

FOIA MARKER

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PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state

and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: 141,076,000

FY 96: 140,917,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

Develop methodologies to measure community mobilization or

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

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$45,970,000

FY 96: \$46,869,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What are the baseline figures for the targets listed below?

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of state and local educational agencies to

develop and implement effective HIV education within CSHEPs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets? How will they be measured?

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

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

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

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

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

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

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

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

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

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

Expand the community's capacity to plan, implement, and evaluate

culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

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

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets?

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

Interview persons newly diagnosed with HIV infection to identify

missed opportunities for earlier diagnosis and CD4+ testing;

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

At the CP level these figures are listed as one pot of money -- please clarify.

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state

and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: 141,076,000

FY 96: 140,917,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

Develop methodologies to measure community mobilization or

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

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$45,970,000

FY 96: \$46,869,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What are the baseline figures for the targets listed below?

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of state and local educational agencies to

develop and implement effective HIV education within CSHEPs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets? How will they be measured?

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

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

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

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

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

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

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

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

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

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

Expand the community's capacity to plan, implement, and evaluate

culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

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

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets?

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

Interview persons newly diagnosed with HIV infection to identify

missed opportunities for earlier diagnosis and CD4+ testing;

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

At the CP level these figures are listed as one pot of money -- please clarify.

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state

and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: 141,076,000

FY 96: 140,917,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

Develop methodologies to measure community mobilization or

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

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$45,970,000

FY 96: \$46,869,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What are the baseline figures for the targets listed below?

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of state and local educational agencies to

develop and implement effective HIV education within CSHEPs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets? How will they be measured?

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

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

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

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

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

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

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

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

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

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

Expand the community's capacity to plan, implement, and evaluate

culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

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

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets?

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

Interview persons newly diagnosed with HIV infection to identify

missed opportunities for earlier diagnosis and CD4+ testing;

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

At the CP level these figures are listed as one pot of money -- please clarify.

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

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

Characterize persons co-infected with TB and HIV;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Descriptions: Many of the activities in the above-cited action steps are carried out through cooperative agreements with state

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

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

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

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

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

Promote HIV prevention as a relevant issue in business settings.

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

Market the comprehensive workplace HIV/AIDS program to business.

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

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

Develop methodologies to measure community mobilization or

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

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

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

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

Develop community coalitions for HIV prevention;

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$45,970,000

FY 96: \$46,869,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What are the baseline figures for the targets listed below?

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

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

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

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

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

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

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

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

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

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

Enhance the capacity of state and local educational agencies to

develop and implement effective HIV education within CSHEPs;

Enhance the capacity of colleges and universities to provide HIV education for students and staff, preferably as part of an institution-wide health promotion program;

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: \$48,215,000

FY 96: \$48,162,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets? How will they be measured?

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

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

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

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

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

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

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

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

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

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

Expand the community's capacity to plan, implement, and evaluate

culturally competent and linguistically specific HIV prevention guidelines and programs tailored to the needs of specific populations;

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

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

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

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

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

FY 95: \$185,666,000

FY 96: \$209,764,000

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

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

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

PREVENTION

Agency: The Centers for Disease Control and Prevention

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

Objectives:

What is the baseline for the below-listed targets?

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

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

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

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

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

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

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

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

Develop alternative methods to provide HIV counseling and testing services;

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

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

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

Interview persons newly diagnosed with HIV infection to identify

missed opportunities for earlier diagnosis and CD4+ testing;

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

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

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

FY 95: \$169,035,000

FY 96: \$179,006,000

At the CP level these figures are listed as one pot of money -- please clarify.

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

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

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

and local health departments. In addition, specialized projects and studies also serve to focus attention on these activities, these include: Evaluation of HIV Infection Reporting Systems Project, Recent HIV Infection Projects, Surveillance to Evaluate Prevention Projects, Adult Spectrum of Disease Project, the TB Project, Mode of Transmission Validation Project, the Medical Examiner Study, and the Enhancement of AIDS Surveillance Efficiency Project.

FY 95: 141,076,000

FY 96: 140,917,000

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

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

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

RESEARCH

Agency: National Institutes of Health

Goal: Enhance understanding of the etiology and pathogenesis of HIV infection.

Objective 1: Support research to further understanding of HIV immunopathogenesis.

Action Steps: Delineate the cellular and molecular mechanisms associated with viral immunopathogenesis.

Descriptions: Delineate the direct and indirect mechanisms underlying HIV-induced depletion and dysfunction of target cells/tissues;

Define the virologic (load and phenotype), immunologic (specific and nonspecific), genetic, and environmental factors that contribute to disease progression and nonprogression;

Delineate the molecular mechanisms by which virus-derived factors regulate HIV replication and pathogenesis, with special emphasis on the use of primary virus isolates and cells;

Delineate the role of immune activation and host factors, including cytokines, in HIV replication and pathogenesis;

Delineate the role of lymphoid organs, including mucosal-associated lymphoid tissue, in HIV pathogenesis;

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

Delineate the role of lymphoid and hematopoietic precursor cells and their microenvironment in immune impairment;

Develop new assay systems for effective measurement of changes in viral load and host immune function that are predictive of disease progression;

Delineate the range of cell types infected by HIV *in vivo* and their potential role as viral reservoirs; and

Establish and expand collaborative programs to facilitate sharing of key patient samples, animal model resources, and laboratory reagents.

Objective 2: Support research to enhance understanding of HIV-related immune dysfunction.

Action Steps: Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression.

Descriptions: Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection;

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

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

Determine the effects of viral genotype and load on transmission of cell-free and cell-associated virus;

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

Determine the mechanisms of vertical HIV transmission; and

Elucidate unique aspects of HIV transmission and disease progression in underresearched populations.

Objective 3: Support research to enhance understanding of HIV-related malignancies.

Action Steps: Elucidate the etiologic factors and cofactors in the pathogenesis of HIV-related malignancies.

Descriptions: Elucidate the role of HIV infection, immune dysfunction, and interactions with potential cofactors in the development of HIV-associated malignancies;

Identify the characteristics of the host that predispose to development of malignant disease, including genetic, hormonal, growth factor, cytokine, and immunologic characteristics; and

Identify the molecular correlates of HIV-associated malignancies, including but not limited to oncogenes, tumor suppressor genes, tumor promoters and carcinogens, and viral and microbial genes and proteins.

Objective 4: Support research to enhance understanding of HIV-related neuropathogenesis.

Action Steps: Elucidate the pathogenic mechanisms involved

in HIV-associated neurological diseases.

Descriptions: Investigate the contributions of viral infection and virally induced indirect factors (in neuronal and non-neuronal cells) to nervous system impairment;

Delineate how HIV enters and persists in the nervous system and causes functional impairment;

Investigate both biological and environmental factors that may affect nervous system function in the context of HIV disease;

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

Delineate the role of OIs and drug treatment in neurologic complications of AIDS, including peripheral neuropathies, hearing and visual loss, and behavioral changes;

Assess neural tissue and organs as virus reservoirs in HIV disease and as sources of specifically neurovirulent/neuroinvasive viral strains; and

Develop neuroimaging tools for correlative structural-functional studies of progressive HIV-associated neurological disorders.

Objective 5: Support research to enhance understanding of HIV-related opportunistic infections.

Action Steps: Elucidate the pathogenesis of HIV-related opportunistic infections.

Descriptions: Investigate the mechanisms of immune function that mediate protection against the OIs;

Develop *in vitro* techniques and animal models, where needed, to propagate the opportunistic micro-organisms and conduct studies designed to provide details of the basic biology and pathogenic mechanisms of these micro-organisms;

Identify and elucidate the genetic and environmental risk factors associated with susceptibility, development, and progression of opportunistic infections;

Develop and validate diagnostic assays for the reliable and rapid identification of HIV-associated opportunistic infections;

Study the effects of OIs on immune dysfunction; and

Elucidate immunologic markers that are correlative with

disease progression for HIV-associated OIs and develop assays to accurately monitor these markers as a function of therapy.

Objective 6: Support research to enhance understanding of HIV-related wasting syndrome.

Action Steps: Elucidate the etiology and pathophysiology of HIV-related wasting, failure to thrive, and growth retardation.

Descriptions: Define alterations in body composition, nutritional status, metabolic patterns, energy balance, and growth and development associated with HIV infection; and

Elucidate the pathogenesis of HIV-associated wasting and impaired growth and development, including the roles of cytokines, malabsorption, anorexia, opportunistic infections, HIV, and other factors.

Objective 7: Support research to enhance understanding of HIV-related organ and tissue disorders.

Action Steps: Elucidate the etiology and pathogenesis of HIV-related organ/tissue-specific disorders, such as HIV-associated renal, gastrointestinal, endocrine, cardiopulmonary, autoimmune, and other diseases

Descriptions: Investigate the etiologic and pathogenic mechanisms of HIV-associated enteropathy, including the role of HIV, opportunistic infections, tumors, and other factors;

Identify host, viral, environmental, and other factors responsible for the pathogenesis and progression of HIV-associated nephropathy;

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

Elucidate the etiology and pathogenesis of HIV-related cardiopulmonary disease and other organ/tissue-specific manifestations, including autoimmune disease.

FY 95: 345,663,000

FY 96: 374,767,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$46,216 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Enhance understanding of the etiology and pathogenesis of HIV infection.

Objective 1: Support research to further understanding of HIV immunopathogenesis.

Action Steps: Delineate the cellular and molecular mechanisms associated with viral immunopathogenesis.

Descriptions: Delineate the direct and indirect mechanisms underlying HIV-induced depletion and dysfunction of target cells/tissues;

Define the virologic (load and phenotype), immunologic (specific and nonspecific), genetic, and environmental factors that contribute to disease progression and nonprogression;

Delineate the molecular mechanisms by which virus-derived factors regulate HIV replication and pathogenesis, with special emphasis on the use of primary virus isolates and cells;

Delineate the role of immune activation and host factors, including cytokines, in HIV replication and pathogenesis;

Delineate the role of lymphoid organs, including mucosal-associated lymphoid tissue, in HIV pathogenesis;

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

Delineate the role of lymphoid and hematopoietic precursor cells and their microenvironment in immune impairment;

Develop new assay systems for effective measurement of changes in viral load and host immune function that are predictive of disease progression;

Delineate the range of cell types infected by HIV *in vivo* and their potential role as viral reservoirs; and

Establish and expand collaborative programs to facilitate sharing of key patient samples, animal model resources, and laboratory reagents.

Objective 2: Support research to enhance understanding of HIV-related immune dysfunction.

Action Steps: Delineate the molecular and cellular mechanisms of transmission and establishment of infection and their impact on disease progression.

Descriptions: Define the cellular and immune mechanisms that inhibit/enhance the early events in establishing HIV infection;

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

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

Determine the effects of viral genotype and load on transmission of cell-free and cell-associated virus;

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

Determine the mechanisms of vertical HIV transmission; and

Elucidate unique aspects of HIV transmission and disease progression in underresearched populations.

Objective 3: Support research to enhance understanding of HIV-related malignancies.

Action Steps: Elucidate the etiologic factors and cofactors in the pathogenesis of HIV-related malignancies.

Descriptions: Elucidate the role of HIV infection, immune dysfunction, and interactions with potential cofactors in the development of HIV-associated malignancies;

Identify the characteristics of the host that predispose to development of malignant disease, including genetic, hormonal, growth factor, cytokine, and immunologic characteristics; and

Identify the molecular correlates of HIV-associated malignancies, including but not limited to oncogenes, tumor suppressor genes, tumor promoters and carcinogens, and viral and microbial genes and proteins.

Objective 4: Support research to enhance understanding of HIV-related neuropathogenesis.

Action Steps: Elucidate the pathogenic mechanisms involved

in HIV-associated neurological diseases.

Descriptions: Investigate the contributions of viral infection and virally induced indirect factors (in neuronal and non-neuronal cells) to nervous system impairment;

Delineate how HIV enters and persists in the nervous system and causes functional impairment;

Investigate both biological and environmental factors that may affect nervous system function in the context of HIV disease;

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

Delineate the role of OIs and drug treatment in neurologic complications of AIDS, including peripheral neuropathies, hearing and visual loss, and behavioral changes;

Assess neural tissue and organs as virus reservoirs in HIV disease and as sources of specifically neurovirulent/neuroinvasive viral strains; and

Develop neuroimaging tools for correlative structural-functional studies of progressive HIV-associated neurological disorders.

Objective 5: Support research to enhance understanding of HIV-related opportunistic infections.

Action Steps: Elucidate the pathogenesis of HIV-related opportunistic infections.

Descriptions: Investigate the mechanisms of immune function that mediate protection against the OIs;

Develop *in vitro* techniques and animal models, where needed, to propagate the opportunistic micro-organisms and conduct studies designed to provide details of the basic biology and pathogenic mechanisms of these micro-organisms;

Identify and elucidate the genetic and environmental risk factors associated with susceptibility, development, and progression of opportunistic infections;

Develop and validate diagnostic assays for the reliable and rapid identification of HIV-associated opportunistic infections;

Study the effects of OIs on immune dysfunction; and

Elucidate immunologic markers that are correlative with

disease progression for HIV-associated OIs and develop assays to accurately monitor these markers as a function of therapy.

Objective 6: Support research to enhance understanding of HIV-related wasting syndrome.

Action Steps: Elucidate the etiology and pathophysiology of HIV-related wasting, failure to thrive, and growth retardation.

Descriptions: Define alterations in body composition, nutritional status, metabolic patterns, energy balance, and growth and development associated with HIV infection; and

Elucidate the pathogenesis of HIV-associated wasting and impaired growth and development, including the roles of cytokines, malabsorption, anorexia, opportunistic infections, HIV, and other factors.

Objective 7: Support research to enhance understanding of HIV-related organ and tissue disorders.

Action Steps: Elucidate the etiology and pathogenesis of HIV-related organ/tissue-specific disorders, such as HIV-associated renal, gastrointestinal, endocrine, cardiopulmonary, autoimmune, and other diseases

Descriptions: Investigate the etiologic and pathogenic mechanisms of HIV-associated enteropathy, including the role of HIV, opportunistic infections, tumors, and other factors;

Identify host, viral, environmental, and other factors responsible for the pathogenesis and progression of HIV-associated nephropathy;

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

Elucidate the etiology and pathogenesis of HIV-related cardiopulmonary disease and other organ/tissue-specific manifestations, including autoimmune disease.

FY 95: 345,663,000

FY 96: 374,767,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$46,216 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

Expand both predoctoral and postdoctoral training in structural biology; and

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

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

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

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

Foster animal models to study HIV-related malignancies;

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

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

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

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

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

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

Provide additional laboratory and biocontainment facilities for primate research;

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

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

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

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

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

Provide further support for the development of SPF macaque

colonies.

FY 95: 40,836,000

FY 96: 42,558,000

Populations Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

Expand both predoctoral and postdoctoral training in structural biology; and

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

Foster animal models to study HIV-related malignancies;

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

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

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

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

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

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

Provide additional laboratory and biocontainment facilities for primate research;

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

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

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

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

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

Provide further support for the development of SPF macaque

colonies.

FY 95: 40,836,000

FY 96: 42,558,000

Populations Served: All populations

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

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

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: 15,400,000

FY 96: 16,115,000

Populations Served: All populations

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

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

TRANSLATION OF SCIENCE INTO PRACTICE

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FY 95: 15,400,000

FY 96: 16,115,000

Populations Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

Action Steps: Support research on protective immune responses.

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

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

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

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

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

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

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

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

Objective 2: Identify strategies for eliciting protective immune responses.

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

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

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

Evaluate vaccine strategies in AIDS animal models;

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

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

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

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

Objective 3: Evaluate efficacy of vaccine candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Accelerate studies of maternal-infant transmission;

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

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

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

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

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

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

Objective 5: Identify promising vaccine candidates for efficacy trials.

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

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

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

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

Support and maintain the AIDS Vaccine Evaluation Groups;

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

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

Conduct behavioral research pertinent to preparation for Phase III trials.

Objective 6: Conduct vaccine efficacy studies.

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

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

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

Evaluate HIV vaccine candidate efficacy;

Evaluate multiple scientific hypotheses; and

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

FY 95: \$111,831,000

FY 96: \$118,128,000

Pops. Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

Action Steps: Support research on protective immune responses.

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

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

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

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

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

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

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

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

Objective 2: Identify strategies for eliciting protective immune responses.

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

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

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

Evaluate vaccine strategies in AIDS animal models;

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

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

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

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

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

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

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

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

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

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

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

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

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

Accelerate studies of maternal-infant transmission;

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

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

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

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

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

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

Objective 5: Identify promising vaccine candidates for efficacy trials.

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

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

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

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

Support and maintain the AIDS Vaccine Evaluation Groups;

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

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

Conduct behavioral research pertinent to preparation for Phase III trials.

Objective 6: Conduct vaccine efficacy studies.

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

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

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

Evaluate HIV vaccine candidate efficacy;

Evaluate multiple scientific hypotheses; and

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

FY 95: \$111,831,000

FY 96: \$118,128,000

Pops. Served: All populations

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

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

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

Objective 2: Develop and evaluate anti-retroviral therapies.

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

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

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

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

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

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

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

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

therapies, or drugs of abuse;

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

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

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

Objective 3: Develop and evaluate immune-restoring therapies.

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

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

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

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

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

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

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

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

Enhance collaboration among ICDs to facilitate the conduct

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

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

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

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

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

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

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

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

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

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

Objective 5: Develop and evaluate therapies interventions to block perinatal transmission.

Action Steps: Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child.

Descriptions: Support the rapid translation of basic

research observations to strategies for the interruption of vertical transmission; apply the results of clinical trials to the investigation of pathogenesis and to clinical practice;

Develop strategies and agents to interrupt the vertical transmission of HIV from pregnant women to their offspring; explore the potential of combined strategies; evaluate the safety, toxicity, pharmacokinetics, and antiretroviral activity of anti-HIV agents in pregnant women and newborns;

Expand the obstetrical and pediatric infrastructure for the conduct of perinatal trials through collaborative efforts, both national and international;

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

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

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

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

Evaluate the risk of vertical transmission of drug-resistant virus; and

Evaluate factors that contribute to or protect against vertical transmission; develop effective strategies that could more easily be afforded globally to help reduce vertical transmission and perhaps decrease transmission via breast milk.

Objective 6: Develop and evaluate therapies for HIV-related malignancies.

Action Steps: Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis.

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

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

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

Continue and expand screening, discovery, and development of novel therapeutic agents with activity against HIV-associated malignancies;

Develop trials to optimize existing therapies for malignancies in HIV-infected patients;

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

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

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

Coordinate referral of patients with malignancy end points on other studies to malignancy trials; and

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

Objective 7: Develop and evaluate therapies for HIV-related neurologic disease.

Action Steps: Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection.

Descriptions: Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction;

Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop

strategies directed at the prevention and treatment of this complication of HIV infection;

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

Develop therapeutic agents that are capable of crossing the blood-brain barrier and are active against HIV infection in relevant cells in the CNS; develop an understanding of mechanisms involved in penetration of the blood-brain barrier;

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

Develop and utilize *in vitro* and animal models of CNS impairment and ADC to further identify agents that can reverse HIV neuropathogenesis; and

Implement assessments and approaches for the diagnosis of HIV-related dementia in clinical studies.

Objective 8: Develop and evaluate therapies for HIV-related complications.

Action Steps: Develop an understanding of HIV-associated complications, including wasting syndrome, growth failure, metabolic disorders, dermatologic disorders, ITP, nephropathy, oral diseases, and other symptoms and serious complications.

Descriptions: Develop and evaluate therapeutic strategies to ameliorate the various sequelae of HIV infection based on an increased understanding of pathogenesis;

Develop and evaluate therapeutic strategies for alleviating the various symptoms of unclear etiology in HIV-infected persons and improving the quality of life; and

Develop and validate quality-of-life parameters for the various sequelae of HIV infection.

FY 95: 473,262,000

FY 96: 495,839,000

Populations Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for

Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$49,566 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

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

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

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

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

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

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

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

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

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

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

Objective 2: Develop and evaluate anti-retroviral therapies.

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

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

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

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

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

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

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

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

therapies, or drugs of abuse;

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

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

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

Objective 3: Develop and evaluate immune-restoring therapies.

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

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

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

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

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

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

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

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

Enhance collaboration among ICDs to facilitate the conduct

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

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

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

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

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

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

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

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

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

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

Objective 5: Develop and evaluate therapies interventions to block perinatal transmission.

Action Steps: Accelerate the development, evaluation, and implementation of strategies to interrupt vertical transmission of HIV from mother to child.

Descriptions: Support the rapid translation of basic

research observations to strategies for the interruption of vertical transmission; apply the results of clinical trials to the investigation of pathogenesis and to clinical practice;

Develop strategies and agents to interrupt the vertical transmission of HIV from pregnant women to their offspring; explore the potential of combined strategies; evaluate the safety, toxicity, pharmacokinetics, and antiretroviral activity of anti-HIV agents in pregnant women and newborns;

Expand the obstetrical and pediatric infrastructure for the conduct of perinatal trials through collaborative efforts, both national and international;

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

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

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

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

Evaluate the risk of vertical transmission of drug-resistant virus; and

Evaluate factors that contribute to or protect against vertical transmission; develop effective strategies that could more easily be afforded globally to help reduce vertical transmission and perhaps decrease transmission via breast milk.

Objective 6: Develop and evaluate therapies for HIV-related malignancies.

Action Steps: Target the discovery, development, and clinical evaluation of improved therapeutic strategies for the treatment and prevention of HIV-associated malignancies based on an understanding of pathogenesis.

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

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

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

Continue and expand screening, discovery, and development of novel therapeutic agents with activity against HIV-associated malignancies;

Develop trials to optimize existing therapies for malignancies in HIV-infected patients;

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

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

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

Coordinate referral of patients with malignancy end points on other studies to malignancy trials; and

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

Objective 7: Develop and evaluate therapies for HIV-related neurologic disease.

Action Steps: Develop an understanding of the neuropathogenesis of HIV infection and strategies for assessing, preventing, and treating neurologic disease in the course of HIV infection.

Descriptions: Develop novel strategies and agents that are active against putative pathways of HIV-induced CNS dysfunction;

Implement studies related to the delineation of mechanisms responsible for impaired neurocognitive development in children born to HIV-infected mothers, and develop

strategies directed at the prevention and treatment of this complication of HIV infection;

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

Develop therapeutic agents that are capable of crossing the blood-brain barrier and are active against HIV infection in relevant cells in the CNS; develop an understanding of mechanisms involved in penetration of the blood-brain barrier;

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

Develop and utilize *in vitro* and animal models of CNS impairment and ADC to further identify agents that can reverse HIV neuropathogenesis; and

Implement assessments and approaches for the diagnosis of HIV-related dementia in clinical studies.

Objective 8: Develop and evaluate therapies for HIV-related complications.

Action Steps: Develop an understanding of HIV-associated complications, including wasting syndrome, growth failure, metabolic disorders, dermatologic disorders, ITP, nephropathy, oral diseases, and other symptoms and serious complications.

Descriptions: Develop and evaluate therapeutic strategies to ameliorate the various sequelae of HIV infection based on an increased understanding of pathogenesis;

Develop and evaluate therapeutic strategies for alleviating the various symptoms of unclear etiology in HIV-infected persons and improving the quality of life; and

Develop and validate quality-of-life parameters for the various sequelae of HIV infection.

FY 95: 473,262,000

FY 96: 495,839,000

Populations Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for

Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$49,566 over the FY 96 figure.

PREVENTION

Agency: National Institutes of Health

Goal: Prevent new HIV infections through behavioral interventions.

Objective 1: Enhance understanding of determinants of HIV-related behavior.

Action Steps: Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change

Descriptions: 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.

Objective 2: Develop behavioral and social science research intervention strategies.

Action Steps: Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.

Descriptions: 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

Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.

Objective 3: Assess innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.

Descriptions: 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 bi-directional 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.

Objective 4: Prevent the negative consequences of HIV Infection.

Action Steps: 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.

Descriptions: 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; and

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.

Objective 5: Create and test innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications

Descriptions: 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 bi-directional 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.

Objective 5: Strengthen the behavioral and social science infrastructure.

Action Steps: 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

Descriptions: 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;

Promote HIV-related research in predoctoral and postdoctoral programs; facilitate the development of practica 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;

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

Collect, archive, and disseminate existing data for secondary data analysis.

FY 95: 159,720,000

FY 96: 161,595,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$44,298 over the FY 96 figure.

PREVENTION

Agency: National Institutes of Health

Goal: Prevent new HIV infections through behavioral interventions.

Objective 1: Enhance understanding of determinants of HIV-related behavior.

Action Steps: Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change

Descriptions: 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.

Objective 2: Develop behavioral and social science research intervention strategies.

Action Steps: Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.

Descriptions: 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

Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.

Objective 3: Assess innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.

Descriptions: 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 bi-directional 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.

Objective 4: Prevent the negative consequences of HIV Infection.

Action Steps: 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.

Descriptions: 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; and

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.

Objective 5: Create and test innovative dissemination strategies.

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Descriptions: 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);

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Objective 5: Strengthen the behavioral and social science infrastructure.

Action Steps: 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

Descriptions: 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;

Promote HIV-related research in predoctoral and postdoctoral programs; facilitate the development of practica 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;

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

Collect, archive, and disseminate existing data for secondary data analysis.

FY 95: 159,720,000

FY 96: 161,595,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$44,298 over the FY 96 figure.

PREVENTION

Agency: National Institutes of Health

Goal: Prevent new HIV infections through behavioral interventions.

Objective 1: Enhance understanding of determinants of HIV-related behavior.

Action Steps: Strengthen the behavioral science base. Conduct a wide range of studies to expand knowledge of the principles of behavior and behavior change

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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.

Objective 2: Develop behavioral and social science research intervention strategies.

Action Steps: Translate findings from behavioral and social science research to design, implement, and evaluate interventions in diverse settings and populations.

Descriptions: 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

Support research on overcoming barriers associated with the implementation and replication of potentially effective prevention programs.

Objective 3: Assess innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications.

Descriptions: 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 bi-directional 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.

Objective 4: Prevent the negative consequences of HIV Infection.

Action Steps: 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.

Descriptions: 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; and

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.

Objective 5: Create and test innovative dissemination strategies.

Action Steps: Develop, assess, and rapidly disseminate research findings and treatment strategies to give researchers and communities access to state-of-the-art communications

Descriptions: 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 bi-directional 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.

Objective 5: Strengthen the behavioral and social science infrastructure.

RESEARCH

Agency: National Institutes of Health

Goal: Improve understanding of the natural history and epidemiology of HIV infection and AIDS in all populations.

Objective 1: Collect natural history and epidemiological data to further understanding of HIV transmission and progression.

Action Steps: Develop and assess intervention strategies to assist in the development of treatment and prevention interventions.

Descriptions: 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;

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;

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;

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.

Objective 2: Examine the role of risk factors and mechanisms of HIV transmission to assist in the development of biologically- and behaviorally-based interventions.

Action Steps: Characterize the risk factors and mechanisms of HIV transmission in various populations.

Descriptions: Evaluate HIV transmission in relationship to:

- a. 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);
- b. host factors such as pregnancy, menstrual cycle, hormonal contraceptives, and HLA type;
- 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.

Objective 3: Enhance understanding of HIV-related disease progression to assist in the development of effective treatment strategies for HIV-infected patients.

Action Steps: 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

Descriptions: 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;

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;

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;

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.

Objective 4: Enhance understanding of susceptibility to HIV infection.

Action Steps: Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease.

Descriptions: 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;

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.

Objective 4: Enhance understanding of HIV disease in populations in which HIV is prevalent, emerging, and/or increasing for the purpose of developing treatments and preventive vaccines.

Action Steps: 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.

Descriptions: 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, *M. avium*) in populations at risk for HIV;

Coordinate with the CDC, WHO, and other institutions to maintain a comprehensive view of the epidemic with as much

detailed information about subpopulations as possible;

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.).

FY 95: 179,014,000

FY 96: 188,822,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$48,449 over the FY 96 figure.

RESEARCH

Agency: National Institutes of Health

Goal: Improve understanding of the natural history and epidemiology of HIV infection and AIDS in all populations.

Objective 1: Collect natural history and epidemiological data to further understanding of HIV transmission and progression.

Action Steps: Develop and assess intervention strategies to assist in the development of treatment and prevention interventions.

Descriptions: 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;

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;

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;

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.

Objective 2: Examine the role of risk factors and mechanisms of HIV transmission to assist in the development of biologically- and behaviorally-based interventions.

Action Steps: Characterize the risk factors and mechanisms of HIV transmission in various populations.

Descriptions: Evaluate HIV transmission in relationship to:

- a. 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);
- b. host factors such as pregnancy, menstrual cycle, hormonal contraceptives, and HLA type;
- 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.

Objective 3: Enhance understanding of HIV-related disease progression to assist in the development of effective treatment strategies for HIV-infected patients.

Action Steps: 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

Descriptions: 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;

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;

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;

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.

Objective 4: Enhance understanding of susceptibility to HIV infection.

Action Steps: Identify, evaluate, and apply innovative laboratory and behavioral strategies to study epidemiologically defined populations with regard to transmission and progression of HIV disease.

Descriptions: 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;

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.

Objective 4: Enhance understanding of HIV disease in populations in which HIV is prevalent, emerging, and/or increasing for the purpose of developing treatments and preventive vaccines.

Action Steps: 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.

Descriptions: 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, *M. avium*) in populations at risk for HIV;

Coordinate with the CDC, WHO, and other institutions to maintain a comprehensive view of the epidemic with as much

detailed information about subpopulations as possible;

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.).

FY 95: 179,014,000

FY 96: 188,822,000

Pops. Served: All populations

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

Unmet Needs: The NIH FY 1996 Plan and Budget Estimate for Scientific Opportunities in HIV-Related Research identified areas for further productive research in this area in the amount of \$48,449 over the FY 96 figure.

PREVENTION

Agency: Health Care Financing Administration

Goal: Reduce perinatal transmission among Medicaid-eligible women.

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

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

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

FY 95: Federal resources to be determined.

FY 96: Federal resources to be determined.

Populations Served: HIV positive women eligible for Medicaid coverage.

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

Unmet Need: The pilot project? will not include women of unknown or negative HIV serostatus. This project should be extended nationwide.

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

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

Develop directives in implementation of developed guidelines.

FY 95: Federal resources to be determined.

FY 96: Federal resources to be determined.

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

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

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

CARE AND SERVICES

Agency: Health Care Financing Administration

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

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

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

Description: Medicaid primary health care services.

FY 95: 1,640,000,000 (Federal share)

FY 96: 1,800,000,000 (Federal share)

Populations Served: HIV positive Medicaid-eligible persons.

Constituency Involvement: More information

Unmet Need: NA

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