

FOIA MARKER

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Folder Title:
HHS [Health & Human Services]-ONAP [Office of National AIDS/HIV Policy] Revised

Stack:	Row:	Section:	Shelf:	Position:
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NATIONAL PLAN ON HIV/AIDS

HCFA

Area: Prevention

GOAL: REDUCE HIV TRANSMISSION FROM MEDICAID-ELIGIBLE PREGNANT WOMEN TO THEIR INFANTS

Objective <i>Standards?</i>	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituent Involvement	
			FY 1995	FY 1996 (proposed)			
<u>Encourage Medicaid-eligible pregnant women to make an informed choice with regard to using AZT.</u> <i>pay for screening/testing?</i> <i>have program for...</i>	Develop/obtain and distribute brochures and other materials describing the ACTG 076, its implications, and Medicaid eligibility and coverage policy to Medicaid-eligible women in RI, DE, and SC. NY	Establish a consumer-oriented educational campaign in key states with high female HIV+ rates and small overall populations. <i>do all other states cover?</i>	Federal Resources to be determined <i>what was spent in it prediction.</i> <i>to states?</i>		HIV + females eligible for Medicaid coverage	Significant consultation with high-risk pregnant women and their advocates	The activity will not focus on women of unknown or negative HIV serostatus 

What about providers-- HCFA
 Satisfied their providers know what to do implementation

NATIONAL PLAN ON HIV/AIDS

HCFA

Area: Care and Services

Goal: QUALITY HOME HEALTH CARE FOR HIV INFECTED MEDICARE AND MEDICAID BENEFICIARIES

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituent Involvement	
			FY 1995	FY 1996 (proposed)			
Provide quality standards for appropriate home health care access and treatment of HIV disease	Identify current home health care practices through literature review and survey of best practices <i>+ consensus review ~</i>	Develop and implement quality standards for appropriate home health for HIV+ Medicaid recipients in partnership with private sector organizations and PHS Develop directives on implementation of these guidelines through each	Federal Contribution to be determined	NA	HIV-infected, Medicare/ Medicaid beneficiaries using home health care	Significant constituent consultation throughout project development	Implementation may vary depending on the direction and resources of each project partner

NATIONAL PLAN ON HIV/AIDS

HCFA

Area: Care and Services

Goal: QUALITY HOME HEALTH CARE FOR HIV INFECTED MEDICARE AND MEDICAID BENEFICIARIES

> Would rework HCFA completely to →

HCFA → Cost → of Care

Area - Services

Goal - Provide primary care to medicaid eligible HIV persons

Objective	Action Steps	Description	FY95	FY96	Pop.	Constit	Unmet need
Provide quality 1 ^o care	- Assess state compliance & program standards - Eval./consider Waivers - Encourage compliance with latebreaking SOC, i.e. ACTG 076.	Medicaid 1 ^o Care Services	1640 (Fed. share)	1800 (Federal share)	elig		

Home health care (from previous page)

HCFA

Area: Services
Goal: Provide primary care to Medicare eligible
Objective

Provide
quality
10
Care

Action Steps

- Assess state compliance & program standards
- Encourage(?) compliance with telemedicine/SOC therapies/procedures.
- Identify current home health care practices through ~~the~~ in partnership with private sector orgs. & PHS.

Description

Medicare Program

HIV+ Persons

FY95

500

FY96

600

Pop
Medicare
Elig.
Persons

Constr.

?

Unmet

?

OK
AGENCY FOR CHILDREN AND FAMILIES

Area: Prevention and Treatment

GOAL: Meet the crisis needs of runaway and homeless youth.

turned out funding for HIV/AIDS would make not separate for state as part of overall effort than HIV/AIDS per HIV persons served

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituents Involvement	
			FY 1995	FY 1996 (proposed)			
Stabilize the crisis situation and provide needed services.	Shelter and immediate services including diagnostic medical services and education and prevention related to HIV/AIDS.	Runaway and Homeless Youth Program.	\$40,458,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	\$40,458,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	Runaway and homeless youth.	Agency groups? Are we involved in developing programs?	

how many homeless children

Deficiencies in data -

AGENCY FOR CHILDREN AND FAMILIES

Area: Treatment

GOAL: Provide foster care and adoption services.

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Provide foster care and adoption services to abused, neglected, or otherwise needy children including those with HIV/AIDS.	Diagnostic and treatment services and counseling for children, parents, extended family, foster and adoptive parents, and others related to HIV/AIDS.	Child Welfare Services Program.	\$291,989,000* *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	\$291,989,000* * Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	Children in foster care. # of children / year	Advisory Council HIV/AIDS Adoption Foster Care HIV/AIDS Adoption Foster Care	

11/1/95

AGENCY FOR CHILDREN AND FAMILIES

Area: Treatment

GOAL: Provide services for abandoned infants and young children.

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Provide health and social services to children who have been drug-exposed and/or with HIV/AIDS.	Foster care, health services, counseling and other social services, and recruitment and interdisciplinary training.	Abandoned Infants Assistance Program	\$14,406,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	\$14,406,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	Abandoned infants and young children who have been drug-exposed and/or with HIV/AIDS.		

AGENCY FOR CHILDREN AND FAMILIES

Area: Prevention and Treatment

GOAL: Provide comprehensive child development services for low-income preschoolers.

Objective	Action Steps	Programs				Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
Provide comprehensive services to children, including those with HIV/AIDS, their parents, and families.	Services to Head Start families may include prevention and education, identification, and intervention related to HIV/AIDS; children with HIV/AIDS are enrolled in the on-going Head Start program.	Head Start Program.	\$3,534,429,000* * Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	\$3,934,728,000* * Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	Head Start children and families including pregnant women.	

AGENCY FOR CHILDREN AND FAMILIES

Area: Treatment

GOAL: Provide interdisciplinary services for the developmentally disabled, including HIV/AIDS infected persons.

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Provide assistance and services to increase and support the independence, productivity, and integration into the community of persons with developmental disabilities.	Twenty-seven of the current 51 grantees operate pediatric HIV/AIDS clinics.	University Affiliated Program	\$18,979,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	\$18,979,000 * *Represents resources available for the total program; estimate of resources related to HIV/AIDS not known.	Developmentally disabled persons.		

OFFICE OF POPULATION AFFAIRS

Area: Prevention

GOAL: REDUCE THE NUMBER OF NEW INFECTIONS

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituent Involvement	
			FY 1995	FY 1996 (proposed)			
Provide counselling, education and testing as needed to Title X program clinics	1.) Include HIV/AIDS education in all clinic education programs. 2) Include HIV/AIDS prevention in STD screening programs. 3) Provide HIV testing or referral for testing to all Title X clients who request testing.	The Title X program provides family planning and related reproductive health services to approx. 4.5 million clients annually through a network of 4,500 clinics. Clients are predominantly young women; most are members of low-income families, and 30% are adolescents and 2/3 are below age 25	\$193M ↓ where in PHS table 193 for just counseling and testing.	\$199M Janice Klein	4.5M women/yr.	For non-profit grantees, clients participate on boards of directors. For all grantees, clients participate on committees approving all information and educational materials.	Program estimated 50% 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

INDIAN HEALTH SERVICE

Area: (Prevention)

Data Collection

Bullant
OK

GOAL: REDUCE THE NUMBER OF NEW INFECTIONS

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Maintain surveillance of HIV infection in American Indians and Alaska Natives	Timely and complete case reporting to appropriate local, state and national entities and the IHS AIDS Prevention Activities Office	Area AIDS Coordinators will be responsible for reporting	\$912,000	\$912,000	Federally recognized American Indians and Alaska Natives.	Local and National Indian Health Advisory Boards	

Program name
INDIAN HEALTH SERVICE

Area: Prevention

GOAL: REDUCE THE NUMBER OF NEW INFECTIONS

7 Maintain training and information <u>activates</u> to provide health education and risk reduction messages	Teaching empowerment t skills at the individual and community level that will enhance the individual's ability to actualize assimilated knowledge as behavior change.	The changed behavior includes adjustments of beliefs and the formation of AIDS community based task forces at the local level	\$2,321,000	\$2,321,000	American Indians and Alaska Natives population, tribal leaders, women, youth, individuals practicing high risk behavior, and IHS/tribal health care workers.	Local and National Indian Health Advisory Boards	

SON.

Agency for Health Care Policy and Research

Current HIV-Related Projects

This document summarizes current projects that are supported by the Agency for Health Care Policy and Research and that have a primary focus on HIV-related issues. Projects have been placed in three major areas:

- Health Services Research - *Research*
- Prevention Research - *Prevention*
- Services: Information Dissemination - *Trans. Science into Practice*

Note that many of the projects are grants awarded in response to investigator-initiated proposals. The focus of unsolicited proposals, as well as the results of the scientific and technical review of each proposal, are difficult to predict. Therefore, we anticipate that new projects will be funded in FY 96, but the specific nature of these projects is not known at present. FY96 projects will most likely deal with policy-relevant issues in cost, quality, and access to HIV-related health services, as projected in the AHCPR sections of the DHHS HIV Research Plan.

OK
no \$ for '96 because

AREA: Health Services Research

1. HIV Costs and Service Utilization Study (HCSUS)

A. Objectives: (1) To provide national estimates of the cost and use of HIV-related medical and non-medical services.

(2) To provide comprehensive information on unmet needs for service and barriers to accessing services.

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

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

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

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

B. Description: This study will be the first to obtain a true national random sample of people with HIV infection receiving treatment. Approximately 3200 adult patients in urban areas, ~~500 adult patients living in rural areas, and 400 children (age less than 13)~~ will be enrolled. ~~Patients will be interviewed four times over an 18-month period; data will also be abstracted from medical and billing records.~~

C. FY95 Resources: \$4,000,000.

D. FY96 resources: \$4,000,000.

E. Populations Covered: HIV-infected individuals receiving treatment.

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

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

H. Collaborative Relationships: HRSA and NIMH have contributed funds to expand the scope of the core HCSUS project. In addition, proposals for further elaborations are under review at NIDR, NIAAA, and NIDA.

95	96
4,000,000	4,000,000

Page 3 - Current HIV-Related Projects

2. **Women's Interagency HIV Study**

- A. Objectives: To examine health care utilization among participants in the NIH-sponsored Women's Interagency HIV Study (WIHS).
- B. Description: This project supplements the WIHS by adding a health services research component. Utilization data on women with HIV infection will be collected, in addition to the detailed clinical data obtained in the core study.
- C. FY95 Resources: \$55,000.
- D. FY96 Resources: \$75,000.
- E. Populations Covered: Women with HIV infection participating in the WIHS.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA. *more, more info. gathered?*

3. **Multicenter AIDS Cohort Study**

- A. Objectives: (1) To examine factors affecting health care utilization among participants in the NIH-sponsored Multicenter AIDS Cohort Study (MACS).
- (2) To assess quality of life among participants in the MACS and to relate utilization to quality of life measures.
- B. Description: This project supplements the MACS by adding a health services research component. Utilization data on men with HIV infection will be collected, in addition to the detailed clinical data obtained in the core study.
- C. FY95 Resources: \$75,000.
- D. FY96 Resources: \$0. *why?*
- E. Populations Covered: Homosexual/bisexual men participating in the MACS in four urban areas.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA. *more \$ / more info. gathered?*

4. **HIV Epidemiological Research Study**

- A. Objectives: To examine health care utilization among participants in the CDC-sponsored HIV Epidemiological Research Study (HERS).
- B. Description: This project supplements the HERS by adding a health services research component. Utilization data on women with HIV infection will be collected, in addition to the detailed clinical data obtained in the core study.
- C. FY95 Resources: \$50,000.
- D. FY96 Resources: \$50,000.
- E. Populations Covered: Women with HIV infection participating in the HERS.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA. *more \$, more info. gathered.*

95 (95-94)
180,000 ϕ

96
125,000

5. **Health Care Costs and Utilization in AIDS Home Care**

- A. Objectives: (1) To provide longitudinal data on utilization of inpatient, outpatient, home care, pharmaceutical, and other services, and to estimate their associated costs.
(2) To examine the impact of a Medicaid Home and Community-Based waiver on service utilization, costs, functional status, and survival.
(3) To examine any substitutions of formal for informal home care.
- B. Description: Interviews conducted with participants in New Jersey Medicaid Waiver program. Data abstracted from Medicaid claims.
- C. FY95 Resources: \$394,557.
- D. FY96 Resources: \$0
- E. Population Covered: Medicaid recipients with AIDS in New Jersey.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

6. **Ambulatory Care for HIV/AIDS: Models and Outcomes:**

- A. Objectives: (1) To examine types of ambulatory care providers used to treat HIV infection.
(2) To examine patterns of transitions between ambulatory provider types.
(3) To examine service utilization and costs for pediatric HIV patients.
- B. Description: Analysis of Medicaid claims and eligibility data from New York State Medicaid.
- C. FY95 Resources: \$392,103 (from FY94 funds).
- D. FY96 Resources: \$0.
- E. Populations Covered: New York State Medicaid recipients.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

7. **Outcomes of Pharmaceutical Therapy in HIV Disease.**

- A. Objectives: (1) To assess the impact of antiretroviral, antimicrobial, and prophylactic treatment on the natural history of HIV infection.
(2) To assess the effect of pharmaceutical therapies on service utilization, costs, and clinical outcomes.
- B. Description: Develop clinical database linked to Medicaid claims data.
- C. FY95 Resources: \$527,287.
- D. FY96 Resources: \$420,000.
- E. Populations Covered: HIV-infected population in Maryland.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

*unmet,
more data*

how developed

<u>95</u>	<u>(95-94)</u>	<u>96</u>
1,313,947	921,844	420,000

8. **Quality and Costs of Care for HIV Infected Medicaid Patients.**

A. Objectives: (1) To study issues of costs and quality of care, with a focus on women and children.

(2) To examine trends and variation in adherence to scientifically-based clinical guidelines.

(3) To study predictors of variation in treatment, by patient, physician, and practice setting characteristics.

B. Description: Analyses of Medicaid claims and eligibility data, supplemented with AIDS Registry data.

C. FY95 Resources: \$110,704 (from 1994 funds).

D. FY96 Resources: \$0. ?

E. Populations Covered: New Jersey Medicaid recipients.

F. Constituency Involvement: NA (A research grant).

G. Unmet Needs: NA.

9. **Developing Econometric Models to Estimate AIDS Costs.**

A. Objectives: (1) Develop an econometric framework for the simultaneous study of health care usage and survival.

(2) Develop synthetic estimates of per-person lifetime costs of HIV disease for various groups of HIV-infected individuals.

B. Description: Formulation of statistical models and associated computer software.

C. FY95 Resources: \$188,136.

D. FY96 Resources: \$80,000. - why so much less?

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

F. Constituency Involvement: NA (A research grant).

G. Unmet Needs: NA.

10. **Determinants of Physicians' AIDS-Related Practice Behavior**

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

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

C. FY95 Resources: \$216,054 (from 1994 funds).

D. FY96 Resources: \$0. Why?

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

F. Constituency Involvement: NA (A research grant).

G. Unmet Needs: NA.

95
514,894

94-94
188,136

96
80,000

11. **Outcomes of Hospital Dedicated AIDS Units**

- A. Objectives: To compare outcomes of inpatient care for AIDS provided by dedicated AIDS units versus scattered-bed approaches.
- B. Description: Comparative multi-site observational study of 23 hospitals.
- C. FY95 Resources: \$137,538 (from 1994 funds).
- D. FY96 Resources: \$0.
- E. Populations Covered: 1500 patients receiving services in study hospitals.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

12. **Hospital Cost and Utilization Project**

- A. Objectives: Obtain and analyze data on inpatient hospital utilization by people with HIV infection.
- B. Description: Assemble database of hospital discharge data from all hospitals in 12 States.
- C. FY95 Resources: \$500,000.
- D. FY96 Resources: \$500,000.
- E. Populations Covered: Patients with AIDS receiving inpatient care in hospitals in 12 states.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

AREA: Prevention

1. **Demonstrating Computer Support Impact on AIDS Patients**

- A. Objectives: To examine the effects of an in-home computer information and support system on health care costs and quality of life.
- B. Description: Half of three hundred patients with advanced HIV infection are provided with in-home computer system; the other half receive no intervention. Effects of this system are assessed with respect use of prophylactic treatments, early detection of infections, and quality of life.
- C. FY95 Resources: \$430,440.
- D. FY96 Resources: \$390,000.
- E. Populations Covered: Study volunteers.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

2. **Cost-Effectiveness of Preventing AIDS Complications.**

- A. Objectives: Evaluate the cost-effectiveness of alternative strategies for preventing HIV-related opportunistic infections.
- B. Description: Embed clinical and cost data from randomized trials and observational cohorts into a comprehensive decision-analytic, cost-effectiveness model.
- C. FY95 Resources: \$198,541.
- D. FY96 Resources: \$225,000.
- E. Populations Covered: AIDS Patients.
- F. Constituency Involvement: NA (A research grant).
- G. Unmet Needs: NA.

- 1115000?

(95) (95-94) 96
1266519 1,128,981 1,115,000

AREA: Information Dissemination

1. **AIDS Treatment Information Service**

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

B. Description: Reference specialists will use NLM's database of AHCPR guidelines, and NIH, CDC and other Federal agency guidelines and consensus statements to respond to specific requests and to provide appropriate treatment information to callers.

C. FY95 Resources: \$41,300.

D. FY96 Resources: \$53,326. *(Notes added)*

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

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

G. Unmet needs: NA.

2. **Dissemination of AHCPR's HIV-Related Clinical Guidelines.**

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

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

C. FY95 Resources: \$30,000 (to AIDS clearinghouse).

D. FY96 Resources: \$30,000 (to AIDS clearinghouse; proposed).

E. Populations Covered: Clinical practitioners and individuals with HIV infection.

F. Constituency Involvement: NA.

G. Unmet Needs: NA.

Physicians, nurses, etc. do

3. **Effective Strategies of AIDS Programs in San Francisco**

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

B. Description: Examine organizational strategies used by several community-based HIV education agencies.

C. FY95 Resources: \$198,883 (from 994 funds).

D. FY96 Resources: \$0.

E. Population Covered: Community-based HIV education agencies in San Francisco

F. Constituency Involvement: NA (A research grant).

G. Unmet Needs: NA.

95
270,183

95-94
71,300

96
83,326

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

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

B. Description: The guide will describe the recommendations of the PHS Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of HIV, based on results of AIDS Clinical Trials Group 076. The information will be provided in a format and at a reading level that consumers can comprehend.

C. FY95 Resources: \$75,000.

D. FY96 Resources: \$0.

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

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

G. Unmet Needs: NA.

discuss
What about other
groups-clinicians?

FY95 \$7620,543

minus
94

656,526

FY 96 \$582,332

95
75,000

96
0

HRSA-2A

Revision #2

Meeting @ JM 9.1.95

HEALTH RESOURCES AND SERVICES ADMINISTRATION

(Actual)

Pres Budget for 1996?

Area: SERVICES

Goal: Increase the Number of Competent Primary Care Providers Willing to Care For HIV Infected People

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
To increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and manage individuals with HIV infection.	Information dissemination and training activities in collaboration with Federal, State and local HIV care programs	AIDS Educational and Training Centers provide didactic and clinical training for primary health care providers	\$16.3 million	\$16.3 million	People living with HIV disease	Faculty, staff, advisory committees, training panels	Not enough adequately trained health care providers to meet demand. More funding needed for training. ??? how much needed

Order?

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase the Number of Competent Primary Care Providers Willing to Care For HIV Infected People

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
	Disseminate State-of the Art HIV Information to Providers Develop and coordinate HIV provider materials	Quarterly interactive conference calls National HIV Telephone Consultation Service (Warmline) Phone consultation services, newsletters, bulletins Provider guides for HIV priority areas, e.g., ACTG 076 curriculum developmen			Clinicians	PWAs, Faculty, Staff, Advisory Committees etc.	Additional funding to train more health care providers

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Address the difficulties in obtaining dental care

Area: SERVICES

Goal: Reimbursement to Dental Schools of Uncompensated Costs Incurred in Treating Patients With HIV

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
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.	Increase funds to support uncompensated costs. The formula depends on (1) Numbers of HIV positive patients in treatment and (2) uncompensated costs.	AIDS Dental Reimbursement Program: 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.	\$6,937,000	\$6,937,000	Children and Adults Living with HIV	American Association of Dental Schools, American Association of Hospital Dentists, and American Dental Association.	Uncompensated costs that dental schools and hospitals incur are much more than the dollars available under the dental reimbursement program.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

unfunded supplemental applications

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Improve Accessibility and Quality of Care <i>from RWCA</i> 							

are HRS programs?

1 number for all three

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Improve Quality and Availability of Care <i>Program description</i>	Provide technical assistance to Title I and II grantees in strategies to improve access and quality	RWCA Titles I and II			~~Grantees~~ <i>[Handwritten signature]</i>	Participatory process underway to develop self-assessment tools	
	Monitor program implementation through (1) review of applications, quarterly reports, and other grantee submissions; and (2) site visits	RWCA Titles I and II			~~Grantees~~ <i>[Handwritten signature]</i>		

eliminate
yes

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

Objective	Action Steps	Programs				Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
<i>program non-existent</i>	Provide policy guidance to Title I and Title II grantees which emphasizes access to care and quality of life	RWCA Titles I and II			Individuals w/ HIV disease/AIDS and family members	
<i>not GPR? - long str</i>	Develop and implement data collection methodologies which measure the number of persons being served, the range of services they receive, and resultant improvements in access or quality of life	OMB-approved Annual Administrative Report and client-level service documentation demonstration projects			Grantees	Early and ongoing involvement of local implementors in all phases of data collection design, planning, and implementation

and consolidate into evaluation bullet

— yes

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Is this just a
subject of
hard to spend \$ (i.e.
cond. Improvements?

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

I and Title II funds

Objective	Action Steps	Programs				Unusual Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Federal Oversight and Guidance for Ryan White Care Act Titles I & II Why? Possible Aid wording.	Issue annual ^{Dep.} ~~Program~~ Application Guidance which emphasizes ~~comprehensive~~ participatory planning	Ryan White CARE Act (RWCA) Titles I and II			Grantees, Planning Councils, communities and populations affected by HIV Common service orgs PLCs Title IIB 2 HCS	Planing Council Members, PWAs, focus groups, etc. Title IIB 2 HCS	
	Continue refinements and expansions of needs assessment protocol jointly developed by DHS and grantees	RWCA Title I program				Planning Councils; affected communities	

Better Coord: C
AND, HEX, VA

Encourage first
act make
to make
people

[illegible]

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: HIV Health Care and Supportive Services Delivery

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

Objective	Action Steps	Programs					Unusual Needs
		Description	Resources		Populations Served	Constituency Involvement	Unusual Needs
			FY 1995	FY 1996 (proposed)			
Program man.	Monitor grantee compliance with legislative mandates and policy requirements related to comprehensive and participatory planning	RWCA Titles I and II				Grantees	30
	Provide technical assistance to Title I and Title II grantees on planning processes JA	RWCA Titles I and II			Grantees, Planning Councils	Federal program staff; peer consultants	30

completeness

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: HIV Health Care and Supportive Services Delivery

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

Objective	Action Steps	Programs				Unusual Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
	Collaborate with Title II grantees and others in developing mutually beneficial protocols for achieving coordinated state-wide statements of need	RWCA Title II program			Grantees (all RWCA Titles); affected communities	Conference calls, small group meetings, review and comment processes
	Provide policy guidance to Title I and Title II grantees which emphasizes comprehensive and participatory planning processes	RWCA Titles I and II			Grantees; Title I Planning Councils; Title II Consortia; affected communities	

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Develop innovative models of comprehensive managed care for persons with HIV

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
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 which provide patients and their families access to services.	Fund and Evaluate Innovative Models Disseminate results of evaluation	Special Projects of National Significance	\$2,092,302 10% of T2 purpose of program?	\$4,000,000 37% of PWL T-IV	All groups. HIV+	Primary care providers. Community-based organizations. State & Local Health Officials. Ryan White planning bodies. Persons with HIV.	Need more effective linkages among community providers and financially stable medical sites. Lack of adequate evaluation

Nat'l competition for best models
 Fund, evaluate, disseminate
 (but do we disseminate)

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase evaluation capacity in community-based providers' organizations

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Ensure that services provided under SPNS program are fully evaluated for both utilization and impacts.	Increase emphasis on evaluation in ~~Federal Register notices and program guidance documents.~~ Increase the representation of evaluation researchers on review groups. Provide technical support for evaluation activities.	Special Projects of National Significance	\$2,000,000	\$4,000,000	Grantees	Care providers. Evaluation researchers. Patient advocates.	Need more effective linkages between providers and evaluation researchers.

process not program

more providers

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES
Goal: Promote the delivery of quality HIV care

*Need overall goal for SB
Promote access to early int
services thru city based clinics*

Objective	Action Steps	Programs				Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
Promote the delivery of quality HIV care provided through the Bureau of Primary Health Care (BPHC) funded primary care programs and providers	Develop QI/QA guidelines for the clinical management of HIV disease	IS THERE A NAME FOR THIS PROGRAM OR ACTIVITY? <i>RW Title IIIb</i>	~~\$315,000~~		All HIV + or at risk clients	Title III(b) Clinicians Network, the New York AIDS Institute, and other HIV/AIDS state institutions
	Publish and distribute guidelines to all BPHC primary care programs and providers			~~\$150,000~~		
	Train (where necessary) providers in the use of the QI/QA tool for monitoring the quality of HIV clinical care	<i>#2237</i>		~~\$300,000~~		All BPHC funded primary care programs and providers (in C/MHCs, HCH, Ryan White III(b), NHSC, etc.)

*Lack of funding for the III(b) program staff to monitor compliance with the QI/QA indicators
Add \$ for oversight.
More, more services.*

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

1076

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Establish Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission.	Establish 5 new grants, and supplement 3 existing SPNS grantees Establish ongoing WIN Steering Committee Provide TA to grantees	(WIN?) Enhance outreach HIV C & T and linkage of women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission Enhance provider capacity at the community level.	\$1.1 million Name?	\$1.3 million	Adolescent & adult women and their infants - especially pregnant women.	Consumer participation in WIN steering committee and projects' advisory board <u>SPNS</u> Program.	Resources needed to fund 2 approved projects and expand to 5 new sites: \$1.1 million Funds needed to expand to 5 years and enhance evaluation: \$3 million.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

Objective	Action Steps	Programs					Unmet Needs
Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women	Conduct one centralized training for all WIN sites with follow-up local training Evaluate eight sites	<u>WIN Project</u>	\$400,000	\$400,000	MCH and HIV providers including: outreach, counseling and testing, perinatal and HIV care.	AIDS ETC program National Ped. AIDS Resource Center Institute for Family-Centered Care Three SPNS grantees.	~~Extensive TA and training may be needed for certain populations (e.g. SA women, women not currently linked to care).~~ TA + Jann-g

more
more
services

Can all of WIN
be on one page?

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

Appropriate broken out? level of detail?

Just all
misc. together
w/ note that also
response to integrated

Objective	Action Steps	Programs				Unmet Needs
Enhance State's ability to provide AZT for HIV+ Pregnant women Adoptive C HIV	Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop state guidelines Establish MCHB working group to coordinate HIV risk reduction related efforts across programs Development of HRSA Advisory Document ~~Distribute HRSA Advisory Principles - CDC~~ C & T document and other PHS documents to MCHB community AHCPR Consumer Brochure, video	PHS 078 Implementation Plan Working Standards 7 Core	\$10,000 <			

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Improve the availability of comprehensive service programs for children, youth and women.	● Administer RW Title IV Program Describe mechanism permiss	Ryan White Title IV # of grantees mechanism	Approximately \$24 million (of \$26 million budget). ? Funding levels?	Approximately \$27 million (of \$32 million budget request).	Children, youth, women and families.	● participation in grants review ● constituent involvement in grantee program and policy development.	● 30 grant applicants in FY 1995; funds only available for 13 of them 1/3 8/28/95 Funds for existing projects inadequate to meet rapidly growing caseloads; to expand programs for adolescents and to provide needed services such as mental health; substance abuse; family case management; permanently planning.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
	2) Support initial development of care systems linked to research for children, youth and women in 7 new communities.	RW Title IV	\$555,000	\$600,000	Children, youth, women and families.	constituents involved in developing funded programs.	24 States lack comprehensive care systems for children, youth, women; \$1.8 million would support new planning and initial development projects in 24 states.
Enhance research agenda, research opportunities, and clinical care for adolescents with/at risk for HIV through collaboration with NIH.	Develop research priorities, collect data, and develop clinical care guidelines for adolescents with HIV/AIDS.	Adolescent Research/ Clinical Network	\$250,000 million HRSA	\$250,000 million HRSA	Youth (13-21).	One adolescent/ project participates in steering committee, guidelines development.	Title IV program lacks staff resources to support research network, 1.5FTE required. How many served, how many more? \$\$

Integrate - these are the same as above, just new grants

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Increase patient access to clinical research	Enhance linkages between care providers and research entities. c) Make recommendation to grantees to enhance linkages.	Reauthorized CARE Act expected to mandate new research panel to recommend research priorities, assist with care/research linkages.	\$50,000 3	\$200,000 1.5 FTE needed	Children, Youth, Women.	Consumer, Title IV provider, researcher participation in panel. Pediatric AIDS Foundation.	Title IV program lacks staff resources to establish and support panel; 1.5 FTE required. Lack \$\$\$

how is this explained?

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Improve HIV programs for children, youth, families.	Provide leadership, support and technical assistance	Ryan White Title IV	\$10,000	\$10,000	Children, youth, families. grantees.	Youth and families participate in all national meetings, trainings.	Lack of adequate funding for TA <i>Collabs & other agencies.</i>
	Develop standards of care for ~~(1) DGP~~ (2) family centered care, and (3) Counseling, testing, care of women Support ~~two~~ national resource centers for training. TA information.		\$1.9 million	\$1.3 million			

*150
for
first*

1 number

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

17 cost \$330K
to bring 4 per
to meet needs

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Build youth and family leadership to provide ~~program input and advocate,~~ provide direction at local, state, national levels.	Convene youth and family leadership conferences and distribute report ~~Provide Published Essential Allies,~~ a guide involving youth/families in program planning, leadership bodies ~~Families advocate for Title IV by educating state/national legislators.~~	● MCHB funds cooperative agreement with <u>Institute of Family-Centered Care</u> to provide training/technical assistance to youth and families.	\$330,000	\$350,000	● Youth and families participate in and present at all National Title IV meetings. ● Families serve on boards/committees of <u>20</u> projects.	● Youth and families participate in and present at all National Title IV meetings. ● Families serve on boards/committees of <u>20</u> projects. ● National Positive Youth Alliance.	● Funds only permit 2 youth and 2 family members/project to attend national leadership meetings. Need Equality Exposure of Leadership Annuit not yet achieved.

Funds ~~total~~ don't match OMB figures.

22

HRSA-2A

Revision #2

Meeting c JM 9.1.95

HEALTH RESOURCES AND SERVICES ADMINISTRATION

order of goals

Area: SERVICES

Goal: Increase the Number of Competent Primary Care Providers Willing to Care For HIV Infected People

Can use FY 96 as they will be

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
To increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and manage individuals with HIV infection.	Information dissemination and training activities in collaboration with Federal, State and local HIV care programs	AIDS Educational and Training Centers provide didactic and clinical training for primary health care providers	\$16.3 million	\$16.3 million	People living with HIV disease	Faculty, staff, advisory committees, training panels	Not enough adequately trained health care providers to meet demand. More funding needed for training ??? how much needed

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase the Number of Competent Primary Care Providers Willing to Care For HIV Infected People

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
	Disseminate State-of the Art HIV Information to Providers Develop and coordinate HIV provider materials	Quarterly interactive conference calls National HIV Telephone Consultation Service (Warmline) Phone consultation services, newsletters, bulletins Provider guides for HIV priority areas, e.g., ACTG 076 curriculum developmen			Clinicians	PWAs, Faculty, Staff, Advisory Committees etc.	Additional funding to train more health care providers

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Reimbursement to Dental Schools of Uncompensated Costs Incurred in Treating Patients With HIV

Address difficulties in getting care.

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
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.	Increase funds to support uncompensated costs. The formula depends on (1) Numbers of HIV positive patients in treatment and (2) uncompensated costs.	AIDS Dental Reimbursement Program: 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.	\$6,937,000	\$6,937,000	Children and Adults Living with HIV	American Association of Dental Schools, American Association of Hospital Dentists, and American Dental Association.	Uncompensated costs that dental schools and hospitals incur are much more than the dollars available under the dental reimbursement program.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

Objective	Action Steps	Combine Titles I-IV Programs				Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
Improve Accessibility and Quality of Care	Allocate appropriated funds to eligible entities for need-responsive service provision	Ryan White CARE Act (RWCA) Titles I and II	Funding levels? →		Individuals w/ HIV disease/AIDS and family members	RW Planning Councils
	Develop a ~~minimum drug formulary~~ for federally-assisted AIDS Drug Assistance Programs (ADAP) for ~~states~~ <i>with needy clients.</i>	Primarily RWCA Title II program	- 42 cities - 50 states		Low income people w/ HIV disease/ AIDS	
	Develop federal Strategy and guide grantees in developing local strategies for implementing findings of ACTG 076	RWCA Titles I and II			Pregnant women w/ HIV/AIDS; neonates and children born to HIV+ women	

does not exist.
 076 should be a separate goal.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Improve Quality and Availability of Care <i>Program Overview</i>	Provide technical assistance to Title I and II grantees in strategies to improve access and quality	RWCA Titles I and II			Grantees	Participatory process underway to develop self-assessment tools	
	Monitor program implementation through (1) review of applications, quarterly reports, and other grantee submissions; and (2) site visits	RWCA Titles I and II			Grantees		

Eliminate

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase Access to Care and Improve Quality of Life for People with HIV Disease and AIDS

Objective	Action Steps	Programs				Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
<i>program man. eliminate</i>	Provide policy guidance to Title I and Title II grantees which emphasizes access to care and quality of life	RWCA Titles I and II			Individuals w/ HIV disease/AIDS and family members	
Improve Access to Care and Quality of Life <i>GTRA?</i>	Develop and implement data collection methodologies which measure the number of persons being served, the range of services they receive, and resultant improvements in access or quality of life	~~OMB approved~~ Annual Administrative Report and client-level service documentation demonstration projects			Grantees	Early and ongoing involvement of local implementors in all phases of data collection design, planning, and implementation

and consolidate into evaluation bullet yes.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Objective under all RWCA.

Area: HIV Health Care and Supportive Services Delivery

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

Objective	Action Steps	Programs				Unusual Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
Federal Oversight and Guidance for Ryan White Care Act Titles I & II	Issue annual ^{new} Program Application Guidance which emphasizes comprehensive and participatory planning	Ryan White CARE Act (RWCA) Titles I and II			Grantees, Planning Councils, communities and populations affected by HIV	Planing Council Members, PWAs, focus-groups, etc. Title IIIB
	Continue refinements and expansions of needs assessment protocol jointly developed by DHS and grantees	RWCA Title I program				Planning Councils; affected communities

Possible Aid wording.

Unmet

Comm service

Better coord: C
HMO, HCFA, VA
Cdc Reduction Planning.

Encouraging not
of money
to make
resources
used -> they are
used.

VA
- MHC (Kyniculture)
- AT-DC
- NIH
- 16 (PK)
@ total length

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: HIV Health Care and Supportive Services Delivery

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

Objective	Action Steps	Programs					Unusual Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Program man,	Monitor grantee compliance with legislative mandates and policy requirements related to comprehensive and participatory planning	RWCA Titles I and II				Grantees	
	Provide technical assistance to Title I and Title II grantees on planning processes JA	RWCA Titles I and II			Grantees, Planning Councils	Federal program staff; peer consultants	

compass

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: HIV Health Care and Supportive Services Delivery

Goal: Develop Comprehensive and Participatory Planning Processes at the State and Local Level to Guide Decision-making for Allocation of Title I and Title II funds

Objective	Action Steps	Programs				Unusual Needs
		Description	Resources		Populations Served	Constituency Involvement
			FY 1995	FY 1996 (proposed)		
	Collaborate with Title II grantees and others in developing mutually beneficial protocols for achieving coordinated state-wide statements of need	RWCA Title II program			Grantees (all RWCA Titles); affected communities	Conference calls, small group meetings, review and comment processes
	Provide policy guidance to Title I and Title II grantees which emphasizes comprehensive and participatory planning processes	RWCA Titles I and II			Grantees; Title I Planning Councils; Title II Consortia; affected communities	

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Develop innovative models of comprehensive managed care for persons with HIV

Should not just be managed care.

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
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 which provide patients and their families access to services.	Fund and Evaluate Innovative Models Disseminate results of evaluation purpose of program? 10% of Title II 30% of I-IV	Special Projects of National Significance	\$2,092,302 <i>DD</i>	\$4,000,000	All groups. <i>HIV+</i>	Primary care providers. Community-based organizations. State & Local Health Officials. Ryan White planning bodies. Persons with HIV.	Approvable APR 5/97 Need more effective linkages among community providers and financially stable medical sites. Lack of adequate evaluation Angela Powell

→ National competition — see SL's notes

Certain pgs.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: SERVICES

Goal: Increase evaluation capacity in community-based providers' organizations

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Ensure that services provided under SPNS program are fully evaluated for both utilization and impacts. part of description of program	Increase emphasis on evaluation in ~~Federal Register notices and program guidance documents.~~ Increase the representation of evaluation researchers on review groups. Provide technical support for evaluation activities.	Special Projects of National Significance	\$2,000,000	\$4,000,000	Grantees	Care providers. Evaluation researchers. Patient advocates.	Need more effective linkages between providers and evaluation researchers.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Goal - Services
 1/11/14
 1/14/14

Area: SERVICES
 Goal: Promote the delivery of quality HIV care



Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Promote the delivery of quality HIV care provided through the Bureau of Primary Health Care (BPHC) funded primary care programs and providers	Develop QI/QA guidelines for the clinical management of HIV disease Publish and distribute guidelines to all BPHC primary care programs and providers Train (where necessary) providers in the use of the QI/QA tool for monitoring the quality of HIV clinical care	IS THERE A NAME FOR THIS PROGRAM OR ACTIVITY? RW Title III b	\$315,000	\$150,000 \$300,000	All HIV+ or at risk clients	Title III(b) Clinicians Network, the New York AIDS Institute, and other HIV/AIDS state institutions All BPHC funded primary care programs and providers (in C/MHCs, HCH, Ryan White III(b), NHSC, etc.	Lack of funding for the III(b) program staff to monitor compliance with the QI/QA indicators. Add \$ for awareness. More, more services

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

What are all the programs doing on perinatal transmission

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Establish Women's Initiative for HIV Care for Women and Reduction of Perinatal Transmission.	Establish 5 new grants, and supplement 3 existing SPNS grantees Establish ongoing WIN Steering Committee Provide TA to grantees	Enhance outreach HIV C & T and linkage of women of childbearing age in an ongoing care system and to reduce perinatal HIV transmission. Enhance provider capacity at the community level.	\$1.1 million	\$1.3 million	Adolescent & adult women and their infants - especially pregnant women.	Consumer participation in WIN steering committee and projects' advisory board <u>SPNS</u> Program.	Resources needed to fund 2 approved projects and expand to 5 new sites: \$1.1 million Funds needed to expand to 5 years and enhance evaluation: \$3 million.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

Objective	Action Steps	Programs					Unmet Needs
Improve provider capacity for outreach, counseling, testing and care for women of childbearing age for early identification and linkage to care for pregnant women	Conduct one centralized training for all WIN sites with follow-up local training Evaluate eight sites	<u>WIN Project</u>	\$400,000	\$400,000	MCH and HIV providers including: outreach, counseling and testing, perinatal and HIV care.	AIDS ETC program National Ped. AIDS Resource Center Institute for Family-Centered Care Three SPNS grantees.	Extensive TA and training may be needed for certain populations (e.g. SA women, women not currently linked to care). TA + Training

more
more
services.

→ training
the staff to
provide the services
for care.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Reduce the Peri-Natal Transmission of HIV

*Appropriate
broken out?
level of detail?*

Objective	Action Steps	Programs				Unmet Needs
Enhance State's ability to provide AZT for HIV+ Pregnant women <i>Colo. C HCF #</i>	Collaborate with Association of Maternal & Child Health Programs (AMCHP) to develop state guidelines Establish MCHB working group to coordinate HIV risk reduction related efforts across programs ~~Development of HRSA Advisory Document~~ ~~Distribute HRSA Advisory Principles - CDC~~ C & T document and other PHS documents to MCHB community AHCPR Consumer Brochure, video	PHS 076 Implementation Plan <i>Standard 7 Core</i> <i>Working</i>	\$10,000 <i>from HCF # to develop brochures</i> \$10,000	Children, youth, women (For A-F) <i>PH</i> <i>CHES</i> <i>RW</i> <i>Health</i> <i>Learn</i> <i>Resource</i>	AMCHP State Title V program HRSA grantees and MCH community (B-F)	Funds needed for evaluation <i>95</i> <i>100,000</i> <i>20</i> <i>96</i> <i>100,000</i>

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Improve the availability of comprehensive service programs for children, youth and women.	● Administer RW Title IV Program Mechanisms (grants to CBOs) descrip. of services	Ryan White Title IV	Approximately \$24 million (of \$26 million budget). ?	Approximately \$27 million (of \$32 million budget request).	Children, youth, women and families.	● participation in grants review ● constituent involvement in grantee program and policy development.	● 30 grant applicants in FY 1995; funds only available for 13 of them. 138 Funds for existing projects inadequate to meet rapidly growing caseloads; to expand programs for adolescents and to provide needed services such as mental health; substance abuse; family case management; permanently planning.

1/3 of

grant apps.

138

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
	2) Support initial development of care systems linked to research for children, youth and women in 7 new communities.	RW Title IV <i>integrated into data</i>	\$555,000	\$600,000	Children, youth, women and families.	constituents involved in developing funded programs.	24 States lack comprehensive care systems for children, youth, women; \$1.8 million would support new planning and initial development projects in 24 states.
Enhance research agenda, research opportunities, and clinical care for adolescents with/at risk for HIV through collaboration with NIH.	Develop research priorities, collect data, and develop clinical care guidelines for adolescents with HIV/AIDS. <i>- "outreach to NIH"</i>	Adolescent Research/ Clinical Network <i>ja</i>	\$250,000 million HRSA	\$250,000 million HRSA	Youth (13-21).	One adolescent/ project participates in steering committee, guidelines development. NIH	Title IV program lacks staff resources to support research network, 1.5FTE required. How many served, how many more? \$\$

should be integrating research into the program.
Integration care staff

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Area: Services/Research

Goal: Expand access to Comprehensive, Coordinated Services and Research for Children, youth and families affected by HIV/AIDS.

Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Increase patient access to clinical research	Enhance linkages between care providers and research entities. c) Make recommendation to grantees to enhance linkages.	Reauthorized CARE Act expected to mandate new research panel to recommend research priorities, assist with care/research linkages.	\$50,000 <i>not created yet?</i>	\$200,000 <u>1.5 FTE needed</u>	Children, Youth, Women.	Consumer, Title IV provider, researcher participation in panel. Pediatric AIDS Foundation.	~~Title IV program lacks staff resources to establish and support panel; 1.5 FTE required.~~ <u>Lack \$\$\$</u>

HEALTH RESOURCES AND SERVICES ADMINISTRATION

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Objective	Action Steps	Programs					Unmet Needs
		Description	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Improve HIV programs for children, youth, families.	Provide leadership, support and technical assistance	Ryan White Title IV	\$10,000	\$10,000	Children, youth, families. grantees.	Youth and families participate in all national meetings, trainings.	Lack of adequate funding for TA
	Develop standards of care for ~~(1) PCR~~ (2) family centered care, and (3) Counseling; testing, care of women						
	Support ~~two~~ national resource centers for training. TA information.		\$1.9 million	\$1.3 million			

Collab. & other agencies.

1st action step

HEALTH RESOURCES AND SERVICES ADMINISTRATION

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Objective	Action Steps	Programs				Unmet Needs	
		Description	Resources		Populations Served		Constituency Involvement
			FY 1995	FY 1996 (proposed)			
Build youth and family leadership to provide ~~program input~~ and advocate, ~~provide~~ direction at local, state, national levels.	Convene youth and family leadership conferences and distribute report ~~Provide Published Essential Allies,~~ a guide ~~once~~ involving youth/families in program planning, leadership bodies. ~~Families advocate for Title IV by educating state/national legislators.~~	● MCHB funds cooperative agreement with Institute of <u>Family-Centered Care</u> to provide training/technical assistance to youth and families.	\$330,000 <i>good group.</i>	\$350,000 <i>20 x 4 = \$80</i>	● Youth and families participate in and present at all National Title IV meetings. ● Families serve on boards/committees of <u>20</u> projects.	● Youth and families participate in and present at all National Title IV meetings. ● Families serve on boards/committees of <u>20</u> projects. ● National Positive Youth Alliance. <i>Annex</i>	● Funds only permit 2 youth and 2 family members/project to attend national leadership meetings. <i>Need Equality Exposure of the students</i> <i>not yet included.</i>

Funds total don't match OMB figures.
 $81,000$

PDA

Area: Therapeutic Agents

Goal: Ensure the safety and effectiveness of therapeutic agents

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit Involve-ment	
			FY 1995	FY 1996 (proposed)			
Expedite access and approval of safe and effective drugs and biologics	Encourage quality applications and data submissions to review division to ensure timely and efficient pre- and postmarket review	Conduct meetings with sponsors to discuss drug development plans; expanded access programs; accelerated approval	25,235	25,536	All	All	N/A <i>enough staff?</i>

Comments from
Sh 10/27/95

What does
this figure
represent
rest of reviews?
staff?

lower priority
diseases
dedicated
staff

Area: Vaccines

Goal: Ensure the safety and effectiveness of immunization and therapeutic vaccines

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit Involve-ment	
			FY 1995	FY 1996 (proposed)			
Expedite regulatory review of promising products for immunization and therapeutic vaccines	Expand partnership between FDA and its counterparts from outside organizations involved in vaccine development	Encourage early consultation; develop guidance documents; exchange information; and work with other agencies and international organizations	11,863	12,005	All	All <i>Constit. membership on FDA Advisory Boards.</i>	N/A <i>2nd yr. 8/1/96</i>

Area: Diagnostic Reagents/Test Kits

Goal: Ensure the effectiveness of test methodologies for HIV detection

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			
Expedite improved test methodologies for HIV detection, confirmation, and viral load	Ensure timely and efficient pre- and postmarket review	Encourage early consultation with sponsor and develop guidance documents	8,732	8,836	All	All <i>Board membership</i>	N/A <i>more staff</i>

Area: Blood and Blood Products

Goal: Reduce transfusion-transmitted HIV infection

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit. Involve-ment	
			FY 1995	FY 1996 (proposed)			
Ensure supply and safety of the national blood supply	Establish policies, expedite review of product applications, conduct approval inspections, establishment surveillance, and enforcement activities	Encourage high risk donors to exclude themselves; update list of unsuitable donors; quarantine and test blood; investigate incidents to identify and rectify common errors in blood banks	17,458	17,667	All	All <i>On 10/1/88</i>	N/A <i>more studies</i>

↓
Tom Study

Area: Medical Devices

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

Objective	Action Steps	Programs					Unmet Needs
		Description	Resources (\$000)		Pop. Served	Constit. Involve-ment	
			FY 1995	FY 1996 (proposed)			
Expedited access and approval of safe and effective medical devices	Encourage quality application and data submissions to ensure timely and efficient pre- and postmarket review	Conduct meetings with sponsors on study design; produce guidance documents	9,457	9,570	All	All <i>on any boards?</i>	N/A <i>Staff</i>

72,745 73614

S. M. A. 2A
 Revision #2
 Meeting C
 Jan 9.1.95

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

AREA: Treatment

GOAL: TO REDUCE THE RATE OF TRANSMISSION OF HIV AMONG HIGH RISK SUBSTANCE ABUSERS AND THEIR SEXUAL PARTNERS.
CMHS

Objective	Action Steps	Programs				Unmet needs
		Description	Resources		Population s Served	Constituenc y Involvement
			FY 1995	FY 1996 (proposed)		

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.	○ 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 ○ Increase productive work capacity as a result of receiving services	HIV/AIDS Mental Health Services Demonstration Program	\$1.5 million-SAMHSA (\$1.4 million-NIH \$1.5 million-HRSA) <i>Counting are the 1.4 and 1.5 included in NIH's; HRSA's figures?</i>	\$1.5 million-SAMHSA \$1.4 million-NIH \$1.5 million-BRSA	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/ethnic minority populations	Health professionals, consumers and community services	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 providing our client populations with a spectrum services relating to diverse needs
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1.5

1.5

4.4

4.4

19.68

23.43

20.58

26.33

23.49

Enhance the ability to have an impact upon the HIV/AIDS epidemic by training mental health care providers and other health care workers.	○ Assess neuropsychiatric/ psychosocial aspects of HIV/AIDS to prevent the spread of HIV infection ○ Establish linkages with health care providers ○ Include AOD related HIV prevention in all training curriculums ○ Train mental health professionals, etc. who serve people with serious mental illness ○ Provide training about pre/post HIV antibody counseling and testing, physiological, and psychological aspects of HIV/AIDS, culturally sensitive, linguistically and gender appropriate interventions/methodologies ○ Address managed care and training issues ○ Evaluate effectiveness of training techniques in developing	AIDS Health Care Worker Training	\$2.93 million	\$2.93 million	HIV/AIDS Mental Health Care Providers <i>Clients</i> whose client population may include gay and bisexual men, women, racial and ethnic minority groups, injecting drug users and their sex partners, sex workers, women, infants, children, adolescents, and sex partners of people with HIV/AIDS.	Health professionals and community services	Additional financial resources and increased collaboration with other federal agencies would broaden the scope of training to include all health professionals <i>WAScent efforts.</i>
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problem?
HRS-A?
HCF

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Area: Treatment

GOAL: TO REDUCE THE RATE OF TRANSMISSION OF HIV AMONG HIGH RISK SUBSTANCE ABUSERS AND THEIR SEXUAL PARTNERS.
CSAT

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Population s Served	Constituenc y Involvement	
			FY 1995	FY 1996 (proposed)			
To demonstrate the efficacy of Outreach as an intervention for facilitating access to substance abuse treatment to high risk and hard to reach substance abusers To demonstrate the comprehensive HIV outreach interventions effect behavior changes in diverse populations.	○ Determine chronic, hardcore drug users and their sex and/or needle-sharing partners ○ Facilitate entry into substance abuse treatment ○ Provision of services, including medical diagnostic services for HIV, STDs, and TB ○ Information-sharing, skills and other prophylactic means to effect behavior change ○ Evaluate effectiveness of programs	HIV/AIDS Community Outreach Program <i>P. W. G.</i>	\$7.5 million	\$7.5 million	Chronic, hard core substance abusers and their sex/needle-sharing partner(s), including those individuals who have severe drug problems, frequently inject heroin and/or cocaine and/or are polydrug users. Emphasis within various racial/ethnic populations, women, residents of public housing projects and homeless individuals.	Health professionals, consumers and community services <i>prom</i>	Additional resources for medical treatment of HIV/AIDS, STDs, TB or other medical services would provide the opportunity to provide services to a more vast population. <i>10 novel Sub abuse initiative</i>

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Population s Served	Constituenc y Involvement	
			FY 1995	FY 1996 (propose d)			
To 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 disease including HIV/AIDS and tuberculosis.	○ Train health care professionals to provide comprehensive services and care ○ Enhance curricula by including training for diverse populations	AIDS Training Grants	\$2.8 million	\$ 	People with or at risk for substance abuse, mental illness and transmission of HIV/AIDS	Health professionals and consumers	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 and HIV/AIDS and other STDs.

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Population s Served	Constituenc y Involvement	
			FY 1995	FY 1996 (proposed)			
To demonstrate the effectiveness of fostering greater services integration by linking substance abuse treatment, primary medical care, mental health and HIV/AIDS, STD and TB services	○ Develop and foster linkages among services ○ Evaluate efficacy of linked services	CSAT/BPHC Linkage Initiative <i>100% linkage</i>	\$7.7 million	\$0 (Funds for FY 1996 are subsumed under the new Consolidated Demonstration Program)	Injecting drug users, other high risk substance abusers and their sexual partners	This collaborative effort serves as a catalyst, recognizing and linking AOD tx, mental health and primary care services and HIV and/or AIDS. Additional resources could join this effort with other agencies to enhance the services rendered.	

Relate to the BPHC unmet need.

Advisory Process Council to determine how this will be spent. It'll be more than \$7.7.

SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION

Area: Prevention

GOAL: TO REDUCE THE NUMBER OF NEW INFECTIONS

CSAP

Objective	Action Steps	Programs					Unmet needs
		Descriptions	Resources		Populations Served	Constituency Involvement	
			FY 1995	FY 1996 (proposed)			

To reduce the number of new infections by 25% Demonstrate the differential effectiveness of incorporating HIV/AIDS Prevention curricula into ongoing substance abuse prevention programs	- Supplementation of high risk youth grants for ATOD prevention so for the purpose of including HIV/AIDS prevention strategies in their present activities - Develop plan to empower youth with skills knowledge and beliefs - Demonstrate effective strategies to prevent ATOD use/abuse among high risk youth - Include developmentally and culturally appropriate HIV/AIDS education and prevention approaches	High Risk Youth Prep. Outreach Prog.	\$1 million	\$3 million	High risk youth or youth at risk for ATOD, adolescent females and youth at risk for AOD-related violent behavior	Families of youth service workers, the communities that support them and youth at risk for ATOD	Presently, this reaches 25% of high risk youth grantees. All grantees should be supplemented for the incorporation of HIV/AIDS prevention strategies
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how measure
mention in text. → match c

Apply a community designed, community focused approach to the prevention of HIV/AIDS in a culturally appropriate manner, specifically targeting communities of high seroprevalence	○ 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 ○ Reduction of ATOD use ○ Solicit the neighboring communities in the implementation	○ Demonstration Sites ○ Community training in the use of HIV/AIDS curriculum	None	\$5 million	American communities	All aspects of the community	All community coalitions and partnerships should be supplemented
Supplement all FDP grantees so that faculty are skilled in teaching ATOD prevention strategies coupled with HIV/AIDS prevention strategies promoting and augmented response from their patients/clients	○ Supplementation of the FDP grantees	○ Educating faculty from health professions concerning HIV/AIDS and ATOD ○ Training faculty from health professions on HIV/AIDS and diverse client populations	None	\$650,000	All Americans secondary to the impact this program will have on all health professionals	Health professional institutions, consumers and communities services	Additional resources could provide education and training, leading to program implementation, which will impact a large component of the population

Workplace Initiative

Comments
from Jeff
on 10/27

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National Plan for Combatting AIDS

DRAFT

June 14, 1995

- Goal 1: Data Collection
- 2: Public Involvement/Understanding
- 3: School Based Programs
- 4: Behavior Change
- 5: Increase Individual Knowledge of serostatus

141,076

45,970

48,215

185,666

169,035

589,962,000

#1 identical to President's
Budget!

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DRAFT

Area
Goal 1

Prevention

Strengthen existing systems and develop new systems to accurately monitor the HIV epidemic as a basis for assessing and directing prevention programs. (to support prevention need data...)

Data to plan prevention

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, implement projects that evaluate and expand the uses of HIV infection and AIDS case surveillance and serosurveillance data so that these data systems can more effectively guide public health policy and provide relevant information necessary to direct and evaluate prevention activities. improved understanding of the natural history of HIV infection as well as the risk factors and protective factors for sexual, drug-related, health-care worker-related perinatal HIV transmission will have contributed to more effective prevention strategies for all affected populations.	- Evaluate HIV infection reporting systems (named, anonymous, unique identifier) used nationally for their ability to monitor the epidemic, provide linkages to medical and social services, and to assess their impact on a person's decision to be tested. - Characterize high risk behaviors of persons with evidence of recent HIV infection such as persons with documented HIV seroconversion, high CD4+ counts, or diagnosis of HIV infection in adolescents. - Assess the impact of public health guidelines and recommendations and prevention efforts. - Characterize persons co-infected with TB and HIV. - Evaluate ways to improve the completeness and quality of risk ascertainment on persons reported with HIV and AIDS. - Identify and characterize previously unreported AIDS cases among deaths investigated by local medical examiners to assess the impact of under-diagnosis of AIDS cases on AIDS surveillance among disadvantaged populations that often do not receive adequate health care. - Test the efficiency of new techniques for reporting HIV and AIDS surveillance data from health care providers and laboratories to health departments.	- Evaluation of HIV Infection Reporting Systems Project - Recent HIV Infection Projects - Surveillance to evaluate prevention projects - Adult spectrum of disease project - TB project - Mode of transmission validation project - The medical examiner study - Enhancement of AIDS surveillance efficiency project	\$141,076	\$140,917	All major racial/ethnic categories and major risk groups	Regular consultation with national, state, and local public health officials and many other relevant organizations <i>PWAs, comm. groups.</i>	- Surveillance of risk behaviors that contribute to HIV transmission. - Monitoring HIV incidence

Through TB reporting?

Which studies to how linked/integrated with NH

How does this system capture recent infections? Risk factors trying to tease out -> refine?

Cooperative agreements with state & local

Departments

- AIDS Case Surveillance P1
 - AIDS incidence
 - morbidity/mortality
- HIV infect. Surveill.
 - HIV Family of Surveys
 - Childbearing
 - Sentinel Hospital
 - Clinic-based HIV
 - Blood Collection Centers
- Occupationally Acquired HIV Infection
- Adolescent/Adult + Ped Spectrum of Disease
- Supplement to HIV/AIDS Surveillance
- Medical Examiners Project
 - C-1
 - HERS
 - CDC
 - SF men

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Area
Goal 1

Prevention
Continued

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
dy-104 Linkage - NH nat. hist. studies Evaluation of 1st bullet?	- Collect additional data on persons reported through HIV/AIDS surveillance which may be important for the planning and evaluation of prevention and care programs, such as <u>social/economic status</u>, <u>levels of disabilities</u>, <u>drug use history</u>, <u>sex behavior history</u>, <u>utilization of HIV testing and medical care services</u>, and <u>reproductive history in women</u>. - Assess the interrelationship of behaviors, HIV markers and surrogates, and their potential role in surveillance systems. - Assess the interaction of socioeconomic, behavioral, and biologic factors in HIV transmission. - Determine the role of female-specific biological factors that are linked to acquisition and transmission of HIV infection and that influence the course of HIV disease. - Determine factors contributing to the efficiency of sexual transmission of HIV. - Assess the risk of transmission of HIV and TB from HIV-infected health-care worker to patient and vice versa - Develop systems to monitor the emergence of multidrug-resistant TB in the HIV infected. - Continue to develop improved methods for projecting or modeling the HIV epidemic.	- Supplement to HIV/AIDS surveillance - Natural history & epidemiology studies - Pediatric & perinatal studies - Unusual case investigations - Domestic blood safety - Surveillance of strain variation - HIV/AIDS case reporting - Health care worker surveillance - Opportunistic infection surveillance studies					

10 Prevention A.2

@ Project CAPES

Some looking at HIV for women and kids

* Role in reproductive decision-making

@ x-ray, and other methods

20 Prevention

WACS

HERS

PIDS

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Area **Prevention**
Goal 1 **Continued**

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apppr.)	FY 1996 (proposed)			
Link i NIAID or other study - sponsoring group? Connections to 1st bullet on previous page? Verifying Lab Kestite Linked? What are prevention partners? Evaluating prevention efforts needed data & methods	• Develop methods to differentiate HIV-specific antibodies generated in participants in HIV vaccine trials from those generated in response to HIV infection. • Develop methods to identify potential cases of HCW-to-patient transmission. • Expand HIV reporting systems to collect information about primary & secondary HIV prevention services needed and received by HIV-positive clients (working w/ HRSA). • Work with providers and users of lab services to develop & implement systems which provide assurance that the capacity and quality requirements for HIV testing are met. • Work with international partners to study TB, implement vaccine trials, enhance clinical management, assess prevention efficacy, and improve program management of HIV/AIDS. • Share with prevention partners information on the need for and benefits of HIV reporting. • Develop methods to integrate various sources of data and to describe progress in HIV prevention. • Develop methods to evaluate the use of HIV infection and AIDS surveillance systems to assess early intervention strategies.	• NIR case investigations • HIV sero-incidence surveys • HIV seroprevalence surveys • HIV seroprevalence surveys	Dentist Case & case factoring CM - getting info unmet need				Vaccines - • HIV sero-inc. + altitudes gay/bi men. 3 sites • Reactivity to vaccine to NIAID • CDC, NIAID, Los Alamos, WHO, ...

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*Take into
consideration
for info.
dissemination*

DRAFT

Area Prevention
Goal 2 Increase the public understanding of, involvement in, and support for HIV prevention.

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
~~By 1994~~ provide leadership in HIV & STD prevention by (1) establishing a national agenda through the media; (2) promoting credible messages based on science through credible channels; and (3) encouraging and supporting prevention efforts at the local level. ~~By 1994~~ establish a collaboration of partners composed of national, State, and local organizations to facilitate (1) diffusing social marketing principles applied to HIV/STD prevention at the local level; (2) identifying and promoting mechanisms to exchange technology and information; and (3) developing guidelines for applying social marketing principles to local HIV/STD prevention.	- Monitor changes in public knowledge about how HIV is and is not transmitted. <i>Done how?</i> - Develop methodologies to measure community mobilization or changes in institutional behavior in relation to mass media public information and education programs. <i>Done how?</i> - Develop new mass media messages, in collaboration with the public health systems and with international, national, state, and local private sector organizations and agencies. - Expand the relationship between CDC and the <u>entertainment industry</u> to improve messages and role modeling for HIV prevention. <i>→ modeling</i> - Develop communication interventions with appropriate organizations to ensure that consistent, accurate HIV prevention information is provided to the public. - Develop community coalitions for HIV prevention. - Coordinate and disseminate information messages through the media that explain new scientific findings and policies concurrent with the release of new scientific information. - Develop leadership of health/education officials to effectively deliver HIV prevention messages through partnerships. <i>What is this?</i> - Evaluate the role of communications in changing individual knowledge, community norms, and individual behavior through establishment of model programs.	- National Health Communications - Prevention Collaborative Partners - Local demonstration sites - Coordination with community planning - CDC National AIDS Clearinghouse - CDC National AIDS Hotline - Business Responds to AIDS - Labor Responds to AIDS -HIV/AIDS workplace policies <i>Linkage to professional orgs.</i>	\$45,970	\$46,869	All major racial/ethnic categories Young persons (18-25) Persons engaging in behaviors that place themselves at risk for HIV infection. All population segments Business & labor leaders, employees, and families	Regular consultation with over 200 <u>prevention collaborative partners</u> composed of national, state, & local organizations Regular consultation with over 50 business & labor partners Regular consultation with influential leaders	More effective use of social marketing principles in HIV prevention programs Further implementation of strategies to promote adoption of BRTA & LRTA comprehensive programs Family education materials More effective materials to encourage abstinence and other prevention behaviors HIV prevention materials for use by <u>religious communities</u>

> linkage to HRSA?

*ATIS
MSHA, CDC, HRSA
Katz (name line)
Kuk
Schneider - HRSA
Sevin - MSHA*

could be problematic if not associated to care system that's ready to deliver.

June 30, 1995

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DRAFT

Area
Goal 2 Prevention
Continued

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, apply social marketing principles at the local level for the purpose of (1) demonstrating the participatory social marketing process--skills and resources needed to effectively engage the community; (2) measuring the effects of behavior-based social marketing interventions; and, (3) documenting the lessons learned. By 1997, facilitate the application of prevention marketing principles in CDC-funded community planning efforts by (1) promoting guidelines for consideration of these principles at the local level for prevention interventions and (2) providing interactive technical assistance on social marketing technology principles (or	• Expand the relationship between CDC and academic experts in mass communications to develop methods for measuring the impact of mass media on individual and community behaviors. • Develop ways of measuring the mobilization of community groups, i.e., changes in community norms, capacity. • Monitor business policies and employee education programs regarding HIV/AIDS. • Implement a BRTA initiative to develop HIV prevention and service programs for the workplace and the community. • Sponsor and participate in national meetings of businesses and religious, civic, medical, social, and voluntary agencies which conduct HIV prevention and service programs.	• Supervisor/ labor leader training • Employee education • Employee family education • Community service and volunteerism • National Organizations/ Partnerships including business, labor, religious, voluntary, and media • National & Regional Minority Organizations	doing training? providing materials?	Heathley People 2000 (CSC) followed this in putting this together	?	?	?

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Area Prevention
Goal 2 Continued

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
prevention marketing) to public health agencies as well as HIV Prevention Community Planning Groups ~~By 1997~~ promote HIV prevention as a relevant issue in business settings. ~~By 1997~~ provide & promote a network of resources & referrals to assist in implementing the Business Responds to AIDS (BRTA) Comprehensive HIV/AIDS Workplace Program. ~~By 1997~~ market the comprehensive workplace HIV/AIDS program to business. ~~By 1997~~ establish and execute a research agenda to formulate & assess strategies and resources to advance the knowledge of effective work-place HIV programs.	Relevant how? As a place to do prevention education - sensitivity, A, A/DK, unique cohort for educ. -> not reached inschools, collect, etc. CDC is developing & will then market? What is this? Evaluation of BRTA.				?	?	?

Centers for Disease Control and Prevention

Area Prevention

Goal 3

Implement comprehensive school health education programs to prevent risk behaviors that cause HIV infection and related health problems.

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, increase by 15% the proportion of school districts that require age-appropriate HIV education at each grade level, K-12, especially at grades 9-12, preferably as part of a comprehensive school health education program. By 1997, increase by 15% the proportion of colleges and universities that provide HIV education for students and staff, preferably as part of an institution-wide health promotion program.	• Monitor state-level policy and program requirements that support effective HIV education within comprehensive school health education programs (CSHEPs). • Monitor district-level policy and program requirements that support effective HIV education within comprehensive school health education programs. • Monitor the prevalence of behaviors that cause HIV infection and related health problems among school and college students. • Implement and revise as necessary, CDC guidelines for effective school health education to prevent the spread of HIV infection. <i>What are these?</i> • Enhance the capacity of state and local educational agencies to develop and implement effective HIV education within CSHEPs • Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program. • Ensure the integration of education to prevent HIV infection, other STDs and the use of alcohol and other drugs among youth. • Strengthen the capabilities of state and local departments of education and health to collaboratively help schools, colleges and universities implement effective HIV education programs for youth.	HITAS? • Support for state and local educational agencies • National organizations • Colleges & universities • Teacher training sites • Youth surveys • Projects to reach out-of-school youth <i>Questionnaire?</i> <i>OMB approved?</i>	\$48,215	\$48,162	All major racial/ethnic categories Young persons engaging in behaviors that place them at risk for acquiring HIV through sexual exposure	Met with a wide range of constituency groups to: 1) improve existing programmatic efforts; 2) improve assistance and resources provided by CDC; and, 3) explore strategies that the nation	• Not all youth are accessible through existing institutional-based efforts • Not all states monitor youth health-risk behaviors

to provide info to all co.

Youth Risk Behavior Surveillance System

Research on HIV-Prevention Programs in Schools.

Other Prevention Programs in Schools.

Research on Innovative School-Based Programs

Cost-Effect. Research

P. 7

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Area Prevention
Goal 3 Continued

DRAFT

Objectives	Action Steps	Programs					
		Descriptions	Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, decrease by 10% at each grade level the proportion of 9th-12th grade students who report they have engaged in sexual intercourse. <i>related work</i> ~~By 1997~~, among 9th-12th grade students who report they have engaged in sexual intercourse, decrease by 10% the proportion who report they have engaged in sexual intercourse during the past 3 months. By 1997, among 9th-12th grade students who report they have engaged in sexual intercourse during the past 3 months, increase by 10% the proportion who report they used a condom at last intercourse.	• Increase the effectiveness of HIV education for youth served by state and local departments of education and college and universities through the efforts of selected national organizations. • Enhance the capacity of state and local agencies to help prevent HIV infection and HIV-related problems among youth through the efforts of training and demonstration centers established for state & local departments of education (and colleges & universities). • Establish teacher training coordinators in every interested state to help teachers provide effective HIV education within a CSHEP. • Identify and disseminate, through training and demonstration centers and through teacher training coordinators, HIV education programs that have been shown to be effective in reducing behaviors that cause HIV infection and related health problems. • Synthesize and apply the results of research to increase the effectiveness of HIV prevention education for youth. • Conduct formative evaluations of state and local departments of education policies, curricula, teacher training, and school efforts to prevent behaviors that cause HIV infection and related health problems. • Develop a standardized report for each state to profile the nature of priority health problems and risk behaviors among youth in that state and school efforts to prevent these problems and behaviors.	<i>SM - lack of coord. to other agencies. etc - id what works, need more linkage & behavior scientists. etc. HIV/MH+ *Behavioral</i> <i>data back - good. data sharing amongst agencies.</i>				health or education organizations, 3) colleges & universities, 4) state public health departments, as well as young people themselves. Meetings included an annual constituency meeting, quarterly training programs, & communication through an electronic bulletin board/network.	<i>Same unmet needs as previous page?</i>

Centers for Disease Control and Prevention

Area Prevention
Goal 3 Continued

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, decrease by 10% the proportion of 9th-12th grade students who report they have <u>injected illicit drugs.</u>	• Conduct evaluations of the effectiveness of existing school-based interventions to reduce behaviors that result in HIV infection and related health problems. • Develop state-of-the-art school-based interventions and evaluate their effectiveness in reducing behaviors that result in HIV and related health problems. • Conduct and apply meta-evaluations of existing research data about the effectiveness of school-based interventions in reducing health risks behaviors among adolescents.	<i>Don't know what the program is</i> <i>Other areas of Drug Abuse ~ Crack / Cocaine connection</i> <i>Arv / sex connection.</i>					

Centers for Disease Control and Prevention

Area - Prevention

Goal 4

Prevent or reduce behaviors or practices which place individuals at risk of HIV infection, or if infected, place others at risk.

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, at least 90% of individuals with known HIV infection will be abstinent or will have used a condom at last sexual intercourse, and at least 50% of individuals who have engaged in high-risk sexual behaviors within the past 12 months will be abstinent, in a mutually monogamous relationship, or have used a condom at last sexual intercourse. By 1997, at least 75% of injecting drug users will have stopped injecting drugs or used sterile or decontaminated injection equipment at last injection.	• Collaborate with prevention partners to assess risk behaviors and practices in selected communities. • Identify barriers to implementation of HIV prevention programs at community, state, and national levels. • Collaborate with selected communities in developing and implementing a model behavioral intervention program that comprehensively addresses community needs and uses available community resources and prevention partners in selected sites. • Design, develop, and test effective community-level interventions to change risk behaviors through altering community norms and values to support healthy behaviors. • Expand the community's capacity to plan, implement, and evaluate culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations. • Enhance the capacity of CDC staff to plan, administer, and evaluate behavioral change strategies and community-based interventions to provide public health leadership and assist our prevention partners in designing and managing effective strategies for HIV prevention programs.	• Cooperative agreements for HIV - c state prevention. • Directly funded CBOs • National organizations • National Minority Organizations • HIV intervention research studies	\$185,666	\$209,764	All major racial/ethnic categories and persons engaging in behaviors that place them at risk for acquiring HIV	HIV Prevention Community Planning--state & local health departments formed community planning groups to assist in developing HIV prevention plans Regular & extensive consultation with representatives from state & local health departments, community planning groups, and national organizations	Lack of behavioral risk surveillance data for program planning and evaluation purposes More effective application of behavioral science to HIV prevention programs Need to develop and maintain prevention capacity for high risk women, youth and gay men of color

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Area Prevention
Goal 4 Continued

DRAFT

Objectives	Action Steps	Descriptions	Programs			
			Resources in thousands			
By 1997, at least 80% of the health care & public safety workplaces will implement programs & procedures for preventing HIV transmission at work sites. By 1997, reduce unintended pregnancies to no more than 40% of pregnancies among women with or at risk for HIV infection. By 1997, the number of individuals donating blood and found to be infected with HIV at the time of donation will decrease by 50% through self-deferral. By 1997, among selected populations of youth in high-risk situations, increase by 10% the proportion who report they used a condom at last sexual intercourse	- Enhance the capacity of local health departments and other relevant community agencies to collaboratively provide effective HIV education for youth in high-risk situations. - Establish scientifically-based evaluation components for HIV prevention activities. - Use evaluation of components to design or refine HIV prevention programs and/or redirect HIV prevention resources. waters? → pop planning, Any links → link to HCW data collection (Goal 1) and labor Responds to AIDS (Goal 2)? → Collab c Red Cross, NHLBI, etc? FDA? How different from school based goal? Going for those not in school? Data collection mechanism?	Collab c School program	1 (a)			

Clarifications →

- Budget
- Names c programs (linking descriptions)
- Distinguishing oversight from program funding
- focusing report on programmatic stuff (compressing oversight Role...)
- Reworking unmet needs.
- Accounting vis-a-vis collab →
 - SAMSHA
 - NIH
- OIG → rect/ also wants to implement the policies within the HP...?
- incorporating constituencies → p. 5 of APO update

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Area
Goal 5

Prevention

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

DRAFT

Objectives	Action Steps	Descriptions	Programs				
			Resources in thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
By 1997, at least 85% of the estimated 1,000,000 HIV-infected individuals will know their HIV serostatus. By 1997, at least 90% of health care sites <i>defined as...</i> receiving public funds and serving at-risk persons will provide appropriate HIV counseling and testing services. <i>What's the % now?</i> By 1997, at least 80% of known HIV infected individuals, either directly or through referral, will receive <u>primary and secondary</u> prevention services. <i>infect others</i> <i>→ Why does the HIV+ person need 1st prevention the horse is out of the barn?</i>	<i>Are there enough places to even get tested?</i> - Working with governmental & nongovernmental partners, enhance community-level assessments of needed primary & secondary prevention services. - Identify opportunities for common HIV prevention data collection & development of uniform data sets. - Integrate HIV prevention services into standards of care for the diagnosis and treatment of HIV disease. - In collaboration with the FDA, develop, test, & implement rapid HIV testing procedures. - Strengthen the capacity of state, and local health departments to provide partner notification services to private health care providers offering HIV counseling & testing. - Develop alternative methods to provide HIV counseling & testing services. - Work with professional groups, hospitals, and state health departments to ensure that health care workers receive adequate training on primary and secondary HIV prevention (with HRSA). - Study the impact of discrimination as a barrier to prevention services. - Assist publicly funded counseling & testing sites to establish selection criteria and systems for monitoring the quality of referral laboratories. - Interview persons newly diagnosed with HIV infection to identify missed opportunities for earlier diagnosis and CD4+ testing. - Conduct a study of incident AIDS cases to determine what services HIV-positive clients are receiving over time to identify service gaps (in collaboration with HRSA). - Provide guidelines and training to HIV counselors to improve the quality of counseling.	Counseling, testing, referral & partner notification programs <i>as part of coop. agree to state & local h.e.s.</i> <i>extend to which this has been done?</i> <i>SM - just taking back.</i>	\$169,035	\$179,006	All major racial/ethnic categories and persons engaging in behaviors that place them at risk for acquiring HIV	HIV Prevention Community Planning--state & local health departments formed community planning groups to assist in developing HIV prevention plans Regular & extensive consultation with representatives from state & local health departments, community planning groups, and national organizations	More effective long term intervention programs for HIV positive individuals Determination of the best balance of CTRPN programs with other HIV prevention strategies Lack of resources to support comprehensive referral and data monitoring systems

Develop Rx
Texts
Dx

Collab.

Constr ~> CCGs (ACG, CERA)
Coet

- where I could pare down I
did.

Linda Vogel ~>

International not
broken out —

National Institutes of Health

Area Research

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

Objectives	Action Steps	Programs				
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Natural History and Epidemiology <i>(Review data on the N.H. + Epi.)</i> <i>Collect data to examine the transmission of HIV & progression of HIV-related disease to assist in the development of biologically based interventions.</i>	Develop and assess <u>intervention strategies</u> to reduce or prevent HIV transmission <i>Objective</i> <i>P.39</i>	Support development and evaluation of improved, acceptable, effective physical and non-irritating chemical barrier methods and conduct research on existing barrier methods to prevent sexual transmission of HIV and STDs; Develop strategies and conduct studies to evaluate vaccines, drugs, and other interventions such as cesarean sections, vaginal cleansing, and breast-feeding practices that prevent perinatal transmission. ~~These should include randomized trials where possible, cooperation between study groups, and re-analysis of data from existing studies, where appropriate;~~ Assess the efficacy of combined strategies that decrease blood-borne transmission of HIV; for example, evaluating existing needle exchange programs, the use of bleach as a disinfectant, and drug abuse prevention and treatment on reducing HIV transmission and seroincidence;	48,656	48,137 PB 73,000 Bypass	All populations ↓ Community, mts, Pits, On sci. advisory groups - (Council, ARAC, etc...) Any outside boards for the charts?	24,929 Δ from the NIH FY 1996 Comprehensive Plan + Estimate for Scientific Opportunities in AIDS Research.

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

Natural History/Epi.

TOTAL	FY95 Approp	FY96 Pres. Bond	Bypass	Δ
	17,014	188,822	237,271	404,49

for overall unmet need.

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

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

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

omit?

not in plan.

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology <i>Enhance understanding of HIV-related disease progression to assist in the development of effective strategies for HIV-infected patients</i>	Elucidate the progression of HIV-related disease, from early infection through long-term consequences and sequelae, with the goal of understanding, preventing, and treating those factors that may lead to disease <i>(Objective #3, p.44)</i>	Identify pathogenic mechanisms and cofactors for disease progression and disease-specific outcomes in well-defined subsets of individuals (e.g., high-CD4 long-term survivors, low-CD4 long-term survivors, rapid progressors). ~~Studies should include investigation of behavioral, genetic, virologic, immunologic, and host factors;~~ In diverse populations, describe the full spectrum of HIV-related disease, including OIs, HIV-related malignancies, wasting, and organ-specific complications; evaluate the impact of sociodemographic variables, gender, age, and route of transmission on HIV disease progression, time to AIDS, and specific outcomes; Study the natural history of early HIV infection; Evaluate issues specific to HIV-infected children, including: (1) mechanisms that contribute to impaired growth and neurodevelopment, (2) impact on childhood infectious diseases and the safety and efficacy of immunization, and (3) childhood-specific complications including lymphoid interstitial pneumonitis;	53,565	59,574 PB <i>54,883 Bypass</i>	All populations	<i>} Are we over-funding in this area?!</i>	

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

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

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology <i>Enhance understanding of susceptibility to HIV infection at the biological level.</i>	Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease <i>(Objective #4, p. 47)</i>	Apply cutting-edge laboratory approaches and behavioral strategies to assess susceptibility to infection and transmission and monitor disease progression and response to intervention in population studies; Facilitate the transfer of novel laboratory and behavioral strategies from basic research to epidemiologic applications; Promote development and application of laboratory approaches to elucidate mechanisms, cofactors, and timing of maternal-fetal-infant transmission of HIV infection; Assess new virologic parameters (e.g., viral burden, genotype/phenotype) applicable to body fluids that correlate with infectiousness for evaluating interventions (e.g., spermicides/microbicides, vaccines); Identify laboratory parameters associated with HIV-related outcomes, such as intermediate end points preceding HIV-associated infections and malignancies, predictors of long-term survival or rapid progression, and markers of exposure to HIV without infection;	23,074	23,210 <i>PB</i> 28,395 <i>Bypass</i>	All populations		<i>Δ 5,185</i>

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

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Natural History and Epidemiology <i>Enhance understanding of HIV infection in populations in which HIV is prevalent, emerging, and/or increasing for the purpose of developing better Rx + Vxs.</i>	Perform the epidemiologic studies of HIV infection, related conditions, and risk behaviors in domestic and international populations in which HIV is prevalent, emerging, and/or increasing <i>(Objective #5 p. 49)</i>	Identify emerging high-risk groups in the United States through seroincidence studies and identification of behavior risk factors in the population. Examples of groups that need particular attention and further evaluation include minorities, women, adolescents, children, young gay men, homeless mentally ill, drug users, and the incarcerated; Develop infrastructure to define populations in the United States and throughout the world with high incidence and prevalence suitable for vaccine and other intervention trials; Delineate the epidemiology of behavioral risk factors for HIV in defined population-based studies; Measure the occurrence of other infectious agents, e.g., other viruses (HTLV-1, HSV-2, hepatitis B and C, etc.), sexually transmitted diseases, and mycobacterium (e.g., MTB, <i>M. avium</i>) in populations at risk for HIV; Coordinate with the CDC, WHO, and other institutions to maintain a comprehensive view of the epidemic with as much detailed information about subpopulations as possible;	29,448	31,644 <i>PB</i> 28,303 <i>Bypass</i>	All populations		
							<i>Are we overfunding this?</i>

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

Who are they?
Cooperating?
AHCPR?

Area Research

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

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis <i>Enhance understanding of HIV pathogenesis</i>	Delineate the cellular and molecular mechanisms associated with the viral immunopathogenesis of HIV-related immune dysfunction <i>(Objective #1, p. 61)</i>	Delineate the direct and indirect mechanisms underlying HIV-induced depletion and dysfunction of target cells/tissues;	201,040	217,368 <i>PB</i>	<i>All populations</i> <i>168,661 Bypass</i>		<i>Basic Research is overfunded?</i> <i>Payline -></i>
		Define the virologic (load and phenotype), immunologic (specific and nonspecific), genetic, and environmental factors that contribute to disease progression and nonprogression;	<i>FY 95 122,052</i>				
		Delineate the molecular mechanisms by which virus-derived factors regulate HIV replication and pathogenesis, with special emphasis on the use of primary virus isolates and cells;					
		Delineate the role of immune activation and host factors, including cytokines, in HIV replication and pathogenesis;					
		Delineate the role of lymphoid organs, including mucosal-associated lymphoid tissue, in HIV pathogenesis;					
		Further develop and utilize experimental models to examine the pathogenesis of lentiviral infections;					

Etiology + Pathogenesis TOTAL

<i>FY95 Approp.</i>	<i>FY96 Res. Bud.</i>	<i>Bypass</i>	<i>Δ</i>
345,663	374,767	420,913	46216
			<i>(unmet need)</i>

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis	Delineate the cellular and molecular mechanisms associated with the viral immunopathogenesis of HIV-related immune dysfunction (continued)	Delineate the role of lymphoid and hematopoietic precursor cells and their microenvironment in immune impairment;					
		Develop new assay systems for effective measurement of changes in viral load and host immune function that are predictive of disease progression;					
		Delineate the range of cell types infected by HIV <i>in vivo</i> and their potential role as viral reservoirs; and					
		Establish and expand collaborative programs to facilitate sharing of key patient samples, animal model resources, and laboratory reagents.					
~~Etiology and Pathogenesis~~	Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression	Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection;	28,140	34,233 PB	All populations		
		Determine the impact of early events in the establishment of HIV infection on the clinical course of disease;					
		Determine the cell or tissue type that serves as the portal of entry of HIV and the impact of STDs and other pathogenic processes that influence HIV transmission;					
		Determine the effects of viral genotype and load on transmission of cell-free and cell-associated virus;					

Keep?

114,152 Bypass

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

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

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

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis	Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression (continued)	Determine the roles of specific and nonspecific mucosal immunity and host factors that inhibit/enhance HIV transmission; Determine the mechanisms of vertical HIV transmission; and Elucidate unique aspects of HIV transmission and disease progression in underresearched populations.					
Etiology and Pathogenesis Enhance knowledge about HIV-related cancers.	Elucidate the etiologic factors and cofactors in the pathogenesis of HIV-related malignancies (Objective 3a, p. 64)	Elucidate the role of HIV infection, immune dysfunction, and interactions with potential cofactors in the development of HIV-associated malignancies; Identify the characteristics of the host that predispose to development of malignant disease, including genetic, hormonal, growth factor, cytokine, and immunologic characteristics; and Identify the molecular correlates of HIV-associated malignancies, including but not limited to oncogenes, tumor suppressor genes, tumor promoters and carcinogens, and viral and microbial genes and proteins.	28,544	28,941 PB 16,795 Bypass	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis <i>Enhance understanding of HIV-related neuropathogenesis.</i>	Elucidate the pathogenic mechanisms involved in HIV-associated neurological diseases <i>(Objective 3.b, P.65)</i>	Investigate the contributions of viral infection and virally induced indirect factors (in neuronal and non-neuronal cells) to nervous system impairment; Delineate how HIV enters and persists in the nervous system and causes functional impairment; Investigate both biological and environmental factors that may affect nervous system function in the context of HIV disease, ~~using neurological and appropriate neuropsychologic assessment tools;~~ Study the effects of neurotrophins and immunoregulatory and proinflammatory cytokines on both host and viral gene expression; Delineate the role of OIs and drug treatment in neurologic complications of AIDS, including peripheral neuropathies, hearing and visual loss, and behavioral changes; Assess neural tissue and organs as virus reservoirs in HIV disease and as sources of specifically neurovirulent/neuroinvasive viral strains; and	38,984	41,067 <i>PB</i> 47,363 <i>B. Pass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		Develop neuroimaging tools for correlative structural-functional studies of progressive HIV-associated neurological disorders.					
Etiology and Pathogenesis Enhance understanding of HIV-related OIs.	Elucidate the pathogenesis of HIV-related opportunistic infections (Objective 3C, P.67)	Elucidate the mechanisms of immune function that mediate protection against the OIs; Develop <i>in vitro</i> techniques and animal models, where needed, to propagate the opportunistic micro-organisms and conduct studies designed to provide details of the basic biology and pathogenic mechanisms of these micro-organisms; Identify and elucidate the genetic and environmental risk factors associated with susceptibility, development, and progression of opportunistic infections; Develop and validate diagnostic assays for the reliable and rapid identification of HIV-associated opportunistic infections; Study the effects of OIs on immune dysfunction; and Elucidate immunologic markers that are correlative with disease progression for HIV-associated OIs and develop assays to accurately monitor these markers as a function of therapy.	32,222	35,151 PB 48,775 Bypass	All populations		

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Etiology and Pathogenesis <i>Enhance understanding of HIV-related wasting</i>	Elucidate the etiology and pathophysiology of HIV-related wasting, failure to thrive, and growth retardation <i>(Objective 3d, P.74)</i>	Define alterations in body composition, nutritional status, metabolic patterns, energy balance, and growth and development associated with HIV infection; and Elucidate the pathogenesis of HIV-associated wasting and impaired growth and development, including the roles of cytokines, malabsorption, anorexia, opportunistic infections, HIV, and other factors.	2,931	2,918 ^{PB} 6,638 <i>Bypass</i>	All populations		
Etiology and Pathogenesis <i>Enhance understanding of HIV-related organ/tissue disorders.</i>	Elucidate the etiology and pathogenesis of HIV-related organ/tissue-specific disorders, such as HIV-associated renal, gastrointestinal, endocrine, cardiopulmonary, autoimmune, and other diseases <i>(Objective 3e, P.75)</i>	Investigate the etiologic and pathogenic mechanisms of HIV-associated enteropathy, including the role of HIV, opportunistic infections, tumors, and other factors; Identify host, viral, environmental, and other factors responsible for the pathogenesis and progression of HIV-associated nephropathy; Elucidate the etiology and pathogenesis of endocrine dysfunction and the role of alteration in the endocrine/immune axis in progression of HIV disease; and Elucidate the etiology and pathogenesis of HIV-related cardiopulmonary disease and other organ/tissue-specific manifestations, including autoimmune disease.	13,802	15,089 ^{PB} 19,571 <i>Expon</i>	All populations		

▶ Objective 3a-e compressed ~
 FY 95 PB Bypass
 102,681 108,077 119,571
 ▶ Compress 1-3e
 FY 95 PB Bypass
 345,663 374,767 420,983

Area Research

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

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics <i>Identify & develop novel anti-HIV therapies.</i>	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry <i>(Objective 3.1, p. 83)</i>	Identify promising targets for anti-HIV therapy and extend knowledge of their mechanisms of action, develop assays for identifying drugs active against those targets, and develop new compounds active at those targets, with an emphasis placed on identifying agents active at novel targets other than reverse transcriptase inhibitors; Complete preclinical development, in cooperation with industry when appropriate, of promising new compounds and combinations of compounds and novel natural products, including assessment of efficacy, toxicity, teratogenicity, and fertility in animal models;	154,833	162,200 ^{FB} <i>134,980 Bypass</i>	All populations		

Therapeutics
~~*TOTAL*~~

<i>FY95</i> ~~<i>Approp.</i>~~	<i>FY96</i> ~~<i>Res. Bud.</i>~~	<i>Bypass</i>	<i>Δ</i>
473,262	495,839	545,405	49,566

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry (continued)	Continue and accelerate screening of large numbers of natural and synthesized compounds for anti-HIV activity in the AIDS Drug Screen, with a particular emphasis on the detection of agents that act at unique steps of the HIV life cycle, on an understanding of the molecular basis of bioavailability and pharmacokinetics, and on ability to follow up on lead compounds for the development of analogues; develop and screen combinatorial libraries; emphasize central nervous system penetration; develop formulations that would be suitable for infants and children; ~~Emphasize basic and applied research to advance cross-NIH development of gene therapy; support development of preclinical laboratories to advance gene therapies;~~ Determine the high-resolution molecular structures for several of the HIV proteins and apply these structures to the rational design of drugs as part of the targeted drug development program; determine generalizable and effective approaches for the use of macromolecular structure in designing drugs to combat HIV infection and AIDS; make resolved structures available in publicly accessible data bases;					

} Coord. E
Energy ?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Improve screening, discovery, and preclinical development of therapeutic agents that demonstrate activity against retroviruses, fostering activity by and in collaboration with industry (continued)	Increase understanding of the mechanisms and limitations of drug resistance; study the effect of various agents on HIV replication and viral variation; evaluate early markers of resistance; evaluate the activity of anti-HIV drugs in various cell types (including macrophages) and in various stages of the cell cycle; and Develop new compounds capable of inhibiting the sexual transmission of HIV, such as topical microbicides (which may inhibit HIV and STDs associated with enhanced HIV transmission), HIV-specific viricides, and systemic agents.					
Therapeutics <i>Evaluate new AR therapies.</i>	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies <i>(Objective #2, p. 85.</i>	Support and improve clinical trials of potential therapeutic agents and combinations of agents in studies to determine pharmacokinetics and bioavailability and evaluate anti-HIV combinations that are non-cross-resistant, synergistic, and toxicity-sparing and that may delay development of drug-resistant HIV strains; enhance collaboration between and within ICDs to facilitate opportunities for clinical trials; Increase the understanding of the pathogenesis of HIV disease based on the evaluation of antiretroviral agents in clinical trials;	145,105	151,627 <i>PB</i> <i>Bypass</i> 216,181	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies (continued)	Implement the development and evaluation of virologic, immunologic, and clinical markers to assess drug activity and determine the prognostic value of these markers in response to therapeutic interventions; Support research and development of clinical trials <u>methodology and study design</u> so that appropriate pathways are taken rapidly to evaluate the activity, clinical efficacy, and the ultimate acceptability of new agents and approaches that translate into clinical use; Improve the utilization of GCRCs for the conduct of single and multi-institutional clinical trials; Establish and expand appropriate career training programs for laboratory investigators, clinical investigators, and translational scientists; Develop and validate quality-of-life parameters included in patient assessments of clinical trials;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Perform clinical trials of agents active against HIV based on an understanding of pathogenesis with emphasis on improved design and methodologies, and integrate clinical trials with ongoing natural history studies (continued)	Support research on the effectiveness of pharmacologic (including compliance with therapies and STD prevention) and non-pharmacologic (including psychosocial) interventions (including nutritional factors and adherence improvement);					
		Investigate possible interactions between therapies for HIV-related disease and other substances that HIV-infected individuals might use, such as drug abuse treatment medications, oral contraceptives or other prescription drugs, nonprescription drugs, alternative or complementary therapies, or drugs of abuse;					
		Coordinate studies to encourage co-enrollment of patients on all trials where appropriate (co-enrollment would not only allow for better utilization of limited resources but also enable assessment of concomitant medications and their interactions, improving the efficiency of the primary study);					
		Develop a coordinated plan to evaluate long-term therapeutic strategies, e.g., develop plans for long-term followup, enroll patients in sequential randomized trials once they have reached an end point in their initial trial; and					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		Evaluate new and existing compounds capable of inhibiting the sexual transmission of HIV, such as topical microbicides and HIV-specific viricides; nested studies to evaluate the infectivity of body fluids, such as semen and cervical secretions in trials of antiretroviral therapies.					
Therapeutics <i>Evaluate immune-restorative therapies</i>	Extend our understanding of immunopathogenesis through the development and testing of strategies that enhance and/or restore the deficient immune systems of HIV-infected individuals <i>Objective #3, P.89</i>	Evaluate therapeutic approaches that test specific hypotheses of HIV immunopathogenesis; Develop and validate new methods to evaluate immune function in the context of clinical trials; Continue and accelerate the testing of cytokines and modulators of cytokines either alone or in combination with antiretroviral agents for the purpose of reconstituting the deficient immune systems of HIV-infected individuals; Develop and evaluate various approaches of active and passive immunotherapy for both HIV infection and its sequelae;	18,619	19,349 <i>PB</i> 21,779 <i>Bpass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Extend our understanding of immunopathogenesis through the development and testing of strategies that enhance and/or restore the deficient immune systems of HIV-infected individuals (continued)	Develop a program of reconstituting the immune systems of HIV-infected individuals ~~by administration of cellular elements in an autologous, syngeneic, or allogeneic fashion, including use of expanded peripheral blood T cells, bone marrow transplantation, thymic transplantation, cord blood, stem cells, and/or xenogeneic transplantation;~~					
		Develop new therapeutic strategies based on gene therapy approaches to protect or potentially reconstitute the immune system;					
		Use structural biologic techniques to determine the structures of various cytokines and cytokine receptors as potential targets for HIV therapies; and					
		Enhance collaboration among ICDs to facilitate the conduct of immune-based therapeutic trials and to enhance pathogenesis-related research in HIV-infected individuals.					

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics <i>Evaluate OI therapies</i>	Target the discovery, development, and evaluation of potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection, including those specific to women, children, and drug users <i>(Objective #4, p. 89)</i>	<i>Using data from basic research</i> Support basic research on OIs in order to increase fundamental knowledge and to identify new therapeutic targets and strategies and understand how pathogens contribute to morbidity, such as ~~wasting syndrome~~ . Determine the high-resolution molecular structures for OI proteins and apply these structures to the rational design of drugs as part of the targeted drug development program and determine generalizable and effective approaches for the use of macromolecular structure in designing drugs to combat OIs associated with AIDS;	107,915	111,887 PB 97,787 Bypass	All populations		
Therapeutics	Target the discovery, development, and evaluation of potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection, including those specific to women, children, and drug users (continued)	~~Support discovery and preclinical programs to develop therapies especially targeting cryptosporidia, microsporidia, JC virus, CMV, HPV, and azole-resistant fungal organisms, with emphasis on bioavailable agents with favorable pharmacokinetics. Develop in vitro culture systems for OIs such as <i>Pneumocystis carinii</i>;~~					

> already in basic section.

already in basic section.

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		Further conduct clinical trials for the prophylaxis and treatment of HIV-associated OIs in HIV-infected individuals, including pregnant women and children and drug users. ~~Important OIs include <i>Mycobacterium tuberculosis</i> infection (TB), <i>Mycobacterium avium</i> complex, cytomegalovirus infection, cryptosporidiosis, microsporidiosis, cryptococcal disease, azole-resistant fungal infection, toxoplasmosis, PCP, acyclovir-resistant herpes infections, progressive multifocal leukoencephalopathy (PML), bacterial infections, and other infections whose course is affected by HIV.~~ Evaluate immune-based therapies as adjuncts for treating OIs;					
Therapeutics	Target the discovery, development, and evaluation of potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection, including those specific to women, children, and drug users (continued)	Determine the optimal strategies and combinations of agents to prevent and treat multiple OIs ~~(i.e., multiple opportunistic pathogen prophylaxis studies (MORPSI), and their effects in combination with antiretroviral agents. Strategies need to focus on time of initiation, compliance, pharmacologic interactions, toxicities and adverse reactions (e.g., trimethoprim sulfamethoxazole reactions), and minimizing development of resistance; studies should include quality of life assessments and cost benefit analyses;~~					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Target the discovery, development, and evaluation of potential agents for prevention and treatment of HIV-associated OIs and other infections modified by HIV infection, including those specific to women, children, and drug users (continued)	Develop and utilize animal models for preclinical efficacy and safety testing of potential agents for OIs, including mutagenicity and teratogenicity; Develop clinically useful assays for the rapid diagnosis, treatment response, and sensitivity testing of OIs, especially TB, MAI, enterics, CMV, HSV, fungi, toxoplasma, and JC virus; Support training of basic investigators, clinical investigators, and translational investigators for OI research; and Determine the role and capability of preexisting immunity (both induced and natural) to control OI infections and the ability of HIV-infected individuals to respond to vaccination throughout the course of infection and disease.					
Therapeutics <i>Enhance understanding</i> <i>Develop interventions for vertical transmission.</i>	Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child <i>(Objective #5, P. 91)</i>	Support the rapid translation of basic research observations to strategies for the interruption of vertical transmission; apply the results of clinical trials to the investigation of pathogenesis and to clinical practice;	5,690	6,138 <i>PB</i> 29,474 <i>Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child (continued)	Develop strategies and agents to interrupt the vertical transmission of HIV from pregnant women to their offspring, including ~~antiviral agents, anti-HIV immunoglobulin, and monoclonal antibodies, HIV vaccines, adjuvants, virucides, and other intrapartum interventions;~~ explore the potential of combined strategies; evaluate the safety, toxicity, pharmacokinetics, and antiretroviral activity of anti-HIV agents in pregnant women and newborns;					
		Expand the obstetrical and pediatric infrastructure for the conduct of perinatal trials through collaborative efforts, both national and international;					
		Support the long-term followup of all women and children who participate in perinatal trials to evaluate potential distant effects of antiretroviral agents and/or biologicals;					
		Investigate the role of the placenta in transmission of anti-HIV drugs from mother to fetus;					
		Develop and improve sensitive and specific diagnostic parameters that are cost-effective to permit early differentiation of HIV-infection status in children born to HIV-infected mothers;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
		Assess the potential efficacy and feasibility of obstetric interventions to prevent vertical transmissions, such as cesarean deliveries and other aspects of intrapartum care; Evaluate the risk of vertical transmission of drug-resistant virus; and Evaluate factors that contribute to or protect against vertical transmission; develop effective strategies that could more easily be afforded globally to help reduce vertical transmission and ~~perhaps~~ decrease transmission via breast milk.					
Therapeutics <i>Develop treatments for HIV-associated malignancies,</i>	Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis <i>(Objective, #6, P.93)</i>	<u>Support basic research on HIV-associated malignancies to increase fundamental knowledge of the etiology, pathogenesis, and biology of these neoplasms; develop preclinical models for testing potential therapeutic strategies;</u> Identify novel mechanisms and targets (e.g., cytokines, angiogenesis, viral or hormonal cofactors) for treatment and prevention of HIV-associated tumors, including Kaposi's sarcoma, non-Hodgkin's lymphoma, HPV-associated malignancies, and others, and develop new therapeutic strategies on the basis of these findings;	16,642	16,939 PB	All populations		
				17,430 Bypass			
				<i>Indicated in basic section.</i>			

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis (continued)	Use structural biologic and biochemical information to rationally design drugs to inhibit specific pathogenic factors of HIV-associated malignancies ~~(e.g., oncoprotein of HPV);~~					
		Encourage the development and coordinate the conduct of clinical trials that concurrently evaluate therapeutic strategies directed against the malignancy with anti-retroviral and anti-OI strategies in order to assess the effects of such treatment on the malignancy as well as on the underlying HIV infection, immune function, and clinical course;					
		Continue and expand screening, discovery, and development of novel therapeutic agents with activity against HIV-associated malignancies ~~(e.g., agents with better CNS penetration, agents with better safety profiles);~~					
		Develop trials to optimize existing therapies for malignancies in HIV-infected patients, ~~including therapeutic adjuncts such as hematopoietic colony-stimulating factors and supportive care; develop and validate quality-of-life assessments;~~					

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Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Therapeutics	Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis (continued)	Encourage collaborative studies to develop mechanisms for early identification of patients at high risk for malignancy and to develop and assess interventional strategies to reduce or prevent the development of malignancies;					
		Support training of <u>basic investigators</u> , <u>clinical investigators</u> , and <u>translational scientists</u> for research of malignancies in HIV-infected patients;					
		Improve diagnostic methods for early diagnosis of malignancies and for early detection of recurrent cancer;					
Therapeutics	Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis (continued)	Coordinate referral of patients with malignancy end points on other studies to malignancy trials; and					
		Improve collaboration between various adult and pediatric cooperative groups conducting clinical trials of HIV-associated malignancies and ICDs and industry to accelerate trials completion and approval of active agents.					
Therapeutics <i>Develop treatments for HIV-related neurologic disease</i>	Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection <i>(Obj. # 1, p. 95)</i>	Develop an improved understanding of the biology and epidemiology of neurologic disease in HIV-infected individuals;	11,614	12,268	All populations		
				11,658	Bypass		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apppr.)	FY 1996 (proposed)			
Therapeutics	Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection (continued)	Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction, ~~e.g., inhibitors of quinolinic acid, excitatory neurotransmitters, gp160/120, and other potential neurotoxins;~~					
		Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop strategies directed at the prevention and treatment of this complication of HIV infection;					
		Implement clinical trials addressing nervous system complications of HIV infection and incorporate neurologic assessments into other HIV-related clinical trials;					
		Develop therapeutic agents that are capable of crossing the blood-brain barrier and are active against HIV infection in relevant cells in the CNS; develop an understanding of mechanisms involved in penetration of the blood-brain barrier;					
		Better delineate etiologies of peripheral neuropathy in HIV infection, and develop strategies to prevent and treat this complication;					

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

Area Research

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

Overall Vaccine
 FY95 111,831 PB 118,128 Bypass 154,771

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines Enhance understanding	Increase scientific knowledge about host defense mechanisms and protection against HIV infection and disease Conduct & support research on protective immune responses. (Objective #1, P. 109)	Develop nonhuman primate and other animal models for HIV vaccine evaluation; determine immune responses that affect infection and disease course; focus on chronic infection with attenuated virus versus wild-type virus; determine why disease does not occur or is delayed in some models; Determine the correlates of immune protection against, and immunologically mediated control of, HIV; Study acutely infected individuals, exposed/uninfected humans (and other primates), and rapid/nonprogressors to determine viral and host factors that impact clearance of circulating virus and disease course; ensure that plasma, PBMC, biopsy, autopsy, and other key patient and animal samples, including CNS samples, are accessible to qualified laboratories;	45,735	47,844 PB 57,506 Bypass	All populations		

VACCINES TOTAL

FY95 Approp.	FY96 Res. Bud.	Bypass	
111,831	118,128	154,771	364,730

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Increase scientific knowledge about host defense mechanisms and protection against HIV infection and disease (continued)	Elucidate the three-dimensional structure of viral epitopes and determine the mechanism of escape from antibody-mediated neutralization and recognition by cytotoxic T cells. ~~The identification of epitopes for which escape is not possible should receive more attention;~~					
		Define conserved viral epitopes that are potentially relevant to protective immune responses; devise strategies to enhance their immunogenicity;					
		Determine the molecular nature of HIV genetic and antigenic diversity and incorporate the findings into ongoing vaccine development; focus on characterization of HIV at potential efficacy trial sites;					
		Foster multidisciplinary approaches that bridge basic, animal, and clinical approaches; and					
		Develop quantitative measures of HIV concentration in bodily fluids to determine whether there is a relationship between HIV concentration and transmission.					
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models	~~Develop further multidisciplinary approaches for the design and development of potential vaccine candidates; expand research on mucosal delivery and stimulation of mucosal immune responses (NIAID);~~	24,135	25,465	All populations		
Identify strategies for eliciting protective immune responses	(Objective #2, P.111)			35,473	Bypass		

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Page 3

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models (continued)	Include research on but not limited to: whole-particle designs such as whole-killed HIV and genetically engineered, noninfectious HIV mutants that lack the viral RNA genome or have a defect in a critical protein but contain a full complement of HIV antigenic proteins; live, recombinant viral and bacterial vectors engineered to express one or more HIV proteins; genetically engineered, live-attenuated strains of HIV; synthetic peptide candidates capable of inducing and boosting both cellular and humoral immunity; DNA candidates as HIV vaccines; combination strategies including priming and boosting;					

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

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Apply findings from basic, epidemiologic, and clinical research to the design and evaluation of vaccine strategies in laboratory studies and animal models (continued)	Evaluate strategies to decrease or eliminate HIV from sexual fluids; Characterize and evaluate the potential negative side effects of candidate vaccines, including production of enhancing antibodies and neurotoxicity; and Develop methodologies for comparative <i>in vitro</i> measure of immune function.					
Vaccines <i>Evaluate vaccine efficacy.</i>	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials <i>(Obj. # 3, p. 113)</i>	Prepare for adequate followup of individuals participating in vaccine clinical trials to determine the longevity of immune response, the correlates of immune protection, long-term safety, the impact of participation on risk-taking behavior, and the possible positive or negative effects of vaccine immunization against disease progression and HIV transmission; Utilize infrastructures established for the conduct of AIDS vaccine efficacy trials to implement prevention research activities designed to determine the efficacy of other biomedical or behavioral interventions ~~that could prove of benefit in decreasing the incidence of HIV infection in the population; evaluate promising interventions separately and/or as a component of prophylactic vaccine efficacy trials;~~	19,189	19,912 <i>IB</i> 24,361 <i>Bypass</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	Continue appropriate epidemiologic studies that determine the risk profiles and infection rates of various populations in the United States and internationally in order to identify those groups most likely to be the participants in vaccine trials; Maintain and expand the AIDS Vaccine Clinical Trials Network to include domestic and international sites with access to populations at high risk for acquiring HIV infection and where vaccine or other prevention research activities may be feasible; Maintain the necessary laboratory and epidemiologic research infrastructure at designated sites for conducting domestic and international vaccine efficacy trials; develop optimal assays to distinguish infection from seroconversion to the vaccine; Acquire and analyze HIV isolates from recent seroconverters representative of potential efficacy trial populations so that genetic and antigenic information about virus circulating in the population can be obtained;					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	Conduct behavioral research in populations at high risk for HIV infection, particularly those difficult-to-reach populations that have been historically underrepresented in clinical trials; determine optimal education, risk-reduction intervention, recruitment, adherence, and retention approaches and estimate behavior changes and other factors pertinent to the design and execution of a successful efficacy trial; Establish linkages with communities or community organizations where efficacy trials might be conducted to optimize education, recruitment, and followup activities and to help address community concerns related to AIDS vaccine efficacy trials; Link infrastructure development and vaccine research activities in high-risk populations with other prevention and treatment research activities in these populations, including research on TB and STDs; Conduct research to determine optimal methods of achieving truly informed consent; and					

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify appropriate domestic and international populations and develop infrastructure, including behavioral research and community education and outreach activities, that is necessary for ensuring adequate performance of Phase III efficacy clinical trials (continued)	Conduct research to determine possible adverse social, economic, or legal consequences of participation in clinical trials and develop strategies to mitigate potential harm.					
Vaccines <i>Develop vaccine for newborns and infants.</i>	Identify mechanisms of protective immunity to HIV in newborns and infants and develop a safe and effective immunologic strategy to prevent HIV infection in this population <i>(Objective #4, p.115)</i>	Evaluate genetic and antigenic variation in viruses transmitted from mothers to infants and in maternal isolates that are not transmitted; Accelerate studies of maternal-infant transmission; Develop and maintain domestic and international infrastructure necessary to enroll mothers and infants in prospective long-term followup vaccine trials; Determine the immunogenicity of various vaccines and adjuvants in newborns and infants; Determine which maternal and infant immune responses are associated with nontransmission of HIV; Identify antibody preparations for use as passive or passive/active HIV prevention; Establish criteria for advancement of candidates in Phase I, Phase II, and Phase III clinical trials; and	3,174	3,501 <i>PB</i>	All populations		
				10,386	<i>Bypass.</i>		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Vaccines	Identify mechanisms of protective immunity to HIV in newborns and infants and develop a safe and effective immunologic strategy to prevent HIV infection in this population (continued)	Conduct Phase I, Phase II, and Phase III clinical trials of the most promising candidates that meet established criteria.					
Vaccines <i>Identify suitable candidates for efficacy trials.</i>	Develop criteria for selection of suitable candidate vaccines, support appropriate infrastructure, and conduct Phase I and Phase II trials <i>(Objective #5, P.117)</i>	Utilize vaccine selection committees to carefully evaluate promising candidates; emphasize need for thorough consideration of efficacy in animal models; Conduct Phase I and Phase II clinical trials that will determine safety and delineate comparative immunologic analysis of candidates for preventive vaccines; expand immunologic measurements to include a broad range of cell-mediated and mucosal immune responses; ~~Conduct Phase II trials in high-risk individuals of the most promising preventive vaccine candidates or combinations that proved promising in Phase I trials conducted in low-risk individuals and that have genetic or immunologic relatedness to HIV isolates circulating in the proposed trial population;~~ Support and maintain the AIDS Vaccine Evaluation Groups;	19,398	21,177 <i>FB</i> <i>21,424 B. Phase</i>	All populations		

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (apprpr.)	FY 1996 (proposed)			
Vaccines	Develop criteria for selection of suitable candidate vaccines, support appropriate infrastructure, and conduct Phase I and Phase II trials (continued)	Closely coordinate the evaluation of research findings on prophylactic AIDS vaccines with research on therapeutic AIDS vaccines, e.g., the use of candidate vaccines to ameliorate disease when administration is initiated after establishment of chronic infection; Acquire and analyze HIV isolates from recent seroconverters representative of Phase I and Phase II trial populations so that genetic and antigenic information about viruses circulating in the population can be obtained; and Conduct behavioral research pertinent to preparation for Phase III trials.					
Vaccines <i>Conduct efficacy studies in most appropriate populations.</i>	Establish criteria for selection of suitable vaccine candidates and conduct Phase III clinical trials when established criteria are met <i>(Objective # 6, P. 119)</i>	Establish criteria with concurrence of an advisory group that has the requisite scientific, public health, government, and community expertise; Conduct large-scale efficacy trials of novel preventive vaccine candidates that have proven promising, safe, and immunogenic in Phase II trials and that meet established criteria; Evaluate HIV vaccine candidate efficacy; Evaluate multiple scientific hypotheses; and	200	229 ^{FB} 5,621 <i>Bypass</i>	All populations		

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

Area Research

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

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

Behavioral Research

TOTAL

FY95	FY96	Bypass	
159,720	161,595	205,893	442,98

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

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

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

In Billings

FY94
Actual
214

FY95
Prop.
235

FY96
Prop.
252

In FB

FY94
Actual
1,353

FY95
Approp.
1,364

FY96
PB
1,444

What happened?

Objectives	Action Steps	Descriptions	Programs			
			Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (appropri.)	FY 1996 (proposed)		
Behavioral Research	effective Create and test innovative dissemination strategies. Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications (Obj. #4, p 136)	utilize Develop, ~~and~~ test innovative dissemination strategies for promoting adoption of successful ~~(empirically tested)~~ behavior change interventions by HIV prevention providers; Develop, test, and rapidly disseminate research findings that have immediate implications for the conduct of HIV prevention and education programs conducted in the community; ~~explore novel mechanisms to~~ disseminate behavioral and social science research findings and model approaches to the prevention field (e.g., consensus conferences, interactive computer bulletin boards, media strategies, and mechanisms to reach providers and community-based organizations); Support and strengthen partnerships between community-based organizations and behavioral and social scientists to encourage bidirectional exchange of information and experience to enhance research and prevention efforts; and Utilize new and innovative techniques (e.g., social marketing) to disseminate research to different populations.	1,364 FY95 Est. 235	1,444 352	All populations Bypass	

what happened.

Objectives	Action Steps	Descriptions	Programs				
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Behavioral Research	Strengthen the behavioral and social science infrastructure.	Establish multidisciplinary AIDS research consortia to test novel behavioral approaches, replicate psychosocial and behavioral studies, and promote their use in appropriate populations; collaborate with other agencies of the PHS and outside organizations to maximize research resources;	394	436	All populations		
	Develop multidisciplinary and interagency collaborative efforts to enhance the AIDS behavioral research effort; enhance the behavioral aspect of research into therapeutics, natural history and epidemiology, and vaccines. Train researchers to conduct basic and applied social science research related to HIV. Provide the state-of-the-art physical facilities and equipment that are necessary to conduct HIV-related behavioral and social science research within relevant settings	Promote HIV-related research in predoctoral and postdoctoral programs; ~~facilitate the~~ development of <i>practical</i> and field placements in HIV treatment, prevention, and research settings; provide research career awards; actively recruit ethnic minorities, women, and those dedicated to community-based programs; expand behavioral and social training and research efforts aimed at limiting infections such as TB and malignancies related to HIV infection.	95 Est. 240	396 Bypass			
		Ensure adequate representation of social and behavioral scientists on IRGs, OAR Advisory Committees, and OAR staff;					
		Support and expand computer networking among behavioral and social science researchers; provide additional laboratory and research facilities for human and animal research for behavioral studies; and					

95 Est.
240

396 Bypass

what happened.

Behavioral Overall.

95 Approp.

159,720

FY 96

161,595

Bypass

205,893

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

Area Research

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

Objectives	Action Steps	Descriptions	Programs																
			Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs												
			FY 1995 (appropri.)	FY 1996 (proposed)															
Training and Infrastructure Meet the ~~resource~~ ~~training~~ needs of HIV/AIDS researchers,	Provide both domestic and international training in biomedical and behavioral research on HIV	Increase predoctoral and postdoctoral training, as well as advanced research training, in a range of AIDS-related disciplines to a level comparable ~~(about 3 percent of the budget)~~ to that of other training programs within the NIH; Sponsor an annual AIDS Fellows Meeting to promote collaboration and information dissemination; Increase training of scientists and clinical investigators in basic AIDS research to better link basic and clinical pathogenesis research; ~~Stimulate predoctoral and postdoctoral training in prevention, behavior change, and adherence and compliance to treatment;~~ <i>addressed in behavioral part.</i> Promote training of biomedical and behavioral scientists in the use of high-performance computing systems for HIV-related research; Expand training and research capacity to deal with the epidemic of tuberculosis (TB), including multiple drug resistance associated with HIV infection;	33,978	35,486	All populations														
41,575 Bypass Training & Infrastructure TOTAL <table><tr><td>FY95</td><td>FY96</td><td>Bypass</td><td>Δ</td></tr><tr><td>Approp.</td><td>Res. Bud.</td><td></td><td></td></tr><tr><td>40,836</td><td>42,558</td><td>58,703</td><td>16,145</td></tr></table>								FY95	FY96	Bypass	Δ	Approp.	Res. Bud.			40,836	42,558	58,703	16,145
FY95	FY96	Bypass	Δ																
Approp.	Res. Bud.																		
40,836	42,558	58,703	16,145																

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Training and Infrastructure	Provide both domestic and international training in biomedical and behavioral research on HIV (continued)	Increase participation in the Fogarty International Center (FIC)-sponsored international training and research programs and expand these programs by recruiting trainees from additional countries in Asia and Latin America, with the long-term goal of providing AIDS-related training for leading health scientists from all developing countries; Develop new grant mechanisms to link leading U.S. AIDS research scientists and institutions with leading AIDS research scientists and institutions in foreign countries; Expand both predoctoral and postdoctoral training in structural biology; and Expand the NIH AIDS Loan Repayment Program to bring scientists and physicians to the NIH to expand the cadre of trained intramural researchers.					
Training and Infrastructure <i>Meet the resource needs of HIV/AIDS researchers.</i>	Establish appropriate infrastructure for the conduct of HIV research domestically and internationally <i>(obj. #2, p 151)</i>	Provide additional facilities to study animal models of pediatric AIDS; Foster animal models to study HIV-related malignancies; Continue the Research Facilities Infrastructure Program (RFIP) and General Clinical Research Centers (GCRC) Program;	6,858	7,072	All populations		
				17,128	Bypass		

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

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Training and Infrastructure	Establish appropriate infrastructure for the conduct of HIV research domestically and internationally (continued)	Establish and support repositories of samples obtained from individuals with HIV infection for current and future studies; Increase support for screening for the development of HIV macaque monkey models; Develop and support Regional Primate Research Center (RPRC) expertise in molecular immunology, peptide biochemistry, and pharmacology; Provide for the establishment of specific pathogen-free (SPF) non-human primate programs at all the RPRCs; and Provide further support for the development of SPF macaque colonies.					

Area - Research

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

Objectives	Action Steps	Programs				
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement
			FY 1995 (apppr.)	FY 1996 (proposed)		
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate	Develop and rapidly disseminate important research findings that have immediate impact on prevention, health care, and treatment of HIV-infected individuals, utilizing all NIH, PHS, and public media communications modes;	15,400	16,115	All populations	
		Provide up-to-date information on eligibility criteria for entry into clinical trials, results of trials, and relevant research findings through the AIDSTRIALS and AIDSDRUGS databases as well as the AIDS Clinical Trials Information Service;				
		Maintain an interface with the Cancer Information System and PDQ to provide information on clinical trials for AIDS-related malignancies;				
		Collaborate with other agencies of the PHS and outside organizations to determine the information needs in the biomedical and behavioral research community and identify appropriate mechanisms for dissemination;				
		Provide online access to the full-text guidelines for state-of-the-art care;				

18,527 Bypass

What has the information dissemination done?
Subcommittee of the FHS

Information Dissemination			
TOTAL			
FY95 Appr.	FY96 Pres. Bnd	Bypass	△
15,400	16,115	18,527	2,412

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate (continued)	Continue support of community, regional, national, and international conferences and workshops to facilitate the exchange of scientific information;					
		Provide support for NIH-sponsored annual meetings on pathogenesis, vaccines, and drug development;					
		Collaborate with public and health sciences libraries to facilitate access to needed information by community groups;					
		Disseminate results of behavioral research studies to collaborating centers and service providers for use in planning, designing, and implementing preventive intervention strategies;					
		Continue support for and development of the International Network for AIDS Research and Training;					
		Explore collaborations with the World Health Organization (WHO), the Pan American Health Organization (PAHO), and international AIDS agencies to obtain and disseminate information about international clinical trials;					

why behavioral pulled out?

info. dissem.?

Objectives	Action Steps	Programs					
		Descriptions	Resources in Thousands		Populations Served	Constituency Involvement	Unmet Needs
			FY 1995 (appropri.)	FY 1996 (proposed)			
Information Dissemination	Expedite the dissemination of the latest information on clinical trials, state-of-the-art therapies, health care, and prevention techniques to domestic as well as international audiences as appropriate (continued)	Develop and improve user-friendly information systems and services in HIV/AIDS and provide training for them; Provide the full text of abstracts from meetings, where available, online before scientific meetings; Collaborate with the WHO, the PAHO, and the ~~Global Programme on AIDS~~ UNAIDS to develop the Global HIV/AIDS Network, a computerized AIDS information system; and Working with community groups, develop educational materials to foster the dissemination of information about research and the clinical trials process to primary care providers, community-based HIV/AIDS service organizations, and persons with HIV/AIDS.					