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ONAP [Office of National AIDS Policy] Review 7/22/96 [3]

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CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

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

Develop and coordinate distribution of HIV provider materials.

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

FY 95: $16,300,000
FY 96: $16,300,000
FY 97:

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

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

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

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

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

FY 95: $6,937,000
FY 96: $6,937,000
FY 97:

Populations Served: Children and adults living with HIV.

Constituency Involvement: American Association of Dental Schools, American Association of Hospital Dentists, and American Dental Association. Are consumers included?

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

Increase patient access to clinical research.

Establish quality guidelines and evaluate program effectiveness.

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

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

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

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

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

Support initial development of care systems linked to research for children, youth and women in 7 new communities; Please clarify the specific language in this section as it refers to WIN projects or other care systems.

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

Provide leadership, training, and technical assistance;

Convene youth and family leadership conferences and distribute findings;

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

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

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

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

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

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

FY 97:
RWCA Title I:
RWCA Title II:
RWCA Title III:
RWCA Title IV:

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

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

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

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

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

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

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

CARE AND SERVICES

Agency: Health Resources and Services Administration

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

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

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

Descriptions: Special Projects of National Significance (SPNS).

FY 95: $2,092,302
FY 96: $4,000,000
FY 97:

Populations Served: Persons living with HIV and their families.

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

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

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

Action Steps: Increase emphasis on evaluation;

Increase the representation of evaluation researchers on review groups; and

Provide technical support for evaluation activities.

Descriptions: Evaluation of Special Projects of National Significance

FY 95: $2,000,000
FY 96: $4,000,000
FY 97:

Populations Served: SPNS grantees.

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

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

PREVENTION

Agency: Health Resources and Services Administration

Goal: Reduce the perinatal transmission of HIV.

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

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

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

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

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

Establish ongoing WIN Steering Committee;

Provide technical assistance to grantees;

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

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

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

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

Review currently funded SPNS projects to identify gaps in project coverage for future Requests for Applications (RFAs); and

Evaluate sites.

Descriptions: Enhance outreach for HIV counseling and testing.

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

PHS 076 Implementation Plan.

FY 95: $1,520,000
FY 96: $1,800,000
FY 97:

Populations Served: CARE Act grantees. Adolescent and adult women and their infants, with special attention for pregnant women in addition to MCH and HIV providers.

Constituency Involvement: Health care providers, evaluation researchers, communication experts, and patient advocates. There is also consumer participation in WIN steering committee and projects' advisory board in addition to linkages with other HRSA grantees including those from RWCA and SPNS programs.

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

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

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: ???

PREVENTION

Agency: Indian Health Service

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

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

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

Descriptions: Area AIDS Coordinators will be responsible for reporting.

FY 95: $912,000
FY 96: $912,000
FY 97:

Populations Served: Federally recognized American Indians and Alaska Natives.

Constituency Involvement: Local and National Indian Health Advisory Boards.

Unmet Need: ???

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

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

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

FY 95: $2,321,000
FY 96: $2,321,000
FY 97:

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

Awaiting revised appendices from NIH.

INTERNATIONAL ACTIVITIES

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

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

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

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

Develop mechanism for tracking HHS-related international activities.

Descriptions: International activities mapping project.

FY 95: NA - HIV activities integrated into overall budget
FY 96: NA - HIV activities integrated into overall budget
FY 97:

Populations Served: Program planners and policy makers.

Constituency Involvement: ????

Unmet Need: Staff to initiate and complete project.

PREVENTION

Agency: Office of Population Affairs

Goal: Reduce the number of new infections.

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

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

Include HIV/AIDS prevention in STD screening programs.

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

Descriptions: Title X Program

FY 95: NA -- HIV services integrated into overall budget.
FY 96: NA -- HIV services integrated into overall budget.
FY 97:

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

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

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

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

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

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

Disseminate information about successful service models;

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

Increase productive work capacity as result of receiving services.

Descriptions: HIV/AIDS Mental Health Services Demonstration Program.

FY 95: $1,500,000 (With $1,400,000 from NIH and $1,500,000 from HRSA)
FY 96: $1,500,000 (With $1,400,000 from NIH and $1,500,000 from HRSA)
FY 97:

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

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

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

Objective 2: To demonstrate the efficacy of outreach as an intervention for facilitating access

to substance abuse treatment for high risk and hard to reach substance abusers.

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

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

Facilitate entry into substance abuse treatment;

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

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

Evaluate program effectiveness.

Descriptions: HIV/AIDS Community Outreach Program.

FY 95: $7,500,000
FY 96: $7,500,000
FY 97:

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

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

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

Goal: Improve HIV/AIDS training of clinicians.

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

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

Establish linkages with health care providers;

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

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

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

Address managed care and training issues; and

Evaluate the effectiveness of training techniques.

Descriptions: AIDS Health Care Worker Training.

FY 95: $2,930,000
FY 96: $2,930,000
FY 97:

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

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

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

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

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

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

Descriptions: AIDS Training Grants.

FY 95: $2,800,000
FY 96: $0
FY 97:

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

Constituency Involvement: Health professionals and consumers.

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

CARE AND SERVICES

Agency: Substance Abuse and Mental Health Services Administration

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

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

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

Evaluate the efficiency and effectiveness of linked, integrated services.

Descriptions: The Linkage Initiative.

FY 95: $7,700,000
FY 96:
FY 97:

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

Constituency Involvement: Service providers and consumers

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

PREVENTION

Agency: Substance Abuse and Mental Health Services Administration

Goal: Reduce the number of new HIV infections.

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

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

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

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

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

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

Descriptions: High Risk Youth Program.

FY 95: $1,000,000
FY 96: $3,000,000
FY 97:

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

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

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

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

Reduce ATOD use.

Action Steps: Supplementation of all community partnerships and community coalitions providing communities with the opportunity to design targeted HIV/AIDS messages emphasizing the direct relationship between the use of ATOD and HIV/AIDS; and

Solicit neighboring communities in program implementation.

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

FY 95: $0
FY 96: $5,000,000
FY 97:

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

Constituency Involvement: All community members.

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

Objective 3: Improve training of Faculty Development Program (FDP) grantees.

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

Improve training regarding professional/client interaction.

Descriptions: Supplementation of Faculty Development Program (FDP) grantees.

FY 95: $0
FY 96: $650,000
FY 97:

Populations Served: General public.

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

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

IV. FIGURES, ACRONYMS, AND MEMBERS OF THE INTERDEPARTMENTAL TASK FORCE ON HIV AND AIDS

Figure 1 Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982 -1993

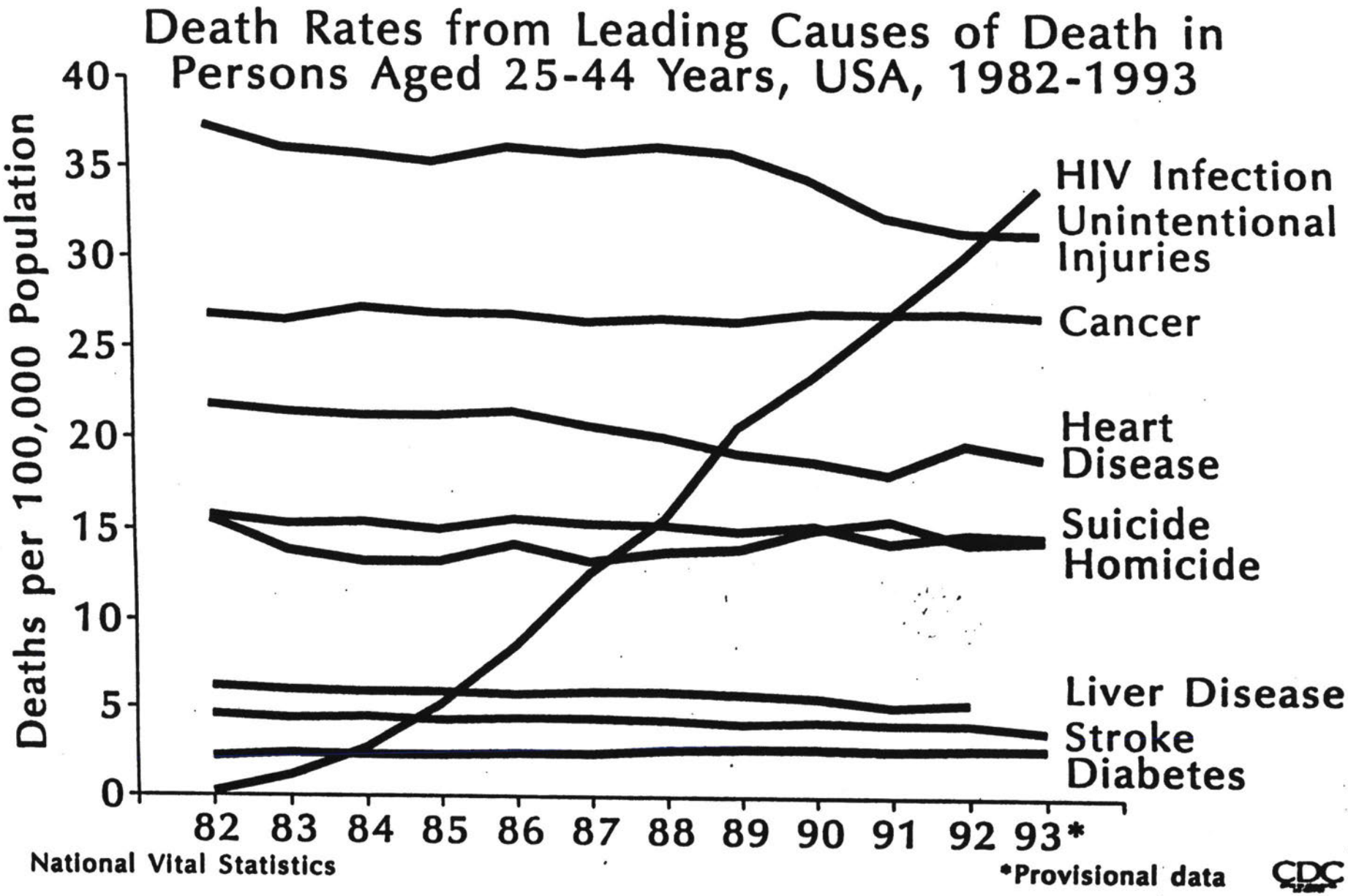
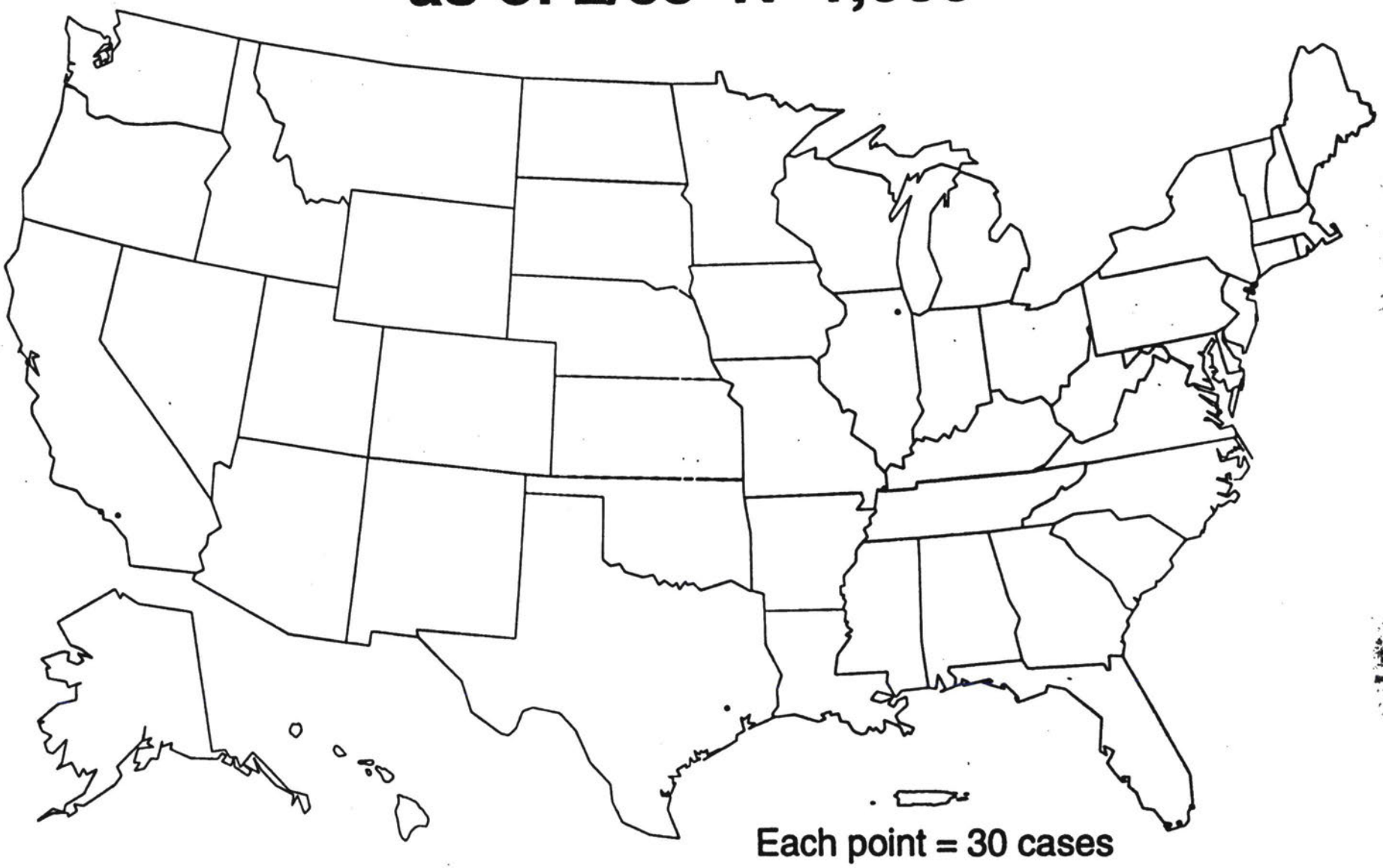

Death Rates from Leading Causes of Death in Persons Aged 25-44 Years, USA, 1982-1993
Deaths per 100,000 Population
40
35
30
25
20
15
10
5
0
82 83 84 85 86 87 88 89 90 91 92 93*
HIV Infection
Unintentional Injuries
Cancer
Heart Disease
Suicide
Homicide
Liver Disease
Stroke
Diabetes
National Vital Statistics
*Provisional data
CDC

Figure 2 Cumulative U.S. AIDS Cases: 2/83 through 12/94

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

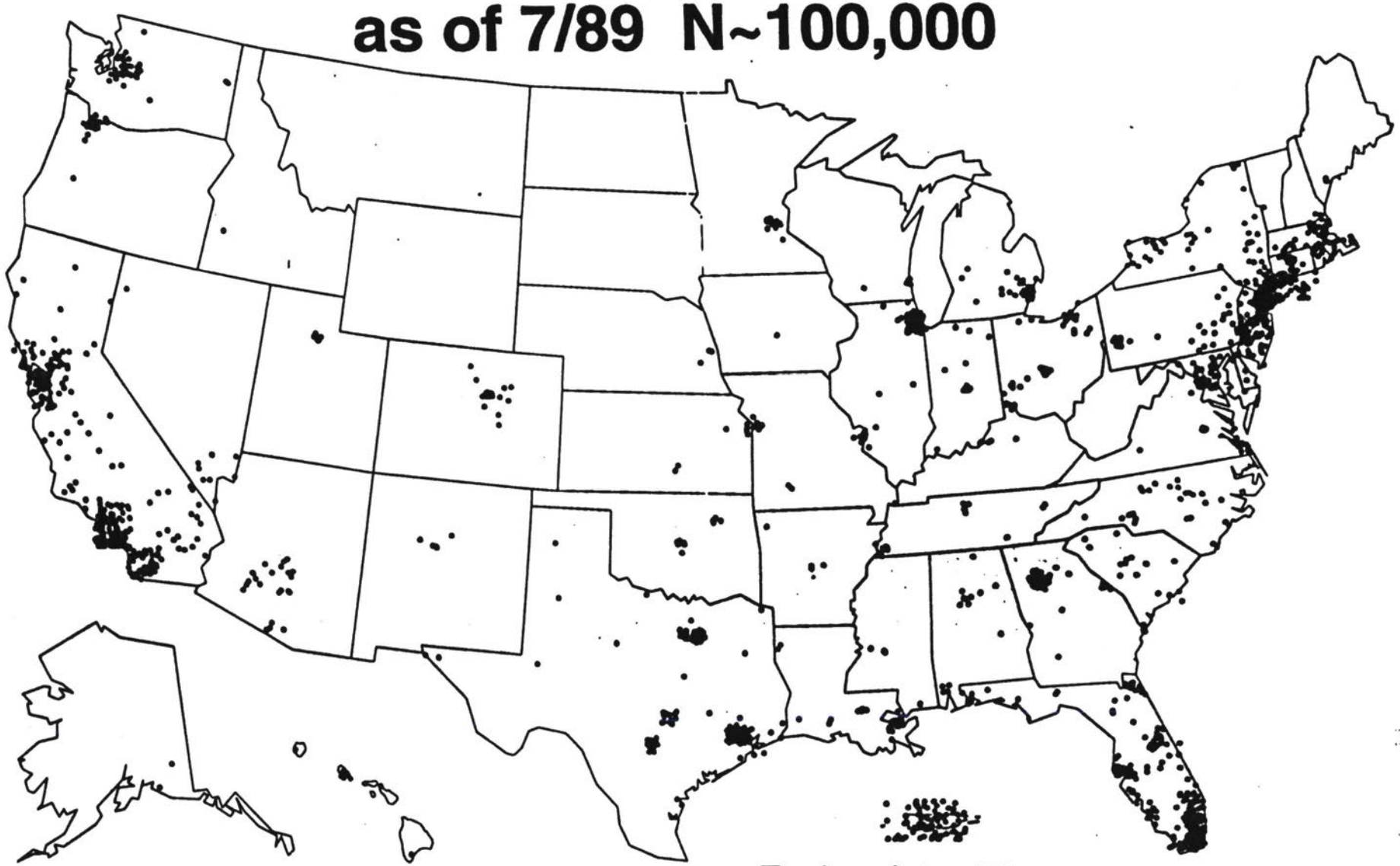


Cumulative U. S. AIDS Cases as of 5/85 N~10,000

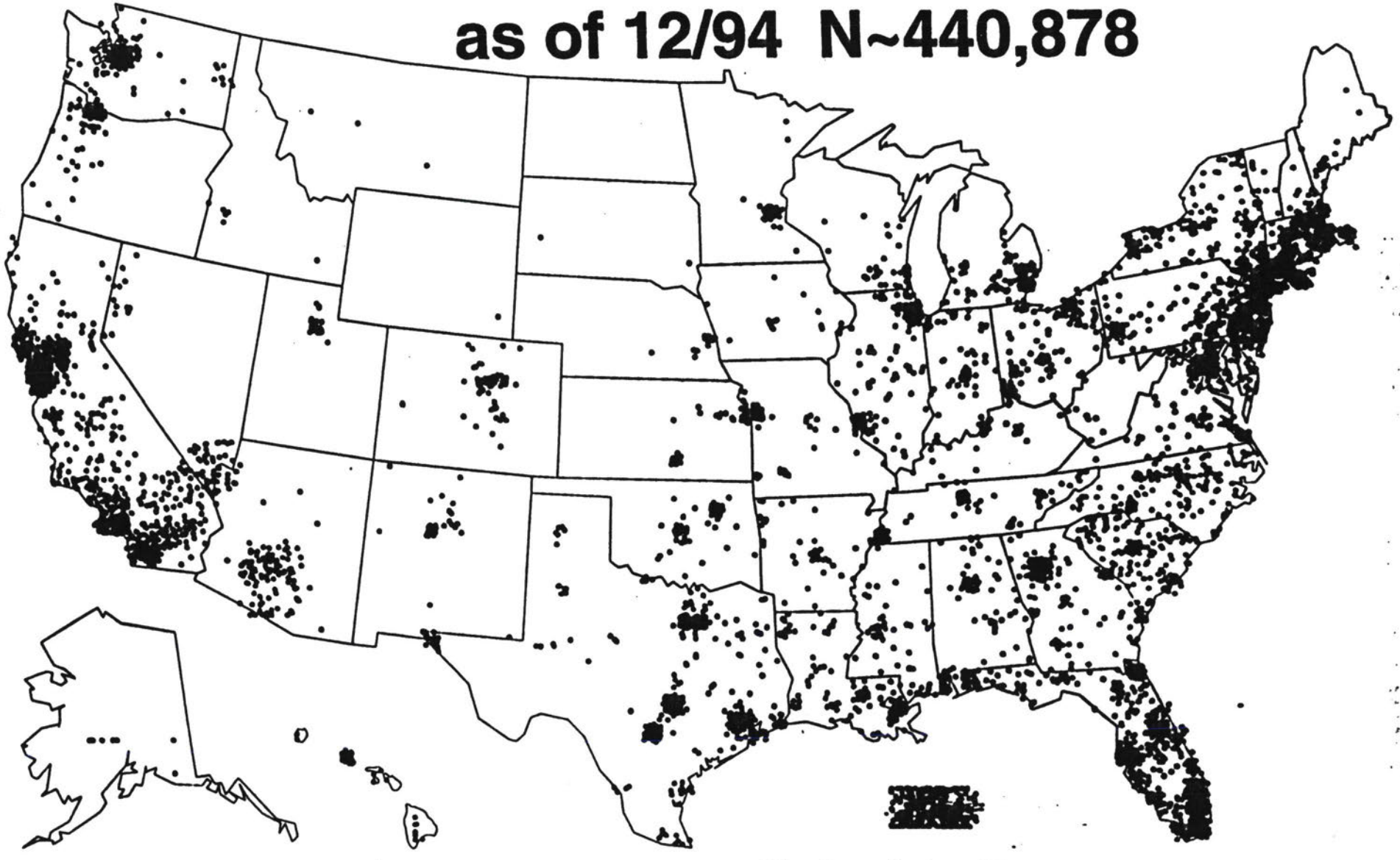


Each point = 30 cases

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



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



Each point = 30 cases

Acronym List

ACTG	AIDS Clinical Trial Group
ADA	Americans with Disabilities Act of 1990
ADC	AIDS Dementia Complex
ACTIS	AIDS Clinial Trials Information Service
ADAP	AIDS Drug Assistance Progams
AETC	AIDS Education Training Center
AHCPR	Agency for Health Care Policy and Research
AIDS	Acquired Immune Deficiency Syndrome
AOD	Alcohol and other drugs
ASO	AIDS Service Organization
ATIS	HIV/AIDS Treatment Information Service
ATOD	Alcohol, tobacco, and other drugs
AZT	
BOP	Bureau of Prisons
BRTA	Business Responds to AIDS
CARE	Ryan White Comprehensive AIDS Resources Emergency Act
CDBG	Community Development Block Grant
CDC	The Centers for Disease Control and Prevention
CMV	Cytomegalovirus
CNS	Central Nervous System
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
DEA	Drug Enforcement Agency
DHHS	Department of Health and Human Services
DOD	Department of Defense
DOJ	Department of Justice
DOL	Department of Labor
EDC	Educational Development Center
EEOC	Equal Employment Opportunity Commission
ENFPA	
FDA	Food and Drug Administration
FBI	Federal Bureau of Investigation
GCRC	General Clinical Research Centers Program
GIPA	Greater Involvement of Persons Infected and Affected by HIV/AIDS

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
ICD	Institute(s), Center(s), Division(s)
IDTF	Interdepartmental Task Force on HIV and AIDS
IHS	Indian Health Service
INS	Immigration and Naturalization Service
IOM	Institute of Medicine
JMD	Justice Management Division
LRTA	Labor Responds to AIDS
MAC	*Mycobacterium Avium* Complex
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
NVC	National Victims Center
OAR	Office of AIDS Research
OI	Opportunistic Infection
OMB	Office of Management and Budget
ONAP	Office of National AIDS Policy
PAC	Presidential Advisory Council on HIV and AIDS
PCP	*Pneumocystis carinii* 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
SPNS	Special Projects of National Significance
SSA	Social Security Administration
SSI	Supplemental Security Income
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TA	Technical Assistance
TB	*Mycobacterium tuberculosis*
UNAIDS	United Nations Programme on AIDS
UNDP	
UNICEF	
USAID	U.S. Agency for International Development
USIA	U.S. Information Agency
USMS	U.S. Marshals Service
VA	Department of Veterans Affairs
WHO	World Health Organization

JL [ ] → walk through with PF

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Implementation
Organization of the Strategy

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Figure 2 Cumulative U.S. AIDS Cases: 2/83 through 12/94

Acronym List

Members of the Interdepartmental Task Force on HIV and AIDS

Message from the Director of the Office of National AIDS Policy

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

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

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

governments, the private sector, and infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work. qp to ★

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

Regional Briefings link c WHCA.

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

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

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

The epidemic challenges us on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged this country to look at things that are difficult to face.

Another challenge is fear
~~There is also fear~~ -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is threatened with fundamental programmatic changes and reductions in funding. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

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

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

National Response not just a Federal Response. | RS drafted language.

death of their own child. The myriad of Federal and State Agencies ~~(i.e. .....)~~ charged with overseeing child welfare issues, coupled with a legal code not designed to dispense compassionate remedies for these orphaned children, ~~has~~ created a bureaucratic nightmare for dying parents seeking to provide a safe and caring home for their children. There is a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of a child's parent(s). It is to focus attention on such cross-cutting challenges that the IDF was created and this strategy developed. Despite the many difficulties, AIDS has also brought forth an outpouring of compassion and caring. In my many meetings around the country with persons living with HIV, I have been inspired by numerous examples of great personal courage. I have been impressed by the dedication with which many communities and individuals have overcome obstacles in preventing infections and caring for those who are sick. By example, it demonstrates that, as a Nation, we, ~~too,~~ can collectively rise to meet the most difficult challenges placed in our path. Those Americans living with HIV, and others who are at-risk of infection, their families, and their communities, deserve a thoughtful, effective, and aggressive strategy to combat the disease. More to today

While ~~Today~~ we are facing great challenges, ~~but~~ we are also facing

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

Preface

The Need for a National Strategy ~~for HIV and~~ AIDS

The National Strategy ~~for HIV and~~ AIDS has been developed to capitalize upon progress already made in fighting the epidemic and to catalyze collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. [Who needs the Strategy → some message on p. 7.]

Since the discovery of the first AIDS cases in ~~the early 1980s~~ 1981, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those ~~that~~ we faced ~~ten~~ 10 or even ~~five~~ 5 years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that ~~a~~ development of an effective vaccine is possible. Nonetheless, the epidemic continues. More than 40,000 Americans ~~people~~ are infected every year, in every ~~geographic area~~ State, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And ~~youth~~ young people are at increasing ~~risk~~ vulnerable to HIV infection. ~~Internationally~~ Globally, the epidemic is threatening the economic stability

of a number of developing nations. [More info. LR] #s, social fabric.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

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

The Strategy as a Catalyst for Change

The National Strategy is intended to ~~serve~~ the public, the President, the Congress, ~~the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV and AIDS.~~ The text that follows will serve as a blueprint ~~that will~~: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS, private sector organizations, and the community.

Executive Summary

== Place Holder ==

I. INTRODUCTION

Scope of the ~~HIV/AIDS Pandemic~~ Epidemic

The pandemic of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) presents unique social, economic, and public health challenges to governments and individuals here in the United States and worldwide. While ~~we have made~~ significant progress in understanding the disease and developing treatments has been since the first case was identified by the CDC in June ~~of~~ 1981, with this progress comes the challenge of preventing new infections, ensuring access to new treatments, and assuring that health care professionals know how to care for their patients. Still, HIV remains a deadly infection for which there is no vaccine, no cure, and for which there is an expanding, but still limited, inventory of available treatments.

An Expanding Public Health Threat

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

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

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users and their partners as well as non-injecting drug users (i.e., crack cocaine and alcohol). Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported with AIDS. and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new pediatric AIDS cases were reported. It is

Make it a footnote.

however, hoped that with greater use of AZT by HIV-positive mothers during pregnancy and delivery, and administration to their babies after birth, the number of new cases in newborns can be reduced. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among young people. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages, in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

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

AIDS is ~~no longer~~ not just an urban problem. The HIV/~~AIDS pandemic~~ epidemic ~~is spreading~~ has and continues to spread into suburban and rural to ~~non-urban~~ areas, including dramatic increases in certain regions of the South and Midwest. ~~In fact,~~ between January 1993 and December 1995 the largest numbers of AIDS cases (86,462) were reported from the South.[1] While most cases are still reported from urban areas, the rate of reported cases in non-metropolitan areas is increasing ~~faster~~ more Rapidly than in urban areas. AIDS cases have now been reported in all 50 States, the District of Columbia, Puerto Rico, Guam, and each of the U.S. territories. (See Figure 2.)

~~Internationally~~ Globally, the toll of the epidemic is greater still. ~~The World Health Organization~~ UNAIDS (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the ~~pandemic~~ epi. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

30 million and 40 million. RS text

~~The Social Impact~~

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. ~~Persons~~ People with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been ~~discharged~~ fired from

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

AIDS is a disease that most often affects people in the prime of life; It kills people during their most productive years. ~~That it~~ AIDS is the leading cause of death among Americans 25 to 44 ~~is~~ this particularly significant since this is the age group that constituted 54% percent of the civilian labor force in 1992.[2] Premature deaths due to AIDS result in the loss of many productive years of life and ~~in many cases~~ often deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of years of potential life lost before age 65.

AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime medical care after diagnosis for an HIV-infected person costs more than ~~care for patients with cancer or heart disease, specifically: $61,211 for heart disease[3], $25,000 to 84,000 for Cancer[4], and $119,000~~ for HIV/AIDS[5] $119,000. ~~And although cancer and heart disease costs may be attributable to striking older and frailer persons, overall DHHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS.~~

Rainbow book.

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

In developing countries, the ~~pandemic~~ epidemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children. In some African nations, ~~95 percent~~ a majority of hospital beds are occupied by AIDS patients. Moreover, the ~~WHO~~ UNAIDS estimates that 10 million to 15 million children will be orphaned due to AIDS by the year 2000. The human toll has been staggering and is likely to continue.

- India -
- Lattoma / PF

The Evolving Challenge of the HIV/AIDS Epidemic

The four decades prior to the report of the first AIDS case in ~~the early 1980s~~ 1981 encompassed a period of unprecedented success in controlling infectious diseases. The emergence of HIV, and the subsequent epidemic of HIV and AIDS, ~~has~~ have posed an evolving series of unique scientific, economic, and social challenges, both domestic and international. ~~Today the challenges we face with the epidemic are very different from challenges we faced previously.~~

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

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV-related immunology and pathogenesis, and, developing therapies for HIV infection and its associated opportunistic infections and malignancies. New and more powerful therapies that offer ~~new~~ greater hope for treatment and prevention have been developed. Scientists now believe that ~~a~~ the development of an effective vaccine is possible.

~~Current day~~ Recent discoveries also create ~~new challenges for the future. We now face~~ new scientific challenges in developing a vaccine and ~~the~~ a new generation of therapeutics for HIV, its associated ~~and opportunistic infections and malignancies~~ conditions.

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

The progress in developing therapies and prevention programs has also created new ~~problems~~ concerns for the health care delivery system. As a result of improved therapies, people with AIDS now live twice as long ~~as they did a decade ago.~~ on average. Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy and their babies after birth. The recent approval of a new class of

Back to NIH.

therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment and prevention. ~~Ensuring access to these therapies is the challenge that confronts us now.~~ We need to improve our efforts in providing people with care earlier in their infection so they can receive the new treatments and we need, ~~as well,~~ to ensure that health care professionals are well-trained and know the best way to provide that care.

Ensuring access to prevention services and medical care for the growing number of people who need, or will need, health care is an enormous task. ~~There are~~ societal and economic changes ~~that~~ are influencing the ways in which ~~the country addresses the issues of~~ health care is delivered and financed ~~access and cost.~~ There is a greater trend towards decentralizing the role of the Federal government in health care and placing more responsibility at the State and local levels, coupled with a movement towards ~~to~~ managed care systems. These changes will influence efforts to strengthen prevention ~~efforts~~ activities and ensure health care and services for people with HIV/AIDS.

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

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

Goal of the National Strategy

The goal of the National AIDS Strategy is to capitalize upon the progress ~~which has been~~ made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To realize this ambition we will need innovative ideas, careful planning, and the strength of public-private partnerships, ~~to make these plans a reality.~~

The text and appendices that follows will serve as a blueprint that ~~will~~: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges occur.

Development of the Strategy

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

of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome[7], the "Coolfont"[8] and "Charlottesville"[9] reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States[10]. There have also been planning efforts on the part of various Agencies and Departments, such as the Department of State's United States International Strategy on HIV/AIDS, the ~~congressionally-mandated~~ annual NIH plan for HIV-related research, and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS. Recommendations have ~~also~~ been ~~issued~~ made by a number of groups, including the National Commission on AIDS[11] and the Presidential Advisory Council for HIV and AIDS. However, until now there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also ~~that~~ incorporates areas such as housing, health care, and civil rights.

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

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

There has ~~also~~ been a reliance on groups outside of government. ~~the same~~ there groups ~~that~~ have been and will continue to be essential partners in developing solutions and capitalizing on ~~the~~ opportunities for progress ~~that lay~~ before us now. The recommendations ~~provided by the~~ Presidential Advisory Council on HIV and AIDS (PAC) have been invaluable. ~~The~~ We have also sought the advice and counsel of ~~the activist and~~ national + community-based advocacy ~~communities~~ organizations, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by ~~a~~ the National Commission on AIDS, the Institute of Medicine of the National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing this Strategy.

health care professionals

Regional Briefings

RS will provide language

~~Goals~~ Common Objectives and Opportunities for Progress

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

- To provide strong (continuing) support for research in order to find additional treatments, ~~and~~ a cure for those currently infected, and a preventive vaccine to protect the uninfected;

- To provide ~~solid~~ strong, continuing support for effective prevention strategies ~~so as~~ to reduce the number of new infections each year until there are no new infections; and,

- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

JL

Alternative language: To ensure that ~~persons~~ people living with HIV are not subject to discrimination and ~~receive~~ have access to services that ~~are caring, ethical, and in accordance with legal standards.~~ affordable, of high quality and responsive to their needs.

~~Also through the consultations~~, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress

I To ensure that people living with HIV are not subject to discrimination unlawful

Jeremy

-- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section (i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

Implementation

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

PF will Read.

Each issue raised in the Strategy will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a small number of Agencies and organizations, while others will require extensive thoughtful effort on the part of many committed participants in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

Organization of the National AIDS Strategy

The National AIDS Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities ~~can be~~ are found in three locations within the document. First, discussion on each substantive area ~~addresses~~ includes broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet

needs. And third, funding tables ~~can be~~ are found in Appendix G.

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

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

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

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

The scope and nature of the HIV/AIDS epidemic have ~~brought~~ State, local, and Federal involvement in many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached $6.8 billion. (See Appendix G). ~~Congress also took note of the~~ rapid increase in cases of HIV and AIDS ~~and passed~~ legislation ~~that sought~~ to address the needs of ~~HIV infected persons~~ and their families, ~~and the Nation's need to find a cure and a vaccine,~~ including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

~~Currently,~~ Federally sponsored activities include direct support for research, training, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance ~~to~~ international ~~organizations and~~

other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for surveillance, prevention, research, and health care responsibilities carried out by State and local governments, academic institutions, private foundations, health care institutions and community-based organizations.

PREVENTION

The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each year until there are no new infections. Achieving this goal will require a ~~dedicated~~ alliance between the Federal government, States, local governments, communities, businesses, the academic community, professional ~~and non-governmental organizations~~, families, health care professionals, and individuals. ~~Achieving~~ this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.[12] The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 Americans ~~will~~ become infected each year. Many more Americans who are not presently infected are at risk for acquiring HIV. HIV infection is a unique prevention challenge because of:

the virus' virulence; the long period of time when people may not be aware they are infected; long duration of infectiousness; nearly always fatal prognosis; and the potential for exponential spread. Moreover, HIV is transmitted primarily as a result of ~~personal and private behaviors --~~ sex and drug use. To be effective, HIV prevention programs must reach ~~tens of millions of Americans~~ people who are ~~characterized by a diversity of~~ in age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

AIDS Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention ~~efforts are~~ support is ~~funded~~ provided by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities ~~also~~ also are 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. The National Institutes of Health (NIH) supports biomedical,

behavioral, and social science prevention research. The National Institute on Drug Abuse (NIDA, ~~NIH~~) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages broader access to prevention information through the integration of prevention ~~interventions~~ services into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

The efforts of Federal Agencies, as well as government-supported research conducted at universities and private organizations, have been instrumental in expanding ~~our~~ the knowledge base about HIV and prevention. However, significant ~~gaps~~ information remain. We know from both research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission; ~~an~~ understanding of the motivations for those behaviors, and ~~an~~ understanding ~~of~~ how best to reach people with messages that will

ensure lasting behavior change.

Prevention priorities must be guided toward gaining knowledge that ~~will~~ improve~~s~~ ~~our~~ efforts to develop effective prevention programs. We need to: improve our understanding about 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 aspect of strengthening prevention activities is to have a clearer understanding of who ~~is being~~ infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in ~~the United States~~ among people who engage in injection drug use ~~which includes the sharing of drug paraphernalia, and/or having sex with an injecting drug user,~~ and their sexual partners, young and minority men having sex with men, through heterosexual ~~transmission~~ 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~~ among persons under 25 ~~years of age~~. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities are also disproportionately represented among ~~new~~ HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. ~~Over~~ More than 50 percent of women with HIV/AIDS are African American or Hispanic. These trends in the epidemic must continue to be ~~taken into~~ considered consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies ~~includes~~ is supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, CDC's AIDS case and case death reporting system provides ~~useful~~ important data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. ~~While~~ effective prevention intervention programs begin with sound information ~~on~~ about who is at risk. Current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) ~~in the population~~ prior to a reported AIDS diagnosis, 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 combined approach and has incorporated data collection design into its community planning process. ~~These~~ Still, shifts in data needs ~~coupled with fiscal restrictions~~ may also require that ~~the~~ CDC reevaluate and reconfigure certain of its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies[13], ~~the~~ CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, ~~and~~ this work should continue.

Prevention Research[14]

Factors that place individuals at risk for acquiring HIV infection

~~are~~ entail a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity, we must not *assume* ~~we~~ to intuitively know which interventions will work, but instead must base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, ~~but~~ when ~~they are it is because~~ the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV-related behavioral research. The three main areas where gaps in our knowledge ~~have~~ where gaps have been identified are: basic behavioral research, intervention research, and social marketing research.

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

To capitalize on what is known and to improve HIV prevention programs that are targeted to reach ~~a~~ diversity of populations 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~~ greater elucidation of the mechanisms underlying addictive behavior ~~may~~ could assist in the development of new therapeutic approaches to addiction, ~~which~~ this may in turn reduce the number of new HIV infections.[15] ~~And~~ although ~~we have~~ there is 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 that may be most effective for an individual or a community.[16]

Intervention Research. A second major gap in research is research to improve prevention interventions, i.e., research that concentrates on modifying behaviors, such as those related to drug use and sexual practices. We know from other behavior-influenced diseases (such as hypertension) and practices (such as cigarette smoking and wearing seatbelts) that basic information about what motivates a person to exhibit these behaviors can be incorporated into intervention research to advance approaches ~~to~~ which reduce 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.[17] Studies have shown that community-based HIV risk reduction programs that are gender-relevant and culturally-sensitive can be effective.[18] ~~A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.~~[19]

However, despite ~~this evidence~~ of success, there is more that we need to know if we are to develop effective prevention programs, ~~for a diversity of Americans.~~ We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavioral change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavioral interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related fields will ~~invariably~~ improve the development of effective prevention interventions.

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

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the

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~~ cannot to, take advantage of current knowledge about program effectiveness.

Prevention Programs

In order to stop new infections, the results of basic behavioral, intervention, and social marketing research must serve as ~~the~~ a foundation for prevention intervention programs that reach people at risk for acquiring or transmitting HIV. Presently, the Federal government supports a range of programs that address the disparate needs of a number of at-risk populations. However, the shifting ~~demographics of the epidemic coupled with restricted resources has~~ ~~economic pressures~~ Resource allocation pressure among many CBOs 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~~ local efforts based on ~~local~~ epidemiology. who is becoming infected. who is infected.

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

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

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

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

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

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for a range of addictions for those in need of such services. This would

include services that accept pregnant women or women with children, indigent members of the community and adolescents.

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

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

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

HIV positive people are at very high for developing ~~of *M. tuberculosis*~~ (TB) **disease**. People infected with both HIV and TB are more likely to develop TB disease than people who infected with ~~only~~ TB. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.[22] In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

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

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

prevention elements and that HIV prevention programs incorporate STD prevention and treatment efforts. ~~Moreover, the~~ traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. ~~Enhanced and innovative~~ linkages between STD and HIV prevention need to be ~~established~~. The newly organized National Center for HIV/STD/TB Prevention at CDC ~~reflects~~ the importance of integrating ~~these~~ inter-dependent aspects of the epidemic and illustrates ~~our~~ determination to integrate and coordinate HIV, STD, and TB programs.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at-risk persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such services, the CDC's counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites.

Incorporating a patient's sexual and drug ~~using~~ history when a medical history is taken, offering HIV-related counseling and

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

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

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

voluntary testing, and providing prevention education to HIV-positive individuals so they do not infect others is also important. ~~It also means~~ offering all pregnant women testing as well as information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level, and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

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

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

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

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

RESEARCH

One of the Federal government's goals is to provide strong support for biomedical research in order to find treatments, and a cure for those currently infected, and a preventive vaccine to protect the uninfected. ~~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~~ these goals require continuing committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, health care professionals, communities where research is conducted, charitable organizations, pharmaceutical ~~companies~~ firms, biotechnology ~~firms~~, and other parts of the private sector. It ~~will~~ also requires an ongoing dialogue between the public and private sectors.

At present, ~~a number of~~ several 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~~ directs the largest portion of these efforts. ~~NIH~~ supports and conducts HIV-related activities in the areas of natural history and epidemiology, etiology and pathogenesis, drug discovery and

therapeutics, vaccines, behavioral and social sciences, and research training. The Veterans ~~Administration~~ Department of Veterans Affairs (VA) also supports a broad range of basic and applied research efforts. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR) funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment, would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of, and risk factors for, transmission through epidemiologic and laboratory studies. ~~The Agency~~ It also supports ~~facilities~~ laboratory facilities employing sophisticated methods for identifying viral variants, among other activities.

Contributions of Research

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

OK

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

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

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

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

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

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

class of drugs, protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, and possibly improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving drugs faster than ever before.

However, despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities, requires a considered and coordinated effort.

Opportunities for Progress

Coordinating Federal Research. Developing and implementing the

Federal government's AIDS research agenda presents both scientific and logistical challenges. Planning and overseeing ~~this massive~~ a Federal effort of this magnitude requires coordination efforts at two levels, one within NIH and the second among the Departments and Agencies supporting HIV research.

Within ~~the~~ NIH, ~~the Agency with the largest portfolio,~~ research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

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

investigation, it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

Add language about the Levine Report?

~~It is also clear that~~ while NIH supports a significant portion of HIV-related research, other Agencies ~~and Departments~~ support a broad spectrum of research related to HIV and AIDS. ~~Multiple Federal Departments and Agencies~~ have responded with research initiatives that bring to bear their unique capabilities and strengths.

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

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

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

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

and the second is to ensure the development and testing of promising vaccine candidates.

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

The issues driving this debate are scientific and social, and stem from the contrasting ways different parts of the world are experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. Both the social and scientific issues must be

considered when planning trials. Given the state of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Both approaches face significant obstacles and it is clear that developing a vaccine cannot be accomplished by the government or the private sector working apart; a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

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

Microbicides. Many scientists believe that in the absence of a

vaccine, the development of a safe, effective, female-controlled mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections, could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs[25]. An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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

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

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

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

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

There is also need for adolescent-relevant information on the part of clinicians and researchers. The Adolescent Medicine HIV/AIDS Research Network, cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA) serves as an important model of collaboration in this area of research. The network has been developed to improve our understanding of disease and health in adolescents; several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network. The Public Health Service should continue to develop, in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program[26], the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, data regarding long-term clinical effectiveness are unavailable. For example, we do not know the optimal stage in the course of HIV disease to begin treatment, for which patient groups, with which regimen, or with single or combination therapy. We also do not know when it is appropriate to switch or add therapies.

If these studies are not done there will be little data describing which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA, it is incumbent on the government to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as

possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug-using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, ~~the~~ NIH, and the advocacy community.

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

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information

about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and ~~Veteran's Administration~~ Department of Veterans Affairs (VA) have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships ~~including~~ that include the NIH, studies of alternative therapies have been conducted; these ~~are~~ important efforts ~~that~~ should continue.

It is cost-effective for the government (DOE) 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~~ made available the use of sophisticated imaging equipment that would be prohibitively expensive for individual researchers or companies to purchase. This shared resource ~~that~~ has accelerated our understanding of molecular structures in a number of research fields, including HIV research. Information gained from this research can form the basis for targeted drug design and development.

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

investment in our future. It must receive consistent and adequate funding if we hope to bring the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, ~~the~~ NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives and the Nation must continue this investment.

CARE & SERVICES

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

Background

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

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

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

After Medicaid, the centerpiece of ~~this~~ the national safety net ~~is~~ consists of programs funded through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, administered by the Health Resources and Services Administration (HRSA). ~~It was~~ the programs were established to fill gaps in coverage and build systems of care to create access to health care for people living with HIV/AIDS. Titles I and II of the CARE Act provide funds for outpatient care, support services, and case management that are given to cities and States primarily on a formula basis so the areas most affected by the epidemic receive a proportional share of available dollars. Title II also provides drug reimbursement funding for persons living with AIDS. Title IIIb of the Act provides early intervention services such as counseling and testing, medical care, and educational services for medically underserved persons with the goal of reducing HIV-related illness. Title IV seeks to increase the availability of care and services for women, infants, children, and youth in a community-based family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

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

Appendix

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

people.

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.

As treatments improve life and extend the productive lives of people with HIV we must continually Re examine the range services that are needed.

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

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

With a strong Medicaid program in place, it ~~continues to be~~ is vital that the Ryan White CARE Act be maintained and expanded to fill the gaps in coverage. Many people with HIV and AIDS are too poor or too disabled to work, yet they are not poor enough or disabled

enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

Integrated Continuum of Care. Many health care providers believe that one of the most potentially effective approaches to treating HIV-positive ~~persons~~ people, ~~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~~ more powerful methods of recruiting people into primary care is knowledge of ~~serostatus~~ HIV serostatus -- ~~persons~~ since people who know they are HIV-positive are more likely to seek health care. Counseling and testing services can serve as a gateway to ~~this care~~ accessing this care. Unfortunately, the majority of Americans who may be at risk for HIV infection do not know whether or not they are HIV-positive. There is a need to develop better outreach education in order to encourage people to come in for counseling and testing and link them to appropriate services as needed. Without the linkage of testing to medical care, the opportunity to prolong life is lost.

Linking ~~an~~ HIV-positive ~~person~~ people with care also provides an opportunity for education about behaviors which may reduce their

chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.[27]

Persons living with HIV face significant obstacles locating affordable housing. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with

specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/~~AIDS~~.

The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems ~~to~~ that address homelessness. ~~Moreover, it~~ It is significant that ~~is~~ estimated ~~that~~ the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In

addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as Public Housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

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

Prisoners. There are also groups of people, such as prisoners, who are not served by these traditional safety net programs. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying the HIV-positive prisoners and ensuring them access to quality care for incarcerated persons is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that

appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level, significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, and strengthening linkages between prisons and outside public health Departments ~~and Agencies~~, and ~~improving discharge planning~~. These efforts can serve to improve discharge planning for HIV-positive prisoners at the time of their release from prison.

Program Coordination. For HIV care and services to have the most beneficial impact, they should be ~~offered as~~ part of a continuum of care. For organizations ~~on~~ at the front lines of the epidemic, building a comprehensive integrated program requires ~~applying to~~ support from numerous Federal Agencies. For example, creating a community-based program that integrates primary care, ~~with~~ substance abuse treatment and prevention, and sexually transmitted disease screening, AIDS prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

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

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

Quality of Care. Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV-positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care

professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

~~However~~ Still, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV-positive ~~persons~~ people. ~~Achieving this~~ Agencies goal attainment will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

No specific actions for Q, minorities.

INTERNATIONAL ACTIVITIES

AIDS is a global pandemic. In the United States it is estimated that between 800,000 and 1 million people are currently infected with HIV. The World Health Organization (WHO) estimates that 18.5 million adults and over 1.5 million children are currently infected worldwide and there will be 10 to 15 million orphans worldwide attributable to HIV/AIDS by the year 2000. WHO also estimates that two to three million new HIV infections can be expected annually, and by the year 2000, thirty to forty million people will have been infected around the globe.

The pandemic jeopardizes decades of economic and social advances in many developing nations. In Africa and Asia, economic advances are threatened, and in some cases, may be reversed due to the pandemic of HIV and AIDS. Socio-economic studies have shown a decrease in overall domestic savings and investment levels, negative effects on foreign investments, reductions in the volumes of imports and exports, and a reduction in receipts from tourism.[28] In many countries, governments will be forced to cope with increasing numbers of cases, weakened health care systems, a deleterious economic impact on the most productive segments of society, and the reduction in the number of healthy men and women able to serve in the government and the military.

JS - to shorten CTS

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CARE & SERVICES

quote
visionary rhetoric
where we've been
where we need to go

> *"AIDS has taken too many friends and relatives and loved ones from everyone of us in this room. It has shaken the faith of many, but it has inspired a remarkable community spirit."*
> *President Clinton, May 20, 1996*
> *Signing of the Ryan White CARE Act Reauthorization*

quote not a perfec

Insert 'vision language'.

1. Record of Accomplishment

The Nation has made significant efforts to ensure that people living with HIV have access to services that are affordable, of high quality, and responsive to their needs. ~~Since~~ January 1993 the Federal government has:

- Increased funding for the Ryan White CARE Act 134 percent in four years;
- Doubled funding for the AIDS Drug Assistance Program ~~in the last two years~~; OK
- Increased funding for Housing Opportunities for People with AIDS 96 percent in four years;
- Preserved the Medicaid guarantee of coverage for the nearly 50 percent of people with AIDS and 92 percent of children with AIDS rely on this health coverage; and
- Revised eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits.

Background

In the early years of the epidemic, the health care infrastructure was particularly unprepared to accomodate the health care needs of

persons with HIV. To meet their complex health care needs, HIV-positive persons were often forced to negotiate a fragmented system of care. There were few programs designed to meet the unique care needs of positive individuals. Moreover, available care services ~~resources~~ were often directed toward meeting the acute care needs of persons diagnosed with AIDS, rather than ~~towards~~ the early ~~preventive care for initial~~ stages of HIV disease. While we still have far to go, the quality and availabilty of services for HIV-postive persons has improved significantly.

People living with HIV now access finance necessary health care services in a variety of ways. Currently, nearly 50 percent of adult Americans and 90 percent of children living with AIDS receive their medical coverage through the Medicaid program and another 5 percent receive Medicare benefits. An estimated 15 percent of people living with AIDS have private health insurance and the remaining 30 percent are uninsured and must rely on personal payment or charity care.[3] ~~Thus,~~ for a disproportionate umber of people living with HIV and AIDS, their lives often depend on the Federal health care safety net. However

For those who qualify, care and services are provided through a number of Federal Agencies (See Appendix C), many in cooperation with local organizations and the AIDS community, that have admirably served those living with HIV. Taken together, these efforts form a valuable, if yet incomplete, safety net for some of the most vulnerable people in our Nation.

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

[3] JL cite. Add Vancouver numbers.

family-centered system of care. HRSA also provides primary care to persons living with HIV through its Community Health Centers and Maternal and Child Health Programs.

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

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

2. Future Opportunities for Progress

The challenge before us today is to ensure that persons living with HIV receive the care they need so they may have the opportunity to live productive lives. 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. As treatments improve and extend the productive lives of people with HIV, we must continually re-examine the range of service that are needed.

The Health Care Safety Net. The cornerstone of care for people living with AIDS in the U.S. is Medicaid. The program provides coverage for hospitalizations, physician visits, x-rays and laboratory tests, home health care, nursing home care, and outpatient prescription drugs. In fiscal year 1996, Federal Medicaid spending for people living with AIDS is estimated at $1.8 billion, nearly six times the amount expended on the Ryan White CARE Act.

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

also

With a strong Medicaid program in place, it is vital that the Ryan

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

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

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

Linking HIV-positive people with care also provides an opportunity for education about behaviors which may reduce their chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

Again, as was true in terms of prevention, acheiving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for people living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person living with HIV 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 people living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.[14]

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People living with HIV and their families face significant obstacles locating affordable housing. The private market alone does not consistently meet their basic housing needs. Housing must often be provided in connection with specialized services that enhance an individual's or family's ability to live independently. In addition, people living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV.

The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems that address homelessness. It is significant that the estimated cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In addition, the Community Development Block Grant (CDBG), and the HOME affordable housing program, as well as public housing programs are key resources that are available to communities, contingent upon eligibility, space availability, and local priorities.

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

Prisoners. Another group of people frequently underserved are prisoners. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying HIV-positive prisoners and ensuring them access to quality care for incarcerated people is especially

challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level, significant advances are being made in the quality of care, improved coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons and strengthening linkages between prisons and outside public health Departments. Success at these efforts can serve to improve discharge planning for HIV-positive prisoners at the time of their release from prison. ~~For example, effort are laready underway to improve linkages between discharge planning and Ryan White CARE Act programs, to assure a contiuum of cre and services for newly released HIV-positive prisoners.~~

Program Coordination. For HIV care and services to have the most beneficial impact, they should be part of a continuum of care. For organizations at the front lines of the epidemic, building a comprehensive integrated program requires support from numerous Federal Agencies. For example, creating a community-based program that integrates primary care, substance abuse treatment and prevention, and sexually transmitted disease screening, HIV prevention, access to clinical trials, and housing assistance would require separate applications to SAMHSA, HRSA, CDC, NIH, and HUD.

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

Evaluation. Strong Federal support for these safety net programs must go hand-in-hand with improved accountability and priority setting. Evaluating current activities can provide valuable information for planners and those at the front lines of the epidemic and assist in providing better care to people 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 to the benefit of HIV-positive people.

Quality of Care. Federally supported programs can and should consistently provide quality care. Quality care for HIV-positive people is possible, but quality care is not consistently available

throughout the health care system. Ensuring consistency in care delivery will require increased training for health care professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

Still, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV-positive people. Again, goal attainment will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

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Members of the Interdepartmental Task Force on HIV and AIDS

Message from the Director of the Office of National AIDS Policy

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

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

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

governments, the private sector, and infected and affected communities and individuals. The urgency of the crisis requires that we build upon what we have already learned, joining together with one another to develop a new, more unified and collaborative approach to addressing the epidemic.

The Strategy was developed through consultation with, and guidance from, many groups and individuals. I would like to thank, in particular, the members of the Interdepartmental Task Force on HIV and AIDS (IDTF) for the time and attention that they, and their staffs, contributed to the development of the Strategy. The IDTF is a group consisting of representatives from executive branch Departments and Agencies that conduct HIV-relevant work.

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

(2)

attendees at regional briefings across the country.

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

This document, then, is a snapshot of where we are and where we think we need to go. ~~Collaboration is one of the hallmarks of this Administration's approach to AIDS policy and Strategy~~ this document is serves as a reference point for lengthier dialogues and collaborative efforts between the public and private sectors that will be necessary to implement this strategy.

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

The epidemic challenges us on many fronts. Because the most common transmission routes are sexual activity and drug use, topics difficult for many Americans to confront directly, HIV has challenged this country to look at things that are difficult to face.

There is also fear -- fear of contracting this disease and unwarranted fear of those who are infected. Fifteen years into the epidemic, persons living with HIV still endure daily prejudice and discrimination based upon their HIV status. We are further challenged by the inadequacies of a social and health care infrastructure that is, in many ways, woefully unprepared to address the needs of HIV-infected persons. Moreover, the safety net provided by programs such as Medicaid and Medicare is threatened with fundamental programmatic changes and reductions in funding. Scientifically, we have made much progress, but the virus continues to be a formidable adversary, challenging the best and brightest among us to find a cure and a vaccine.

It is why a National strategy is needed.

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

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

shorter?

death of their own child. The myriad of Federal and State Agencies (i.e. .....) charged with overseeing child welfare issues, coupled with a legal code not designed to dispense compassionate remedies for these orphaned children, has created a bureaucratic nightmare for dying parents seeking to provide a safe and caring home for their children. There is a need to be sure parental rights are maintained as long as possible, but also to facilitate the orderly and legal transfer of custody upon incapacitation or death of a child's parent(s). It is to focus attention on such cross-cutting challenges that the IDTF was created and this Strategy developed.

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

Today we are facing great challenges, but we are also facing

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

Preface

The Need for a National Strategy for HIV and AIDS

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

Since the discovery of the first AIDS cases in the early 1980s, the epidemic of HIV and AIDS has posed a series of unique challenges. The challenges today are very different from those that we faced ten or even five years ago. We now know the risk factors and the etiologic agent, and we have tests to diagnose infection and protect the blood supply. We are developing new and more powerful therapies that offer hope for treatment and prevention. Scientists now believe that a vaccine is possible. Nonetheless, the epidemic continues. More people are infected every year, in every geographic area, and in every age range. Racial and ethnic minorities are disproportionately represented among existing and new cases of HIV infection. And youth are at increasing risk. Internationally, the epidemic is threatening the economic stability

as in new vs. total #

of a number of developing nations.

The changing face of HIV and AIDS, coupled with a period of overall fiscal restraint and a trend toward managed health care programs, require new approaches and

alternative:

and a changing health care delivery system in the U.S.

(managed care per se is not the problem)

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

The Strategy as a Catalyst for Change

The National Strategy is intended to serve the public, the President, the Congress, the members of the Interdepartmental Task Force on HIV/AIDS, and Presidential Advisory Council on HIV ~~and~~ AIDS. The text that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS.

The Strategy does not prescribe a fixed sequence of steps by which the entire plan, and its identified opportunities, are to be accomplished. The goals, common objectives, and opportunities for progress are intended to serve as a focus for our attention and efforts. The development of a functional implementation plan will be the responsibility of the Office of National AIDS Policy in partnership with the Interdepartmental Task Force on HIV/AIDS, the Presidential Advisory Council on HIV and AIDS, private sector organizations, and the community.

Executive Summary

== Place Holder ==

I. INTRODUCTION

Scope of the HIV/AIDS Pandemic

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

An Expanding Public Health Threat

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

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

As the epidemic in the United States has evolved, the demographics of the epidemic have been shifting. The early years of the epidemic were dominated by cases involving gay or bisexual men living in major urban centers, such as New York, San Francisco, and Los Angeles; this group now represents less than half of all new cases. Among the populations being more heavily affected now are young gay men, women, and heterosexual injecting drug users and their partners as well as non-injecting drug users (i.e., crack cocaine and alcohol). Although gay men no longer represent the majority of new cases, this group represents the majority of persons living with HIV and AIDS. In 1995, nearly 14,000 women were reported with AIDS and now women comprise 14 percent of cumulatively reported AIDS cases. It is estimated that if this trend continues, 80,000 American children will have been orphaned as a result of AIDS by the end of this decade. In 1995, approximately 800 new pediatric AIDS cases were reported. It is

however hoped that with greater use of AZT by HIV-positive mothers during pregnancy and delivery, and administration to their babies after birth, the number of new cases in newborns can be reduced. As the geographic diversity of the disease has widened, the impact of the disease on the country as a whole has also increased.

Adolescents are at special risk. The CDC estimates that one in four new HIV infections in the U.S. occur among young people. A significant number of young people are engaging in sexual intercourse as well as drug and alcohol use at earlier stages in their lives. This fact, coupled with the disturbing number of adolescents who are prone to high-risk behavior due to homelessness, sexual abuse, and other circumstances, places young Americans in a situation that leaves them extremely vulnerable to HIV infection.

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

epidemic in US
pandemic - worldwide ??

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

Internationally, the toll of the epidemic is greater still. The World Health Organization (WHO) estimates that since the beginning of the epidemic, 4.5 million cases of AIDS have occurred worldwide. It has estimated that as of mid-1995, 18.5 million adults and more than 1.5 million children have been infected with HIV since the beginning of the pandemic. WHO also projects that by the year 2000 between 30-40 million people will have been infected with HIV.

The Social Impact

Prejudice and discrimination are still experienced by people living with HIV, their families, and their loved ones. Persons with HIV have been denied medical and dental services, emergency medical treatment, and health insurance. They have been discharged from

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

AIDS is a disease that most often affects people in the prime of life. It kills people during their most productive years. That it is the leading cause of death among Americans 25 to 44 is particularly significant since this is the age group that constituted 54% of the civilian labor force in 1992.[2] Premature deaths due to AIDS result in the loss of many productive years of life and in many cases deprive young children of their parents. In 1994, HIV infection was the fourth leading cause of years of potential life lost before age 65.

AIDS has consistently risen in the rankings as a cause of death, while rates for disease such as cancer and heart disease have been comparatively stable. Direct lifetime medical care after diagnosis for an HIV-infected person costs more than care for patients with cancer or heart disease, specifically: $61,211 for heart disease[3], $25,000 to 84,000 for cancer[4], and $119,000 for HIV/AIDS[5] And although cancer and heart disease costs may be attributable to striking older and frailer persons, overall DHHS spending for research, treatment, prevention, and income supplements is significantly greater for cancer and heart disease than for AIDS.

Anything more recent from Vancouver?

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

In developing countries, the pandemic threatens to reverse decades of progress in strengthening national economies and improving the health status and social well-being of millions of women, men, and children. In some African nations, 95 percent of hospital beds are occupied by AIDS patients. Moreover, the WHO estimates that 10 to 15 million children will be orphaned due to AIDS by the year 2000. The human toll has been staggering and is likely to continue.

The Evolving Challenge of the HIV/AIDS Epidemic

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

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

Building on the knowledge gained from those discoveries, more resources were subsequently directed towards achieving a deeper understanding of HIV-related immunology and pathogenesis, and, developing therapies for HIV infection and its associated opportunistic infections and malignancies. New and more powerful therapies that offer new hope for treatment and prevention have been developed. Scientists now believe that a vaccine is possible.

~~Current day~~ Today's discoveries also create new challenges for the future. ~~We now face new scientific challenges in~~ offering new insights and opportunities for developing a vaccine and ~~the~~ a new generation of therapeutics for HIV and its associated and opportunistic infections and malignancies.

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

The progress in developing therapies and prevention programs has also created new problems for the health care delivery system. [As a result of improved therapies, people with AIDS now live twice as long as they did a decade ago.] Due to NIH-sponsored research we now have the ability to reduce the risk of perinatally acquired HIV infection by treating women with AZT during pregnancy and their babies after birth. The recent approval of a new class of

therapies, protease inhibitors, will again change the direction of HIV/AIDS treatment, ~~and prevention?~~ Ensuring access to these therapies is the challenge that confronts us now. We need to improve our efforts in providing people with care earlier in their infection so they can receive the full benefit of the new treatments and we need, as well, to ensure that health care professionals are well-trained and know the best way to provide that care.

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

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

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

Goal of the National Strategy

The goal of the National AIDS Strategy is to capitalize upon the progress which has been made in fighting the epidemic and to catalyze new and strengthened collaborative efforts among Federal Departments and Agencies, communities, State and local governments, and the private sector. To realize this ambition we will need innovative ideas, careful planning, and the strength of public-private partnerships to make these plans a reality.

The text and appendices that follows will serve as a blueprint that will: document the baseline of current efforts government-wide; link goals to budget objectives; and, guide us in refining our goals and objectives in response to the changing face of the epidemic of HIV and AIDS. This is intended to be a living document that will require regular updating and adjustment as goals are reached and as new challenges ~~occur~~ arise.

Development of the Strategy

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

of Health and Human Services, as evidenced by a series of documents such as the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome[7], the "Coolfont"[8] and "Charlottesville"[9] reports, and the PHS Strategic Plan to Combat HIV and AIDS in the United States[10]. There have also been planning efforts on the part of various Agencies and Departments, such as the Department of State's United States International Strategy on HIV/AIDS, the congressionally-mandated annual NIH plan for HIV-related research, and the Federal Biomedical and Behavioral Research Plan for HIV and AIDS. Recommendations have also been issued by a number of groups, including the National Commission on AIDS[11] and the Presidential Advisory Council for HIV and AIDS. However, until now there has not been a national plan that provides for a government-wide coordinated effort encompassing not just Public Health Service activities, but also that incorporates areas such as housing, health care, and civil rights.

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

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

There has also been a reliance on groups outside of government -- the same groups that have been and will continue to be essential partners in developing solutions and capitalizing on the opportunities for progress that lay before us now. The recommendations provided by the Presidential Advisory Council on HIV and AIDS (PAC) have been invaluable. The advice and counsel of the activist and advocacy communities, participants in the White House Conference on HIV and AIDS, individuals on the front lines of the epidemic, and many HIV-infected persons and their families, friends, and care givers have been essential in identifying areas for focused attention. And finally, the insights provided by ~~a~~ (and) the National Commission on AIDS, the Institute of Medicine of the National Research Council, the General Accounting Office, and the reports of the Office of Technology Assessment have also been extraordinarily helpful in developing this Strategy.

Same as before re briefings

Common Objectives and Opportunities for Progress

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

- To provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected;

- To provide solid support for effective prevention strategies so as to reduce the number of new infections each year until there are no new infections; and,

- To ensure that treatment of persons living with HIV is caring, ethical, and in accordance with legal standards.

I vote for this (2) Alternative language: To ensure that persons living with HIV are not subject to discrimination and (1) receive services that are caring, ethical, and in accordance with legal standards.

Also through the consultations, it became clear that there was consensus regarding the major challenges facing us today, and that these challenges warranted focused attention. There was also a judgment that these challenges represent opportunities for progress

-- opportunities to take steps today to find a cure and a vaccine, reduce the number of new infections, and care for those who are infected.

Based on this counsel, opportunities for progress are presented and discussed within each substantive section ((i.e., prevention, research, care and services, international activities, translation of research into clinical practice, and civil rights)) of the Strategy. (See section on Organization of the Strategy below.) It is these opportunities that will require consideration and broad-based input in the development of implementation plans if we are to meet the challenges they present.

Implementation

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

Each issue raised in the Strategy will require specially tailored approaches and implementation plans. In some cases significant progress has already been made, in others much work remains. Some of these challenges can be resolved with the cooperation of a small number of Agencies and organizations, while others will require extensive thoughtful effort on the part of many committed participants in order to craft workable solutions. It will also be important to build on the less comprehensive planning efforts that have taken place and complement current planning activities.

Organization of the National AIDS Strategy

The National AIDS Strategy is organized into the following substantive areas: prevention, research, care and services, international activities, translation of research into practice, and civil rights.

Information and discussion of Federal activities can be found in three locations within the document. First, discussion on each substantive area addresses broad policy issues and new Federal objectives in terms of the national goals and opportunities for progress. Second, each substantive section has a corresponding appendix that provides information on individual Agency goals, objectives, funding levels, constituency involvement, and unmet

needs. And third, funding tables can be found in Appendix G.

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

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

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

II. OVERVIEW OF FEDERAL EFFORTS

Introduction

The scope and nature of the HIV/AIDS epidemic have brought State, local, and Federal involvement into many HIV-related activities. The Federal government, through its public health responsibilities in such areas as research, prevention, health care, and housing has seen a dramatic increase in its activities since the beginning of the epidemic. In 1985 the Federal government spent $212 million for AIDS research, surveillance, and care. With the dramatic increase in cases, by 1995 that figure had reached $6.8 billion. (See Appendix G). Congress also took note of the rapid increase in cases of HIV and AIDS and passed legislation that sought to address the needs of HIV-infected persons and their families, and the Nation's need to find a cure and a vaccine, including the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Act and the NIH Revitalization Act of 1993.

Currently, Federally sponsored activities include direct support for research, training, prevention and education, housing, medical care, support services, information dissemination, enforcement of civil rights, and assistance to international organizations and

other nations. While Federal Agencies are responsible for responding directly to the epidemic of HIV and AIDS, they also collaborate with and provide support for surveillance, prevention, research, and health care responsibilities carried out by State and local governments, academic institutions, private foundations, health care institutions and community-based organizations.

PREVENTION

The Nation's prevention goal is to develop effective prevention strategies that will reduce the number of new infections each year until there are no new infections. Achieving this goal will require a dedicated alliance ~~between~~ among the Federal government, States, local governments, communities, businesses, the academic community, professional and non-governmental organizations, families, health care professionals, and individuals. Achieving this ambitious end will require a clear definition of the different roles and responsibilities of the Federal government, and an ongoing dialogue with its partners in the public and private sectors about the responsibilities each has in reaching this goal.

We know that HIV prevention works. We also know that the task of preventing HIV transmission faced by the United States in controlling the epidemic of HIV and AIDS has reached enormous proportions.[12] The Centers for Disease Control and Prevention (CDC) estimates that approximately 800,000 to 1 million Americans are presently HIV-infected, many of whom are unaware of their HIV status. Moreover, the CDC estimates that approximately 40,000 to 60,000 Americans will become 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

new estimate

the virus' virulence, the long period of time when people may not be aware they are infected, long duration of infectiousness, nearly always fatal prognosis, and potential for exponential spread. Moreover, HIV is transmitted primarily as a result of personal and private behaviors -- sex and drug use. To be effective, HIV prevention programs must reach tens of millions of Americans who are characterized by a diversity of age, race, ethnicity, geographic locale, sexual orientation, and sexual and drug use behaviors.

Prevention activities are currently supported by several Federal Agencies. (See Appendix A.) Most Federal prevention efforts are funded by Department of Health and Human Services (HHS), although other Departments such as the Department of Defense (DOD), and the Department of Veterans Affairs (VA) also support prevention activities. These efforts reflect a continuum from surveillance to research to social marketing initiatives. Agency activities are also reflective of their respective missions. For example, the Centers for Disease Control and Prevention (CDC), the Agency with primary Federal HIV prevention responsibilities, supports a wide range of surveillance and prevention projects, many in partnership with States, local governments, and community-based organizations. Other Agencies focus on specific aspects of prevention. The National Institutes of Health (NIH) supports biomedical,

behavioral, and social science prevention research. The National Institute on Drug Abuse (NIDA, NIH) and the Substance Abuse and Mental Health Services Administration (SAMSHA) support efforts to prevent HIV infection among drug users, while other Agencies support primary prevention efforts as part of medical care, such as at the veterans and military hospitals and clinics. The Health Resources and Services Administration (HRSA) also encourages broader access to prevention information through the integration of prevention interventions into primary health care services and through support of early intervention services for low-income medically underserved persons. HRSA also has undertaken special initiatives designed to reduce perinatal transmission of HIV and has promoted primary prevention through the training of health professionals in the AIDS Education and Training Centers program.

The efforts of Federal Agencies as well as government-supported research conducted at universities and private organizations, have been instrumental in expanding our knowledge base about HIV prevention. However, significant gaps remain. We know from both research and community experience that developing prevention programs that are effective requires knowledge of who is becoming infected and of the behaviors that are enabling transmission, an understanding of the motivations for those behaviors, and an understanding of how best to reach people with messages that will

ensure lasting behavior change.

Prevention priorities must be guided toward gaining knowledge that will improve our efforts to develop effective prevention programs. We need to improve our understanding about 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 aspect of strengthening prevention activities is to have a clearer understanding of who is being infected and what behaviors are placing people at risk for infection. Recent epidemiologic data show that the HIV epidemic continues to spread in the United States among people who engage in injection drug use, which includes the sharing of drug paraphernalia, and/or having sex with an injecting drug user, and their sexual partners, young and minority men having sex with men, through heterosexual transmission 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. It is likely that many Americans, aged 25 to 44, for whom HIV is the leading cause of death, became infected as adolescents. Racial and ethnic minorities are also disproportionately represented among new HIV infections. In 1995, African-Americans accounted for 40 percent of newly reported AIDS cases and Hispanics represented 19 percent of new cases. Over 50 percent of women with HIV/AIDS are African American or Hispanic. These trends in the epidemic must be taken into consideration when prioritizing prevention research and service programs.

A crucial part of effective prevention strategies includes supporting adequate surveillance of HIV infection and related diseases in order to gauge future directions of the epidemic, and assess the effectiveness of prevention interventions. Seroprevalence surveys provide information on the level of HIV infections in selected "sentinel" populations. As the Federal Agency with primary responsibility for monitoring the epidemic, CDC's AIDS case and case death reporting system provides useful data for assessing AIDS prevalence and mortality by gender, race/ethnicity, age, and mode of exposure. This surveillance system also provides essential data on HIV-related opportunistic infections.

There are, however, opportunities for refinement. While effective prevention intervention programs begin with sound information on who is at risk, current CDC surveillance systems do not capture sufficient "front-end" information on the incidence and prevalence of HIV (not AIDS) in the population, and trends in modes of transmission and new infections. (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 coupled with fiscal restrictions may also require that the CDC reevaluate and reconfigure its data collection efforts. As part of the Agency's implementation of the recommendations set forth in the external review of CDC's HIV prevention strategies[13], the CDC has initiated efforts to evaluate current data collection efforts and implement necessary changes, and this work should continue.

Prevention Research[14]

Factors that place individuals at risk for acquiring HIV infection

are a complex combination of behavioral, social, cognitive, and biological influences. Given this complexity we must not *assume* we intuitively know which interventions will work, but instead base our efforts on sound research findings and evaluation. Experience has taught us that prevention efforts can be effective, but when they are it is because the intervention incorporates findings from both experience and relevant research. Many significant scientific questions exist in the field of HIV-related behavioral research. The three main areas where gaps in knowledge have been identified are basic behavioral research, intervention research, and social marketing research.

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

To capitalize on what is known and improve HIV prevention programs that are targeted to reach a diversity of Americans, more information on the determinants of HIV-associated sexual and drug-

using behaviors is needed. For example, although much has been learned about the basic biology of substance abuse, further elucidation of the mechanisms underlying addictive behavior may assist in the development of new therapeutic approaches to addiction, which may in turn reduce the number of new infections.[15] 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.[16]

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

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

individuals and communities, which often hold norms that influence personal behavior. Since the beginning of the epidemic we have made advances in our understanding of factors that are relevant to the design of intervention programs intended to reduce rates of HIV infection. This theoretically based intervention research has identified several significant predictors of changes in sexual and drug-using behaviors among gay men, adolescents, and heterosexual adults.[17] Studies have shown that community-based HIV risk reduction programs that are gender relevant and culturally sensitive can be effective.[18] A recent study has also provided a reason for optimism that the spread of HIV can be contained among injecting drug user populations when there is early community outreach and access to sterile injection equipment.[19]

However, despite this evidence of success, there is more that we need to know if we are to develop effective prevention programs for a diversity of Americans. We must incorporate findings from basic behavioral research into effective prevention interventions. One high priority area is research on interventions that lead to sustained behavior change and reduced recidivism. Another area for investment is research on cultural barriers and strategies to reach populations resistant to certain behavior interventions. A third area is research on the effectiveness of treatment for drug abuse, mental illness, and alcoholism in reducing HIV risk behavior.

Agencies supporting intervention and behavioral research must include scientists from a broad range of disciplines in their planning activities and improve their data-sharing and collaborative efforts with Agencies responsible for implementing prevention programs. Enhancing the dialogue between researchers in these two related fields will invariably improve the development of effective prevention interventions.

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

We know from efforts in other countries that HIV-related social marketing efforts can be successful. However, we have not been as effective as we could be in disseminating information about effective strategies so that this knowledge can be employed in the

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

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

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

design and implementation of prevention interventions. There are good models for prevention interventions that are not making their way to those on the front lines of the epidemic. Community-based organizations, which are responsible for developing a large portion of the prevention programs often do not, or are not able to, take advantage of current knowledge about program effectiveness.

Prevention Programs

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

Community Involvement. For prevention interventions to be effective they must reach communities at risk and be responsive to their unique needs. And for individuals to take control of their

own lives in fighting the spread of this virus, they must first have the information and skills to protect themselves.

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

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

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

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

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

Fundamental to the success of an integrated approach would be the continued expansion of educational activities to prevent substance abuse, and increased outreach efforts to encourage active substance users to seek treatment. We also need to ensure that drug treatment services are available in sufficient numbers for a range of addictions for those in need of such services. This would

include services that accept pregnant women or women with children, indigent members of the community and adolescents.

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

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

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

HIV positive people are at very high for developing of *M. tuberculosis* (TB) **disease**. People infected with both HIV and TB are more likely to develop TB disease than people who are infected with only TB. Studies suggest that the risk of developing TB disease is 7 to 10 percent each year for persons who are infected with both TB and HIV, whereas the risk is 10 percent over a lifetime for persons not infected with HIV.[22] In addition to the health implications for infected persons, there is an increased risk of transmission of TB to household members, health care workers, and other persons having regular contact with the person with TB.

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

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

prevention element, and, that HIV prevention programs incorporate STD prevention and treatment efforts. Moreover, the traditional model of targeting most STD prevention efforts towards individuals who have already contracted one STD is not necessarily effective for HIV prevention. Enhanced and innovative linkages between STD and HIV prevention need to be established. The newly organized National Center for HIV/STD/TB Prevention at CDC reflects the importance of integrating these interdependent aspects of the epidemic and illustrates our determination to integrate and coordinate HIV, STD, and TB programs.

Integration Into Primary Care. To reach our prevention goal, we must also improve the integration of prevention activities and messages into primary health care services. HIV counseling and voluntary testing often provide an important bridge between HIV prevention and care for many at risk persons, including youth, women, and ethnic minorities. To assure that all persons seeking HIV testing can have access to such care services, the CDC's counseling and testing guidelines should acknowledge and address the needs of persons seeking such services, and provide training for personnel at CDC-funded sites to provide that linkage.

In the primary care setting, Incorporating a patient's sexual and drug using history when a medical history is taken, offering HIV-related counseling and

voluntary testing, and providing prevention education to HIV positive individuals so they do not infect others is also important. It also means offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission. Training should be made available to improve primary care providers' skill, comfort level and sensitivity in these areas.

Achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local, and Federal governments.

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

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

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

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

RESEARCH[24]

One of the Federal government's goals is to provide strong support for research in order to find treatments and a cure for those currently infected, and a preventive vaccine to protect the uninfected. It is research that will enable us to reach these goals and until they are a reality, the Federal government must provide solid ongoing support for basic and clinical research.

Achieving this goal will require committed collaborative efforts among the Federal government, universities, researchers, the advocacy community, persons living with HIV and those at risk for infection, communities where research is conducted, charitable organizations, pharmaceutical companies, biotechnology firms, and other parts of the private sector. It will also require an ongoing dialogue between the public and private sectors.

At present, a number of Federal Agencies play a significant role in U.S. AIDS research efforts. (See Appendix B.) These endeavors range from basic molecular research to clinical research to health services research. The National Institutes of Health (NIH) supports the largest portion of these efforts. NIH supports HIV-related activities in the areas of natural history and epidemiology, etiology and pathogenesis, drug discovery and

therapeutics, vaccines, behavior and social sciences, and research training. The Veterans Administration (VA) also supports a broad range basic and applied research efforts. As part of its mission to protect and maintain a viable fighting force, the Department of Defense supports clinical vaccine and therapeutic research. The Agency for Health Care Policy and Research (AHCPR) funds health services research to help determine which medical approaches are the most cost effective. The Department of Energy (DOE), through its support of technologically advanced equipment, provides the opportunity for Federal and private researchers to share resources and thereby analyze molecular structures that, without such equipment, would not be possible. The Centers for Disease Control and Prevention (CDC) monitors and assesses modes of and risk factors for transmission through epidemiologic and laboratory studies. The Agency also supports facilities employing sophisticated methods for identifying viral variants.

Contributions of Research

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

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

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

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

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

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

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

class of drugs, protease inhibitors. When used in combination with other types of anti-retroviral drugs, there is the potential to dramatically reduce the amount of HIV in the bloodstream, and possibly improve a person's clinical status and reduce transmission. A landmark advance in HIV prevention was the demonstration that AZT can dramatically reduce the risk of transmission of HIV infection from a pregnant woman to her child. Advances in effective treatments for HIV-related conditions can prolong and improve the quality of life of persons living with HIV. In addition, the Food and Drug Administration, through its expedited review and accelerated approval programs, is now approving HIV drugs faster than ever before and faster than any European nation.

Can we say this about all drugs or just HIV drugs?

However, despite these advances, many complex biomedical and behavioral challenges remain. Identifying the most promising scientific avenues, and having the appropriate structures and processes in place to ensure that the Nation capitalizes on these opportunities, requires a considered and coordinated effort.

Opportunities for Progress

Coordinating Federal Research. Developing and implementing the

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

Within the NIH, the Agency with the largest portfolio, research is supported throughout 24 institutes, centers, and divisions (ICDs). In order to better plan, coordinate, evaluate, and fund the AIDS research activities of these ICDs the Congress, through the NIH Revitalization Act Amendments of 1993, provided the Office of AIDS Research (OAR) with new oversight and budget authorities. The law requires that the OAR develop a yearly NIH plan and budget for AIDS research and receive directly from the President and the Office of Management and Budget (OMB) a consolidated appropriation for AIDS activities at NIH. This single appropriation allows the OAR to effectively prioritize research resources on the basis of sound scientific judgment and provides flexibility for pursuing the most promising research opportunities.

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

investigation, it is essential that there is oversight and accountability so the most promising approaches are vigorously pursued, gaps in research areas are identified, and the individual Institutes have both the scientific and administrative assistance they need to effectively collaborate with other NIH institutes.

Add language about the Levine Report?

Yes – perhaps calling it Evaluation – since you mention its importance in prevention.

It is also clear that while NIH supports a significant portion of HIV-related research, other Agencies and Departments support a broad spectrum of research related to HIV and AIDS. Multiple Federal Departments and Agencies have responded with research initiatives that bring to bear their unique capabilities and strengths.

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

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

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

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

and the second is to ensure the development and testing of promising vaccine candidates.

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

The issues driving this debate are scientific and social, and stem from the contrasting ways different parts of the world are experiencing the epidemic. Some regions of the world have already experienced the devastating consequences of the epidemic while, in other areas, the epidemic is in its early stages. Some governments have shown a greater interest than others in preparing for vaccine trials as a method of slowing the growth of the epidemic in their countries. Both the social and scientific issues must be

considered when planning trials. Given the state of scientific knowledge, there is some consensus that both the basic and empirical avenues can and should be pursued.

Both approaches face significant obstacles and it is clear that developing a vaccine cannot be accomplished by the government or the private sector working apart -- a public-private partnership will be needed. In order to identify areas for fruitful collaboration and to accelerate the pace of development for vaccines, the Vice President convened a meeting of government scientists and leaders of the pharmaceutical and biotechnology industries to identify barriers to the development of these agents. Further dialogue involving key players regarding critical problems, and opportunities for development, and viable solutions has begun and will continue.

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

Microbicides. Many scientists believe that in the absence of a

vaccine, the development of ~~a~~ safe, effective, female-controlled mechanical or chemical barrier methods that will block HIV transmission or prevent other sexually transmitted infections, could dramatically reduce the sexual transmission of HIV. Worldwide over 80 percent of HIV infections are acquired heterosexually and women are more easily infected than men. In the U.S., the infection rate among women is rising dramatically. Moreover, the risk of becoming infected or infecting others is substantially increased by the presence of other STDs[25]. An easily available and inexpensive microbicide could provide a prevention option for millions of women worldwide.

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

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

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

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

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

There is also need for adolescent-relevant information on the part of clinicians and researchers. The Adolescent Medicine HIV/AIDS Research Network, cooperatively funded by the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Drug Abuse (NIDA), and the Health Resources and Services Administration (HRSA) serves as an important model of collaboration in this area of research. The network has been developed to improve our understanding of disease and health in adolescents. ~~several PHS agencies have cooperatively established the Adolescent Medicine HIV/AIDS Research Network.~~ The Public Health Service should continue to develop in collaboration with researchers, clinicians, and the infected and affected community, clinical practice guidelines for adolescents and expeditiously disseminate the latest information on state-of-the-art therapies, options for trials and eligibility criteria for entry into them, and health care and prevention techniques to U.S. and international communities affected by HIV/AIDS.

Clinical Effectiveness Research. Due in part to the FDA's accelerated approval program[26], the Federal government is now approving new treatments in record numbers and at record speed, but it is not always known whether a treatment confers a clinical benefit for the person. Specifically, while some treatments have shown promise based on surrogate markers and/or laboratory tests, we do not know the durability of this effect, whether these results are generalizable ~~data regarding long-term clinical effectiveness are unavailable~~. to ~~the~~ an persons with HIV infection, and the actual impact of these drugs on reducing mortality. ~~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.~~ Nor do we know the answers to some important clinical questions relating to the most effective use of these drugs: when to switch regimens or add therapies when resistance develops.

If these studies are not done there will be little data describing which of the available treatments is more effective and for whom, and under what circumstances. As a result, patients may be receiving less effective treatments or combinations of treatments, and Federal programs such as Medicaid and Medicare and private insurers may be paying for treatment strategies that are not optimally effective.

With the advent of accelerated approval by the FDA it is incumbent on the government to ensure that post-marketing effectiveness studies, currently mandated through regulation, are carried out. In order for the results to be relevant to as many persons as

possible, it will be necessary that these studies include people representing a diversity of race, ethnicity, gender, age, and drug using behaviors. To develop a mechanism for conducting such studies, the Vice President has initiated discussions to examine possible options. Participants include pharmaceutical firms, public and private payors and insurers, researchers, the FDA, the NIH, and the advocacy community.

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

It is also unlikely that the free market system will push the implementation of head-to-head clinical trials of therapies that have been approved or are in development. However, information

about these therapies is important to improving patient care and ensuring that the Nation's health dollars are wisely spent. The National Institutes of Health and Veteran's Administration have been successful in carrying out this type of valuable research in collaboration with the pharmaceutical industry and these efforts should continue. It is unlikely that the private sector would support research for therapies that are on the market but have not been tested in controlled clinical trials, such as alternative therapies. However, through collaborative partnerships including the NIH, studies of alternative therapies have been conducted; these are important efforts that should continue.

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

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

investment in our future. It must receive consistent and adequate funding if we hope to ~~bring~~ inspire the best and the brightest to meet the research challenges that will lead to a cure, better therapies, and a vaccine.

At present, the NIH receives many more outstanding research applications than it is able to fund; these unfunded proposals represent a lost opportunity for scientific progress. Other Departments and Agencies, such as the Department of Defense and Veteran's Administration also support crucially important research that strengthens the overall U.S. research effort. Research has been key to prolonging and improving the quality of lives of all Americans and the Nation must continue this investment.

CARE & SERVICES

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

Background

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

This, for a disproportionate number of people living w/ HIV/AIDS,

(we want this to include Medicaid)

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

Footnote — I have a cute Chris Vanlowe but Chris #s — For newer uninsured may be higher now.

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

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

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

Housing assistance is provided by the Department of Housing and Urban Development (HUD) through their Housing Opportunities for Persons with AIDS (HOPWA) and other programs. These programs work in partnership with local initiatives incorporating housing assistance into a community's continuum of services.

Opportunities for Progress

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

to add some controversy: As treatments improve and extend the productive lives of people with HIV, we must continually reexamine the range of services that are needed.

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

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

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

enough to qualify for Medicaid. For them, and for their families, the CARE Act provides essential protection.

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

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

Linking an HIV-positive person with care also provides an opportunity for education about behaviors which may reduce their

chances of infecting others. For example, this can mean offering addiction treatment or offering pregnant women information about and access to AZT during pregnancy to reduce the risk of perinatal transmission.

As noted in the Prevention Section, achieving this level of integration will require active collaborative efforts on the part of individual physicians, nurses, other clinicians, managed care plans, medical schools, and professional organizations in addition to State, local and Federal governments.

Housing Services. Housing is an important element in the effort to provide comprehensive care for persons living with HIV. It is the foundation upon which any program of care or services must be built. Without stable housing, a person with HIV/AIDS has diminished access to programs and services and a diminished opportunity to live a productive life. It is estimated that up to 50 percent of persons living with HIV and AIDS will become homeless or are at risk for becoming homeless during the course of their illness.[27]

Persons living with HIV face significant obstacles locating affordable housing. The private market alone does not consistently meet the basic housing needs of persons living with HIV and their families, as housing must often be provided in connection with

specialized services that enhance an individual's or family's ability to live independently. In addition, persons living with HIV must also overcome reduced housing options due to unfounded fears and prejudice regarding AIDS.

Housing assistance is an area that requires significant community involvement and support if it is to be successful. Many communities are part of new efforts to comprehensively plan for the housing needs of their residents, including assessing and addressing the needs of residents living with HIV/AIDS.

The HOPWA program was created in 1992 to provide communities with a tool to meet the increased need for resources, effective planning, and coordination with existing public and private efforts. The program is representative of HUD's "Continuum of Care" approach to building local systems to address homelessness. Moreover, it is estimated that the cost of providing housing services in a HOPWA-funded residential facility is far less than the average day in the hospital.

To further foster community involvement, HUD has also established the Consolidated Planning process for communities that receive funds under the Department's economic and community development programs, including recipients of HOPWA formula allocations. In

addition, the Community Development Block Grant (CDBG) and the HOME affordable housing program as well as public housing programs are key resources that are available to communities, contingent on eligibility, space availability and local priorities.

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

Prisoners. There are also groups of people, such as prisoners, who are not served by these traditional safety net programs. Most prisoners living with HIV are incarcerated in State and local prisons. Medical care for Federal prisoners is provided under the direction of the Department of Justice's Bureau of Prisons. Identifying HIV positive prisoners and ensuring them access to quality care for incarcerated persons is especially challenging. Prisoners do not have the choice of seeking care outside the prison setting and are dependent upon the prison staff to ensure that

appropriate care is provided. They also may have difficulties regarding confidentiality, trust, and less access to research opportunities.

Improving access to appropriate HIV-related care in prisons must be a priority. At the Federal level significant advances are being made in the quality of care, improving coordination, and developing models of care. Improving the quality of care at non-federal prisons will require improving the knowledge and skill of the health care teams in the prisons, strengthening linkages between prisons and outside public health Departments and Agencies, and improving discharge planning. ~~These efforts can serve to improve discharge planning for HIV positive prisoners at the time of their release from prison.~~ For example, Efforts are already under way to improve linkages between discharge planning and Ryan White CARE Act programs, to assure a continuum of care or services for newly released HIV positive prisoners.

Check w/ Patricia Miles

Program Coordination. For care and services to have the most beneficial impact they should be offered as part of a continuum of care. For organizations on the front lines of the epidemic, building a comprehensive integrated program requires applying to numerous Federal Agencies. For example, creating a community program that integrates primary care with substance abuse treatment and prevention, ~~and~~ sexually transmitted disease screening, prevention, access to clinical trials, and housing assistance would require separate applications to SAMSHA, HRSA, CDC, NIH, and HUD.

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

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

This is correct — (Community gives nuts!)

Quality of Care. Federally supported programs can and should consistently provide quality care. Through the efforts of researchers and clinicians, it has been proven that quality care for HIV positive persons is possible, but quality care is not consistently available throughout the health care system. Establishing a standard-of-care and ensuring consistency in care delivery will require increased training for health care

professionals and more accountability through the use of performance measures for quality care.

A Federal program that has achieved success in improving the knowledge and skills of clinicians is the AIDS Education and Training Centers (AETCs) effort sponsored by the Health Resources and Services Administration. A major goal of the AETC program is to train health care professionals in the prevention, early diagnosis, and treatment of HIV infection.

However, this program alone cannot ensure that all health care providers have the knowledge and skills required to provide satisfactory care for HIV positive persons. Achieving this goal will require the cooperation of Federal Agencies, States, professional organizations, professional and medical schools, and individual clinicians.

CIVIL RIGHTS

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

Discrimination undermines the Nation's efforts to prevent and treat HIV infection and bring the epidemic under control. Because of fear of discrimination and stigma, many people do not voluntarily seek testing for HIV, remain unaware of their HIV status, and consequently do not take advantage of care that could help them live longer, healthier lives. In addition, opportunities to educate people are lost. Discrimination can also wrongfully deny persons access to housing, insurance, employment, and health care. The Federal government and some States have enacted laws that protect persons with HIV from discrimination on the basis of their infection. Many of the more common legal issues faced by people living with HIV and AIDS, such as family law issues, estate planning, landlord/tenant problems are regulated by State law.

The primary source of Federal statutory protection for people living with HIV is the Americans with Disabilities Act of 1990

(ADA). Title I of the ADA prohibits discrimination against qualified disabled individuals in employment settings. The Equal Employment Opportunity Commission (EEOC) is responsible for enforcing Title I. Title II of the ADA prohibits discrimination on the basis of disability with regard to public services while Title III prohibits discrimination on the basis of disability in public accommodations. The Department of Justice (DOJ) is responsible for enforcing Titles II and III. In addition, the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) is responsible for implementing portions of the ADA, including investigating and resolving Title II complaints of discrimination by health care and social service programs.

Federal Agencies and recipients of Federal funds are prohibited from discriminating against people with disabilities under Section 504 the Rehabilitation Act of 1973. The DHHS' Office of Civil Rights is also responsible for enforcing Section 504 as it pertains to recipients of DHHS funds such as hospitals, nursing homes, and social service agencies. The Health Care Financing Administration (HCFA) also enforces regulations regarding the treatment of HIV-infected persons.

Opportunities for Progress

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

Federal Policies. The Federal government must also actively work to remedy any of its own existing discriminatory policies. The Director of the Office of National AIDS Policy is working with Federal Agencies to ensure that HIV testing programs follow the recommendations of public health professionals. The Administration will also continue to oppose Congressional attempts to force discharge of infected military personnel who are still able to serve their country.

Leadership. The United States has made progress in fighting discrimination. However, the enactment of laws is insufficient to end discrimination. As a Nation we need to be vigilant and vocal in our efforts to fight discrimination. This is a responsibility

that must be shared among Federal Agencies, States, communities, and the citizens of this country.

Footnotes

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

2. Communication, Department of Labor.

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

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

5. *Journal of the American Medical Association*, July 28, 1993. Add page number/complete reference.

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

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

8. Coolfont Report. A PHS plan for the Prevention and Control of AIDS and the AIDS Virus. Public Health Reports 101:341-348, July-August 1986.

9. Report of the Second Public Health Service AIDS Prevention and Control Conference. Public Health Reports. Vol. 103 Supplement No.1 (Revised). 1988.

10. The Public Health Service Strategic Plan to Combat HIV & AIDS in the United States. U.S. Department of Health and Human Services. 1992.

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

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

13. External Review of HIV Prevention Strategies by the CDC Advisory Committee on the Prevention of HIV Infection. U.S. Department of Health and Human Services, Public Health Service. June 1994.

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

15. *AIDS and Behavior: An Integrated Approach.* Judith D. Auerbach, Christina Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine, National Academy Press, Washington, D.C., 1994. p.79.

16. *AIDS and Behavior: An Integrated Approach.* Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

17. *AIDS and Behavior: An Integrated Approach.* Judith D. Auerbach, Christian Wypijewska, and H. Keith H. Brodie, Editors. Institute of Medicine. National Academy Press. Washington, DC. 1994.

18. JAMA article used in PRIM&R speech

19. Don C. Des Jarlais, Holly Hagan, Samuel R. Friedman, Patricia Friedmann, David Goldberg, Martin Frischer, Steven Green, Kerstin Tunving, Bengt Ljungberg, Alex Wodak, Michael Ross, David Purchase, Margaret E. Millson, Ted Myers. Maintaining Low HIV Seroprevalence in Populations of Injecting Drug Users. JAMA, October 18, 1995 -- Vol. 274, No. 15. pp 1226-1231.

20. Heiner Grosskurth, Frankc Mosha, James Todd, Exra Mwijarubi, Arnould Clokke, Kesheni Senkoro, Philippe Mayaud, John Changalucha, Angus Nicoll, Gina ka-Gina, James Newell, Kokuugonza Mugeye, David Mabey, Richard Hayes. Impact of Improved Treatment of Sexually Transmitted Diseases on HIV Infection in Rural Tanzania: Randomized Controlled Trial. The Lancet, Vol. 346, August 26, 1995.

21. Maria Wawer, Science. 9.08.95, vol. 269, No. 5229

22. Personal communication from CDC Division TB Elimination.

23. Epidemiology of Tuberculosis, Self-Study Module on Tuberculosis, Module Number 2, Division of Tuberculosis, Nation Center for HIV, STD, and TB Prevention, the Centers for Disease Control and Prevention.

24. This section focus primarily on biomedical and health services research. Discussion of behavioral and social science research is presented in the Prevention section.

25. Alan B. Stone, and Penelope J. Hitchcock. Vaginal Microbicides for Preventing the Transmission of HIV. AIDS 1994, 8 (suppl 1):S285-S293.

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

27. Housing and the HIV/AIDS Epidemic: Recommendations for Action. National Commission on AIDS. Washington, D.C. July 1992.

28. *HIV/AIDS Policy Guidance.* U.S. Agency for International Development. September 1995.

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

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

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