim sulfamethoxazole reactions), and minimizing development of resistance; studies should include quality-of-life assessments and cost-benefit analyses;~~					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	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 (continued)	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, especially TB, MAI, enterics, CMV, HSV, fungi, toxoplasma, and JC virus; Support training of basic investigators, clinical investigators, and translational investigators for OI research; and <i>→ why in this section →</i>					
		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.					
Therapeutics <i>Enhance understanding</i> <i>Develop interventions for vertical transmission.</i>	Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child <i>(Objective #5, P. 91)</i>	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;	5,690	6,138 <i>PB</i> 29,474 <i>Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apppr.)	FY 1996 (proposed)			
Therapeutics	Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child (continued)	Develop strategies and agents to interrupt the vertical transmission of HIV from pregnant women to their offspring, including ~~antiviral agents, anti-HIV immunoglobulin, and monoclonal antibodies, HIV vaccines, adjuvants, virucides, and other intrapartum interventions;~~ 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;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		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.					
Therapeutics <i>Develop treatments for HIV-associated malignancies,</i>	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 <i>(Objective, #6, P.93)</i>	Support basic research on HIV-associated malignancies to increase fundamental knowledge of the etiology, pathogenesis, and biology of these neoplasms; develop preclinical models for testing potential therapeutic strategies; Identify novel mechanisms and targets (e.g., cytokines, angiogenesis, viral or hormonal cofactors) for treatment and prevention of HIV-associated tumors, including Kaposi's sarcoma, non-Hodgkin's lymphoma, HPV-associated malignancies, and others, and develop new therapeutic strategies on the basis of these findings;	16,642	16,939 PB	All populations		
				17,430 Bypass			
				<i>Indicated in basic section.</i>			

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	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 (continued)	Use structural biologic and biochemical information to rationally design drugs to inhibit specific pathogenic factors of HIV-associated malignancies ~~(e.g., oncoprotein of HPV);~~					
		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 ~~(e.g., agents with better CNS penetration, agents with better safety profiles);~~					
		Develop trials to optimize existing therapies for malignancies in HIV-infected patients, <u>including therapeutic adjuncts such as hematopoietic colony-stimulating factors and supportive care; develop and validate quality-of-life assessments;</u>					

(copy to be sent to the NIH)

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Therapeutics	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 (continued)	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 <u>investigators</u> , <u>clinical investigators</u> , 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.					
Therapeutics	Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection (Obj. # 7, p.95)	Develop an improved understanding of the biology and epidemiology of neurologic disease in HIV-infected individuals;	11,614	12,268	All populations		

Develop treatments for HIV-related neurologic disease

11,658 Bypass

latic

Page

Develop treatments for HIV-related neurologic disease

basic

11,658 Bypass

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apppr.)	FY 1996 (proposed)			
Therapeutics	Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection (continued)	Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction, e.g., ~~inhibitors of quinolinic acid, excitatory neurotransmitters, gp160/120, and other potential neurotoxins;~~					
		Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop strategies directed at the prevention and treatment of this complication of HIV infection;					
		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;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
		Develop and utilize <i>in vitro</i> 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; <u>implement standardized adult and pediatric neuropsychologic and neurologic assessment batteries in clinical studies and evaluate treatment-induced changes in neurocognitive impairment in a linguistically and culturally sensitive context.</u>					
Therapeutics	Develop therapies for the treatment and prevention of serious HIV-associated complications, including wasting syndrome, growth failure, metabolic disorders, dermatologic disorders, ITP, nephropathy, oral diseases, and other symptoms and serious complications (Objective #8, p.97)	Support research into the biology of the various clinical sequelae of HIV infection (above); Develop and evaluate therapeutic strategies to ameliorate the various sequelae of HIV infection (above) based on an increased understanding of pathogenesis; Develop and evaluate therapeutic strategies for alleviating the various symptoms of unclear etiology in HIV-infected persons (above) and improving the quality of life; and Develop and validate quality-of-life parameters for the various sequelae of HIV infection ~~(above)~~	12,844	15,431	All populations		

Area Research

Goal 4 ~~Conduct and support research to develop vaccines for prevention of HIV transmission and infection~~

Overall vaccine
FY95 111,831 PB 118,128 Bypass 154,711

Objectives	Action Steps	Programs				
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Vaccines Enhance understanding	<u>Increase scientific knowledge about host defense mechanisms and protection against HIV infection and disease</u> Conduct & support research on protective immune responses. (Objective #1, P. 109)	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;	45,735	47,844 PB 57,500 Bypass	All populations	

VACCINES TOTAL

FY95 Approp. 111,831	FY96 Res. Dnd. 118,128	Bypass 154,711	364,669
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Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Increase scientific knowledge about host defense mechanisms and protection against HIV infection and disease (continued)	Elucidate the three-dimensional structure of viral epitopes and determine the mechanism of escape from antibody-mediated neutralization and recognition by cytotoxic T cells. ~~The identification of epitopes for which escape is not possible should receive more attention;~~					
		Define conserved viral epitopes that are potentially relevant to protective immune responses; devise strategies to enhance their immunogenicity;					
		Determine the molecular nature of HIV genetic and antigenic diversity and incorporate the findings into ongoing vaccine development; focus on characterization of HIV at potential efficacy trial sites;					
		Foster multidisciplinary approaches that bridge basic, animal, and clinical approaches; and					
		Develop quantitative measures of HIV concentration in bodily fluids to determine whether there is a relationship between HIV concentration and transmission.					
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models	~~Develop further multidisciplinary approaches for the design and development of potential vaccine candidates; expand research on mucosal delivery and stimulation of mucosal immune responses (NIAID);~~	24,135	25,465	All populations		

Identify strategies for eliciting protective immune responses

(Objective #2, P. III)

35,473 Bypass

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models (continued)	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;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models (continued)	Evaluate vaccine strategies in AIDS animal models: - place additional emphasis on strategies in or about to be in clinical trial, practical immunization schedules, and challenge routes and viral isolates that most closely mimic the human experience; - delineate the mechanisms of immune protection; conduct transfer experiments to help dissect immune correlates; - determine the impact of dose on the nature and effectiveness of the immune response; - examine protection from organ-specific as well as systemic infection; - conduct long-term followup of vaccinated animals that become chronically infected to determine the impact of vaccination on disease progression; Encourage development of candidate vaccines suitable for domestic and international use; Conduct research on adjuvants and novel formulations that have a qualitative or quantitative impact on immunologic responses to vaccine candidates;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models (continued)	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 <i>in vitro</i> measure of immune function.					
Vaccines <i>Evaluate vaccine efficacy.</i>	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials <i>(Obj. # 3, P. 113)</i>	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;~~	19,189	19,912 <i>B</i> <i>24,361 Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	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;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	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					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	Conduct research to determine possible adverse social, economic, or legal consequences of participation in clinical trials and develop strategies to mitigate potential harm.					
Vaccines <i>Develop vaccine for newborns and infants.</i>	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 <i>(Objective #4, p.115)</i>	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	3,174	3,501 <i>P.B. All populations</i> <i>10,386 Bypass.</i>			

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	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 (continued)	Conduct Phase I, Phase II, and Phase III clinical trials of the most promising candidates that meet established criteria.					
Vaccines <i>Identify suitable candidates for efficacy trials.</i>	Develop criteria for selection of suitable candidate vaccines, support appropriate infrastructure, and conduct Phase I and Phase II trials <i>(Objective #5, p.117)</i>	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;	19,398	21,177 <i>FB</i> <i>21,424 Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Develop criteria for selection of suitable candidate vaccines, support appropriate infrastructure, and conduct Phase I and Phase II trials (continued)	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.					
Vaccines Conduct efficacy studies in most appropriate populations.	Establish criteria for selection of suitable vaccine candidates and conduct Phase III clinical trials when established criteria are met (Objective # 6, p. 119)	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	200	229 + B 5,621 Bypass	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Establish criteria for selection of suitable vaccine candidates and conduct Phase III clinical trials when established criteria are met (continued)	Ensure that trials are conducted with the highest regard for social and ethical concerns of the participants.					

Area Research

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

Objectives	Action Steps	Programs				
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Behavioral Research	Prevent new HIV infections through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations (Obj. #1, p. 131)	Develop and evaluate demographically and culturally appropriate behavioral and social interventions based on the changing epidemiology of HIV in different populations and on the incidence, frequency, and change in high-risk HIV-related behaviors; international comparisons are essential for identifying effective interventions; Support multidisciplinary research on behavior change strategies that target the sustained adoption and maintenance of HIV preventive behaviors (e.g., increase use of condoms, virucides, spermicides, and sterile injection drug equipment); Support research on increasing the effectiveness of drug abuse, mental health, and alcoholism treatment for reducing HIV risk behavior; Design and test interventions to increase the recruitment, retention, and adherence to protocols for adopting and maintaining low-risk behavior in prevention research, including vaccine studies; and	50,710	51,302 ^{FB} 66,459 ^{Bypass}	All populations	

LG

include but don't put in

Behavioral Research
TOTAL

FY95 Approp	FY96 Proposed	Bypass	
159,720	161,595	205,893	447,988

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Prevent new HIV infections through behavior interventions. Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations (continued)	Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.					
Behavioral Research <i>Enhance understanding of determinants of behavior.</i>	Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change <i>(Obj. #2, p 133)</i>	Support studies to develop models of behavioral, social, cultural, cognitive, and psychological mechanisms and processes that determine the acquisition, maintenance, and change of HIV-related behaviors in individuals and groups in various populations and settings; Identify processes that exacerbate or minimize adverse consequences of HIV infection for the individual, group, and community; Support basic behavioral and social research on factors that shape and change social norms concerning HIV-related behavior and their influence on individual behaviors; Develop and improve methods to obtain and analyze valid and reliable data on HIV-related behaviors; and Study the process of information diffusion; understanding this process is necessary for effective communication of HIV-related knowledge.	79,959	83,149 <i>PB</i> 101,664 <i>Bypass</i>	All populations		

Objectives	Action Steps	Descriptions	Programs			
			Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Behavioral Research A	Preventing the negative consequences of HIV infection. Discover, develop, and evaluate strategies to prevent or minimize the physical, psychological, cognitive, and social consequences of HIV, including strategies to improve adherence to proven therapies and recruitment, retention, and adherence to clinical trial protocols (Objective #3 p.134)	Identify the behavioral, psychological, cognitive, and social consequences of HIV disease for HIV-seropositive individuals, their support systems, and their communities; develop and evaluate innovative behavioral and social approaches to manage these consequences, including health behavior changes, stress management, and improved access and utilization of care; Discover, implement, and evaluate therapeutic strategies to delay or prevent progression of HIV-associated cognitive dysfunction; Develop and evaluate interventions to increase recruitment, adherence, and retention in HIV treatment studies and clinical trials; Develop and test models of caregiving tailored to the physical, cognitive, and emotional needs of patients with HIV disease, including their significant others, extended family members, and care providers; and Develop and evaluate programs to prevent HIV-related discrimination. by —?	27,293	25,264 PB 35,022 Bypiss	All populations	

What?
Who?
Why?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	ASSESS Create and test innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications (Objective #4, P.136)	Develop and test innovative dissemination strategies for promoting adoption of successful (empirically tested) behavior change interventions by HIV prevention providers; Develop, test, and rapidly disseminate research findings that have immediate implications for the conduct of HIV prevention and education programs conducted in the community; explore novel mechanisms to disseminate behavioral and social science research findings and model approaches to the prevention field (e.g., consensus conferences, interactive computer bulletin boards, media strategies, and mechanisms to reach providers and community-based organizations); Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bidirectional exchange of information and experience to enhance research and prevention efforts; and Utilize new and innovative techniques (e.g., social marketing) to disseminate research to different populations.	1,364	1,444	All populations		

In Budget

FY94	FY95	FY95/96
216	235	252

In FB

FY94	FY95	FY96
Actual	Approp.	FB
1,353	1,364	1,444

What happened

In Budget

FY94
216

FY95
235

FY95-96
252

In FB

FY94
Actual
1,353

FY95
Approp.
1,364

FY96
FB
1,444

What happened?

Duplicate

Objectives	Action Steps	Descriptions	Programs			
			Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Behavioral Research	Create and test ^{effective} innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications (obj. #4, p 136)	Develop, ^{utilize} and test innovative dissemination strategies for promoting adoption of successful ~~(empirically tested)~~ behavior change interventions by HIV prevention providers;	1,364	1,444	All populations	
		Develop, test, and rapidly disseminate research findings that have immediate implications for the conduct of HIV prevention and education programs conducted in the community; ~~explore novel mechanisms to disseminate behavioral and social science research findings and model approaches to the prevention field (e.g., consensus conferences, interactive computer bulletin boards, media strategies, and mechanisms to reach providers and community-based organizations);~~	FY96 Est. 235	352	Bypass	
		Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bidirectional exchange of information and experience to enhance research and prevention efforts; and				
		Utilize new and innovative techniques (e.g., social marketing) to disseminate research to different populations.				

What happened.

Amey College
CD CDC?
CDC Grants?

Objectives	Action Steps	Descriptions	Programs				Unmet Needs
			Resources in Thousands		Populations Served	Constituency Involvement	
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Strengthen the behavioral and social science infrastructure.	Establish multidisciplinary AIDS research consortia to test novel behavioral approaches, replicate psychosocial and behavioral studies, and promote their use in appropriate populations; collaborate with other agencies of the PHS and outside organizations to maximize research resources;	394	436	All populations		
	Develop multidisciplinary and interagency collaborative efforts to enhance the AIDS behavioral research effort; enhance the behavioral aspect of research into therapeutics, natural history and epidemiology, and vaccines. Train researchers to conduct basic and applied social science research related to HIV. Provide the state-of-the-art physical facilities and equipment that are necessary to conduct HIV-related behavioral and social science research within relevant settings	Promote HIV-related research in predoctoral and postdoctoral programs; ~~facilitate the~~ development of <i>practica</i> and field placements in HIV treatment, prevention, and research settings; provide research career awards; actively recruit ethnic minorities, women, and those dedicated to community-based programs; expand behavioral and social training and research efforts aimed at limiting infections such as TB and malignancies related to HIV infection.	95 Est. 280	396	Bypass	what happened.	
		Ensure adequate representation of social and behavioral scientists on IRGs, OAR Advisory Committees, and OAR staff;					
		Support and expand computer networking among behavioral and social science researchers; provide additional laboratory and research facilities for human and animal research for behavioral studies; and					

Behavioral Overall.

95 Approp.
159,720

FY 96
161,595

Bypass
205,893

Behavioral Overall.

95 Approp.

159,720

FY 96

161,595

Bypass

205,893

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Behavioral Research	Strengthen the behavioral and social science infrastructure. Develop multidisciplinary and interagency collaborative efforts to enhance the AIDS behavioral research effort; enhance the behavioral aspect of research into therapeutics, natural history and epidemiology, and vaccines. Train researchers to conduct basic and applied social science research related to HIV. Provide the state-of-the-art physical facilities and equipment that are necessary to conduct HIV-related behavioral and social science research within relevant settings (continued)	Collect, archive, and disseminate existing data for secondary data analysis.					

Area Research

Goal 6 Provide support for training and infrastructure to carry out HIV and AIDS research

Objectives	Action Steps	Descriptions	Programs											
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs							
			FY 1995 (appropri.)	FY 1996 (proposed)										
Training and Infrastructure ~~Meet the resource~~ training needs of HNIATLS researchers.	Provide both domestic and international training in biomedical and behavioral research on HIV	Increase predoctoral and postdoctoral training, as well as advanced research training, in a range of AIDS-related disciplines to a level comparable ~~(about 3 percent of the budget)~~ to that of other training programs within the NIH; Sponsor an annual AIDS Fellows Meeting to promote collaboration and information dissemination; Increase training of scientists and clinical investigators in basic AIDS research to better link basic and clinical pathogenesis research; ~~Stimulate predoctoral and postdoctoral training in prevention, behavior change, and adherence and compliance to treatment;~~ Promote training of biomedical and behavioral scientists in the use of high-performance computing systems for HIV-related research; Expand training and research capacity to deal with the epidemic of tuberculosis (TB), including multiple drug resistance associated with HIV infection;	33,978	35,486 41,575 Bypass	All populations									
Training & Infrastructure 107AL <table><tr><td>FY95 Appr.</td><td>FY96 Prop. Bud.</td><td>Bypass</td><td rowspan="2">Δ 119,145</td></tr><tr><td>40,886</td><td>42,558</td><td>58,703</td></tr></table>								FY95 Appr.	FY96 Prop. Bud.	Bypass	Δ 119,145	40,886	42,558	58,703
FY95 Appr.	FY96 Prop. Bud.	Bypass	Δ 119,145											
40,886	42,558	58,703												

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Training and Infrastructure	Provide both domestic and international training in biomedical and behavioral research on HIV (continued)	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.					
Training and Infrastructure <i>Meet the resource needs of HIV/AIDS researchers.</i>	Establish appropriate infrastructure for the conduct of HIV research domestically and internationally <i>(Obj. #2, p 151)</i>	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;	6,858	7,072	All populations		
				17,128	Bypass		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Training and Infrastructure	Establish appropriate infrastructure for the conduct of HIV research domestically and internationally (continued)	Expand the use of the National Research and Education Network (NREN) for national and international collaboration and data communications; Provide for expansion of breeding facilities to ensure the adequate supply of species of emerging importance, e.g., ~~M. nemestrina~~; Provide NCRR animal model support tied to needs of basic research grants; Provide for the long-term support of advanced in-country research and research infrastructure in those developing countries participating in efficacy trials of candidate HIV vaccines and other priority intervention research; Develop and support animal models predictive of human behavior, specifically, models of non-human primate behavior of impaired impulse control and risk-taking; Provide additional laboratory and biocontainment facilities for primate research; Increase support for the Internet connections program at health sciences centers and hospitals for research and patient care;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Training and Infrastructure	Establish appropriate infrastructure for the conduct of HIV research domestically and internationally (continued)	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.					

Area Research

Goal 7 Develop and support appropriate programs for the dissemination of research information to health care providers and affected communities

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate	Develop and rapidly disseminate important research findings that have immediate impact on prevention, ~~and on health care~~ , and treatment of HIV-infected individuals, utilizing all NIH, PHS, and public media communications modes;	15,400	16,115	All populations		
		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;					

What has the information dissemination done?

Subcommittee of the PHS

18,527 Bypass

Information Dissemination TOTAL

FY 95 Approp.	FY 96 Pres. Bud	Bypass	L
15,400	16,115	18,527	2,412

18,527 *Bypass*

Information Dissemination TOTAL

<i>FY95</i>	<i>FY96</i>	<i>Bypass</i>	<i>L</i>
<i>Approp.</i>	<i>Pres. Bnd</i>		
<i>15,400</i>	<i>16,115</i>	<i>18,527</i>	<i>2,412</i>

What has the information dissemination done? Subcommittee of the PHS

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate (continued)	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;					

why behavioral pulled out?

info. dissem.?

→ diff audience?
for funders

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate (continued)	Develop and improve user-friendly information systems and services in HIV/AIDS and provide training for them; Provide the full text of abstracts from meetings, where available, online before scientific meetings; Collaborate with the WHO, the PAHO, and the ~~Global Programme on AIDS~~ 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.					