

Surveillance

CDC'S HIV/AIDS surveillance system is the nation's source for key information used to track the epidemic. CDC funds and assists state and local health departments, which collect the information. Health departments in turn report their data to CDC so that information from around the country can be analyzed to determine who is being affected and why.

The ultimate surveillance goal is a nationwide system that combines information on AIDS cases, new HIV infections, and behaviors and characteristics of people at high risk so that CDC can track the epidemic and direct HIV prevention funding to where it is needed the most.

Tracking AIDS Trends

During the 1980s, AIDS cases alone provided an adequate picture of HIV trends because the time between infection with HIV and progression to AIDS was predictable. This predictability, however, has diminished since 1996, when HAART became available. Access, adherence, and response to HAART affect whether or when HIV progresses to AIDS. Thus, trends in AIDS cases alone no longer accurately reflect trends in HIV infection. AIDS trends do, however, continue to provide important information about where care and treatment resources are most needed.

Tracking HIV Trends

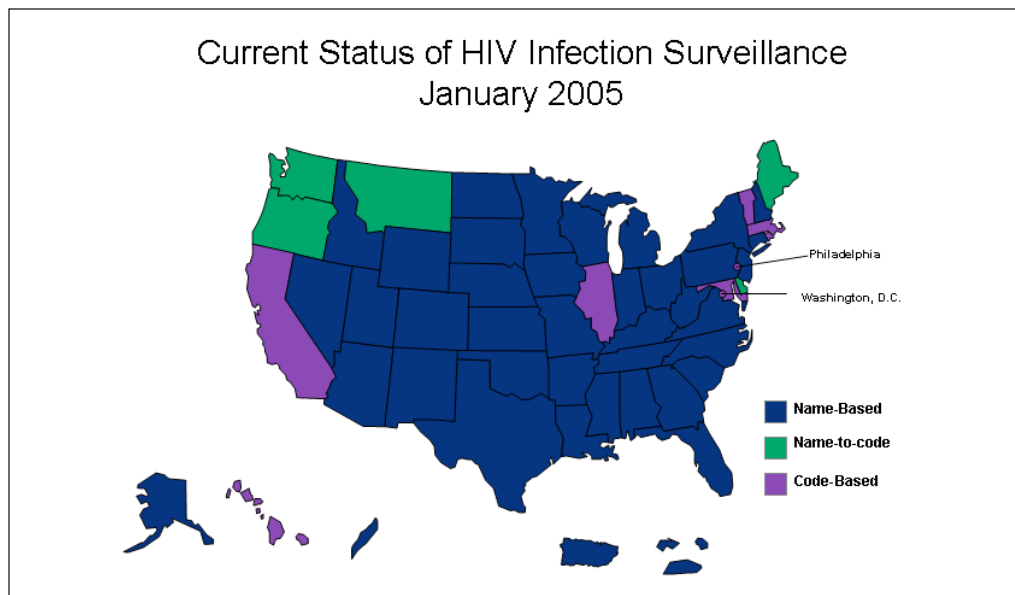
By April 2004, all states had adopted some type of system for reporting HIV diagnoses to CDC. Tracking HIV trends is challenging and depends on several factors, such as how often people are tested, when during the course of their infection they are tested, whether and how test results are reported to health departments, and how case reports (with personal identifiers removed) are forwarded to CDC.

A major advance has been the development of the serologic testing algorithm for recent HIV seroconversion (STARHS). STARHS is a way of analyzing HIV-positive blood samples to determine whether an HIV infection is recent or has been ongoing. In 2001, an expert panel agreed that STARHS is the best method available

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How Is CDC Responding?

for measuring new HIV infections. After funding 5 areas to pilot test this method, CDC has now funded a total of 34 areas to include STARHS in their HIV incidence surveillance activities.



Monitoring HIV Risk Behavior

Behaviors are monitored with regard to risk taking, HIV testing, care seeking, and adhering to treatment for HIV. CDC obtains behavioral information from several different populations.

General population

Several federally supported surveys collect information about HIV-related behaviors of the general population. They are conducted periodically so that trends can be evaluated. Here are a few examples.

- ▲ CDC conducts the Behavioral Risk Factor Surveillance System, the National Survey of Family Growth, and the National Health Interview Study.
- ▲ The National Opinion Research Center (University of Chicago) conducts the General Social Survey, with indirect support from CDC.
- ▲ The Substance Abuse and Mental Health Services Administration conducts the National Survey on Drug Use and Health.

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People who are HIV-infected

MMP (Morbidity Monitoring Project) is a new surveillance system designed to collect information from HIV/AIDS patients who received care from randomly selected HIV care providers. In 2004, CDC awarded funds to 20 states and 6 cities for this project. MMP collects information about access to and use of HIV care, treatment, and prevention services and prevalence of behaviors that can result in HIV transmission and affect disease outcomes (like adherence to therapy). Information is collected from medical records and patient interviews. Patients are selected in a way that will make the data nationally representative for persons who are living with HIV/AIDS and receiving care. Data for planning, evaluation, monitoring, and allocation of resources will be available by the end of 2006.



People who are at high risk for HIV

The NHBS (National HIV Behavioral Surveillance System), for populations at high risk, began in 2003. NHBS conducts surveys in cities with high levels of AIDS among MSM, IDUs, and heterosexuals at high risk to determine their risk behavior, testing behavior, and use of prevention services. In the first cycle,

MSM were interviewed in 17 cities. The second cycle will interview IDUs in 25 cities. In 2006, CDC will expand the system to include heterosexuals at high risk. For states with medium and low levels of AIDS, CDC provides technical assistance and support for behavioral surveys among MSM at specified events, such as gay pride.

HITS (HIV Testing Survey) primarily interviewed adults who were not HIV-infected but were at high risk for HIV infection. HITS collected information about what motivates people to get tested for HIV and what behaviors place people at risk for HIV. HITS was conducted in 24 states during 1995–2003. Data analyses from HITS are ongoing.

How Is CDC Responding?

Monitoring HIV Counseling and Testing Behavior

The HIV Counseling and Testing System (CTS) has been used since 1989 to monitor CDC-funded HIV counseling and testing services. Through this system, each CDC-funded HIV counseling and testing episode is reported to CDC and includes information about demographics, self-reported behavior, and HIV test results. Data from this system are used to guide the development of HIV prevention programs in response to the needs of the community. Beginning in 2005, CTS will be replaced by the Counseling, Testing, and Referral (CTR) module of the Program Evaluation and Monitoring System (PEMS). Data collected by CTR have been updated to include information on new testing technologies and client referrals to medical care and other services and to be consistent with other PEMS data collection and reporting requirements.

Prevention Programs

The primary component in CDC's fight against HIV/AIDS is HIV prevention programs. Programs consist of interventions intended to change risky behavior and improve the health of the people served. Interventions include encouraging early HIV diagnosis; delivering counseling, testing, and referral services; providing educational programs and materials; and training peers to be role models. They are delivered to individuals, groups, and communities in places such as storefronts, gay bars, health centers, housing communities, faith-based organizations, and schools. Street outreach techniques such as using mobile testing vans, offering incentives for participation or referral, and recruiting peers are some of the ways to reach as many people as possible.

CDC provides leadership, capacity building assistance, and funding for programs at the state, local, and community levels. CDC funding supports staffing, program infrastructure, implementation and evaluation of interventions. In many instances, CDC requires that those who receive funding for programs (grantees) have a proven track record of providing effective programs. CDC also strives to ensure that interventions meet local needs. Specifically, CDC asks that interventions be science based and culturally proficient; that

The primary component in CDC's fight against HIV/AIDS is HIV prevention programs.

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is, they should meet the cultural needs, expectations, and values of the populations they serve. Community planning helps ensure that priorities for HIV prevention are determined locally with input from affected communities and that they are consistent with scientific findings about what interventions are most effective for decreasing HIV transmission.

Evaluation (to measure program effectiveness) is an important part of prevention programs. Programs funded by CDC are required to collect and submit evaluation data so that CDC can track and identify the most effective programs. CDC's evaluation efforts take several forms.

- ▲ Evaluation guidance outlining the types of data each funded health department must collect from its grantees
- ▲ Regular reviews of each funded health department to evaluate effectiveness in community planning
- ▲ Ongoing reviews of funded CBOs

In addition, CDC researches the effectiveness of HIV prevention interventions and the diffusion of these interventions. CDC's Prevention Research Synthesis Project identifies interventions that have proven effective with various groups. The Replicating Effective Programs (REP) project takes proven interventions and packages them in a tool kit for distribution. CDC's Diffusion of Effective Behavioral Interventions (DEBI) project then looks at ways to get these effective interventions to a broader audience.

Health Departments

CDC funds and works with 65 state, local, and territorial health departments to support prevention efforts and programs for people living with HIV and people at risk for HIV. All 65 health departments provide HIV counseling and testing services, which include referral and partner notification. A requirement for CDC funding is the development of a community planning process, which unites health departments and community members in developing an HIV prevention plan that reflects their local epidemic and guides HIV prevention efforts in their local area. Health departments also use CDC funds to support CBOs (indirect funding).



How Is CDC Responding?

Nongovernment Organizations

CDC supports community-based, faith-based, and other nongovernment organizations in building partnerships for HIV prevention. These efforts provide interventions for populations at high risk, including people of color, MSM, substance abusers, and correctional facility inmates. To help people living with HIV/AIDS access prevention and treatment services, these organizations also provide HIV counseling and testing services and programs.

Public-Private Partnerships

CDC works with business and labor groups to enhance the health, productivity, and well-being of workers and their families living with, affected by, or at risk for HIV/AIDS. The Business Responds to AIDS (BRTA) and Labor Responds to AIDS (LRTA) programs are worldwide public-private partnerships that serve as a resource to business and labor on a full range of HIV/AIDS issues. These partnerships set up workplace and related programs that combat complacency and stigma and support community activism, volunteerism, and corporate philanthropy.

Another CDC partnership is AIDS: Act Now! This public-private effort has a council of 50 members from business, faith-based, public health, and HIV communities, and the media. In addition, 5 alliances focus on issues such as leadership, youth, media, HIV testing and clinical care, and Internet technology. In total, CDC has obtained the support of more than 100 partners who volunteer their time to explore how they can use their resources, influence, and outreach capabilities to enhance HIV prevention efforts in communities most affected by HIV and AIDS. As communities of color disproportionately bear the effects of the epidemic, most activities under AIDS: Act Now! are directed toward these groups.

Prevention Strategies

Among CDC's strategies for HIV prevention are

- ▲ providing up-to-date scientific information through guidelines
- ▲ promoting early diagnosis of HIV infection
- ▲ addressing the unique prevention needs of HIV-infected persons
- ▲ building the capacity of health departments and CBOs to

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deliver effective prevention programs that reduce risk for HIV transmission

- ▲ increasing the quality of HIV prevention programs through evaluation

Guidelines

Guidelines are written recommendations for health care providers in the public and private sectors. They are developed after consultations with health care providers, public health officials, patient advocates, and policy experts. They are based on available scientific evidence; where evidence is incomplete, the “best practices” opinions of specialists in the field are used.

Revised Guidelines for HIV Counseling, Testing, and Referral (2001)

Guidelines for HIV counseling, testing, and referral (CTR) were published in 1986 and revised in 1994. After a massive effort to review all current scientific evidence, obtain recommendations, and reach agreement on recommendations, CDC published the Revised Guidelines for HIV Counseling, Testing, and Referral in 2001. Using an evidence-based approach, these guidelines advise providers of voluntary HIV CTR how to improve the quality and delivery of HIV CTR. They underscore the importance of early knowledge of HIV status and of testing that is more accessible and available.

Revised Recommendations for HIV Screening of Pregnant Women

In 1995, the US Public Health Service issued guidelines recommending universal counseling and voluntary HIV testing of all pregnant women and treatment for those infected to prevent mother-to-child HIV transmission. Subsequently, mother-to-child HIV transmission declined dramatically. In 2001, the Revised Recommendations for HIV Screening of Pregnant Women were published. These guidelines strengthen the recommendation that all pregnant women be tested for HIV as part of routine perinatal care, while preserving a woman’s right to make her own decisions about testing.



How Is CDC Responding?

Recommendations for Incorporating HIV Prevention into the Medical Care of Persons Living with HIV

In 2003, CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America developed recommendations to help clinicians incorporate HIV prevention into the medical care of HIV-infected individuals. These recommendations include

- ▲ screening for HIV transmission risk behaviors and sexually transmitted diseases
- ▲ providing behavioral risk-reduction messages in the office and referral for other prevention interventions and related services
- ▲ facilitating the notification and counseling of sex partners and needle-sharing partners

Procedural Guidance for Selected Strategies and Interventions for Community-based Organizations Funded Under Program Announcement 04064

The Procedural Guidance provides information to CBOs about the interventions that are allowable under Program Announcement 04064. It is available at www.cdc.gov/HIV/partners/pa04064_cbo.htm.

HIV Prevention Community Planning Guidance

This guidance, revised in July 2003, defines CDC's expectations for health departments and HIV prevention community planning groups involved in HIV prevention community planning. These and other CDC recommendations and guidelines are available at www.cdc.gov/HIV/pubs/guidelines.htm.

Advancing HIV Prevention: New Strategies for a Changing Epidemic

Advancing HIV Prevention (AHP) is a combined effort of CDC and other agencies (government and nongovernment). It is designed to reduce barriers to early diagnosis of HIV infection and increase access to quality medical care, treatment, and ongoing prevention services for people living with HIV. It emphasizes the use of public health approaches proven effective at reducing new infections

Guidelines are written recommendations for health care providers in the public or private sector.

Advancing HIV Prevention is designed to reduce barriers to early diagnosis of HIV.

and spread of disease, such as appropriate routine HIV testing; identification of new cases; partner counseling, testing, and referral services; and increased availability of treatment and prevention services for HIV-infected persons and their partners. AHP is described in more detail in Section 5, The Future.

Other CDC-funded projects help communities improve referrals to care and prevention services.

- ▲ **Project HEART (Helping Enhance Adherence to Antiretroviral Therapy)**, a clinic-based behavioral intervention for patients who have not previously received HAART
- ▲ **Partnership for Health (Safer Sex and Adherence Intervention for HIV Outpatient Clinics)**, an intervention encouraging health care providers to promote safer sex and adherence to therapy
- ▲ **INSPIRE (Interventions for HIV-Positive Intravenous Drug Users: Research and Evaluation)**, a behavioral intervention to help IDUs decrease their risk for HIV, increase access to care, and increase adherence to HAART

Capacity Building

CDC recognizes that organizations funded to conduct HIV prevention, such as health departments and CBOs, often face challenges to meeting the increased prevention needs of populations at high risk for HIV and other sexually transmitted infections. Examples of these challenges are the need

- ▲ to diversify the funding base to help sustain prevention services
- ▲ for effective behavioral interventions that are based on science and are culturally competent
- ▲ for competent staff
- ▲ for effective strategies to link HIV-negative and HIV-infected persons at high risk to services (testing, prevention, and care)

The goal of CDC's HIV prevention capacity building program is to ensure that health departments and CBOs receive scientifically sound and culturally appropriate capacity building assistance through the following:

- ▲ technology transfer—translating scientific research into programs and practice

How Is CDC Responding?

- ▲ technical assistance—providing expert programmatic, scientific, and technical consultation and support to health department and CBO staff
- ▲ training—building the knowledge, skills, and abilities that health department and CBO staff need to deliver effective HIV prevention interventions and to effectively sustain the organizational infrastructure needed to support HIV prevention services
- ▲ information dissemination—sharing information through print materials, meetings, Web sites, and mass media

Diffusion of Effective Behavioral Interventions (DEBI) is an example of capacity building using technology transfer to disseminate science-based behavioral interventions. DEBI endorses the interventions that are identified by CDC's Prevention Research Synthesis Project.

These interventions are

- ▲ **Community PROMISE (Peers Reaching Out and Modeling Intervention Strategies for HIV/AIDS Risk Reduction in their Community)**, a community-level intervention based on behavior change theories
- ▲ **Healthy Relationships**, a small-group intervention for people living with HIV and AIDS
- ▲ **Holistic Health Recovery Program**, a group-level program to reduce harm and promote health for HIV-infected IDUs
- ▲ **3MV (Many Men, Many Voices)**, a group-level STD/HIV prevention intervention for MSM of color
- ▲ **Mpowerment**, a community-level intervention for young MSM
- ▲ **Partnerships for Health**, a provider-delivered counseling program for people living with HIV/AIDS
- ▲ **POL (Popular Opinion Leader)**, an intervention to identify, enlist, and train key opinion leaders to encourage safe behaviors in their social networks
- ▲ **RAPP (Real AIDS Prevention Project)**, a program to involve the community in reducing HIV risk and unintended pregnancy by increasing condom use

The goal of CDC's HIV prevention capacity building is to help individuals, organizations, and communities enhance and sustain their HIV prevention efforts.



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- ▲ **Safety Counts**, an intervention for active injection drug and crack cocaine users, aimed at reducing high-risk drug use and sexual behaviors
- ▲ **SISTA (Sisters Informing Sisters About Topics on AIDS)**, a group intervention for African American women, to help them increase condom use
- ▲ **Street Smart**, a skills-building program to help runaway and homeless youth practice safer sexual behaviors and reduce substance abuse
- ▲ **TLC (Together Learning Choices)**, an intervention for young people, 13–29 years old, who are living with HIV
- ▲ **VOICES/VOCES (Video Opportunities for Innovative Condom Education and Safer Sex)**, a video-based intervention to increase condom use among heterosexual African American and Hispanic men and women who visit STD clinics

A second group of interventions will follow. Plans call for diffusion of more behavioral interventions as well as structural and biomedical interventions.

Evaluation

Evaluation activities focus on results by

- ▲ managing and measuring program performance
- ▲ improving the quality of HIV prevention programs
- ▲ promoting accountability

Program Performance Indicators

As specified in the President's Management Agenda, CDC has incorporated program performance indicators into its cooperative agreements with HIV prevention providers. The purpose is to improve performance and accountability of programs. Beginning in 2005 all directly funded health departments and CBOs will report on measures of HIV prevention planning, service delivery, and evaluation activities. The performance indicators will be used to monitor progress in critical areas of HIV prevention. The specific components of HIV prevention programs addressed by the indicators include

- ▲ HIV infections
- ▲ community planning



How Is CDC Responding?

- ▲ prevention activities
 - Counseling, testing, and referral services
 - Partner counseling and referral services
 - Prevention for HIV-infected persons
 - Health education and risk-reduction activities
 - Prevention of mother-to-child HIV transmission
- ▲ evaluation of reporting compliance
- ▲ capacity building activities

PEMS (Program Evaluation and Monitoring System)

CDC has developed PEMS to strengthen monitoring and evaluation of HIV prevention programs. PEMS is to be used by health departments and CBOs funded through CDC HIV prevention cooperative agreements. PEMS is a secure Internet browser-based software program for data entry and reporting. PEMS software was first released in the fall of 2004 to 42 health departments and 27 CBOs. It allows grantees to collect agency, community planning, and program plan data. The next release, scheduled for fall 2005, will enable grantees to enter client-level data and report to CDC. By the end of 2005, PEMS will be available to over 200 agencies nationwide. PEMS will ensure that CDC receives standardized, accurate, and thorough program data from health department and CBO grantees. The data include

- ▲ agency information
- ▲ program plan details
- ▲ client demographics
- ▲ referral outcomes
- ▲ HIV test results
- ▲ partner elicitation and notification
- ▲ client use of services
- ▲ behavioral outcomes
- ▲ community planning priority populations and interventions

These data will allow more comprehensive reporting of HIV prevention activities, fiscal information, and community planning information. These data will help HIV prevention stakeholders examine program fidelity, monitor use of key program services and behavioral outcomes, and calculate and report the program performance indicators.

To improve the quality of HIV prevention programs, CDC is focusing on results.

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PEMS will help CDC monitor, evaluate, and coordinate HIV prevention programs and support the rapid set-up of special studies and evaluation projects.

Research

Among its many HIV research activities, CDC is involved in research related to

- ▲ diagnostic tests
- ▲ microbicides
- ▲ vaccines

Diagnostic Tests

Since November 2002, the Food and Drug Administration has approved 4 rapid HIV tests. These tests offer many advantages over conventional HIV blood tests. Sample collection is easier (for

example, from a finger prick or oral fluid), and they are easy to use outside of traditional laboratories so they are suitable for doctors' offices and community and outreach settings. Perhaps the biggest benefit of rapid tests is their ability to give results in 30 minutes or less. Because test results are available quickly, rapid HIV tests dramatically increase the number of people who get tested and find out their results that day. This represents a significant public health achievement because those who know they are infected with HIV can get treatment.

Evidence also shows that persons who know they are infected adopt changes that dramatically reduce their risk of transmitting the virus to others.

Rapid HIV tests also help further reduce the number of infected infants born to HIV-infected mothers. HIV transmission from mother to infant can be decreased by almost half if antiretroviral treatment is started during labor.

CDC is involved in many areas of rapid HIV testing, such as the following:

- ▲ Evaluating the accuracy of rapid tests
- ▲ Providing training on rapid tests



How Is CDC Responding?

- ▲ Publishing information in the scientific literature
- ▲ Maintaining an updated Web site
- ▲ Helping other federal agencies introduce rapid HIV testing into their projects
- ▲ Funding demonstration projects

In 2003, CDC funded 21 health departments and CBOs for 2-year demonstration projects for rapid HIV tests. These awards are used for incorporating rapid testing into routine medical care, partner counseling and referral services, short-stay correctional facilities, nonclinical settings, and social networks. These projects have shown that rapid tests are an important part of HIV prevention efforts.

Microbicides

CDC is actively involved in research to identify and test potential HIV microbicides. Microbicides are gels, creams, or suppositories that can kill or neutralize viruses and bacteria. When applied in the vagina before sexual intercourse, they can protect against some sexually transmitted diseases. A safe, effective, and affordable microbicide against HIV could help to prevent many new infections.

Thailand

CDC collaborated with the Thailand Ministry of Health and the Population Council to conduct Phases I and II (safety and efficacy) clinical trials of Carraguard, a candidate vaginal gel microbicide, in HIV-negative women and heterosexual couples. Testing of other compounds will begin in 2005.

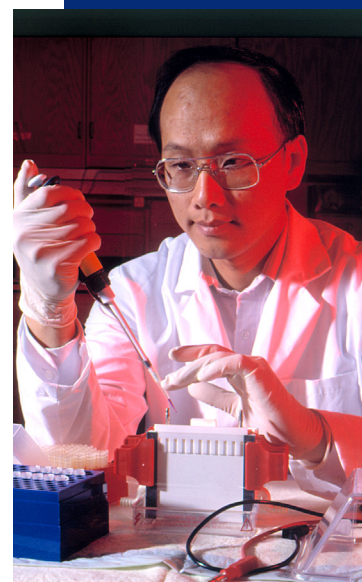
Botswana

CDC is collaborating with the Botswana Ministry of Health to develop a site for Phases I, II, and III (safety and efficacy) testing of microbicide candidates. Plans are under way to begin Phase I studies in 2006.

United States

CDC is conducting preclinical (animals and laboratory) and Phases I and II clinical trials of potential new HIV microbicides. In its own laboratories, CDC is also examining the toxicity and efficacy of some microbicides against HIV.

In November 2002, the Food and Drug Administration approved a simple, rapid HIV test.



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Drugs to Prevent HIV (chemoprophylaxis)

CDC is conducting studies to test an antiretroviral agent, tenofovir disoproxil fumarate. Tenofovir will be tested for safety, tolerance, and effectiveness when used by people at risk before exposure to HIV. Clinical trials began in 2005. Finding a drug that effectively prevents HIV without increasing drug resistance could significantly affect HIV prevention strategies.

Botswana

CDC is collaborating with the Botswana Ministry of Health to conduct safety and efficacy trials of tenofovir among heterosexual persons at risk for HIV infection.

Thailand

CDC is collaborating with the Thailand Ministry of Health to conduct safety and efficacy trials of tenofovir among IDUs.

United States

CDC is conducting clinical trials among MSM to test for the safety of tenofovir.

Vaccines

The intervention most anticipated by everyone working to stop the HIV/AIDS epidemic is a vaccine to prevent infection. CDC is no stranger to vaccine development (considering its experience with other vaccines such as measles, hepatitis B, polio, and smallpox), but developing an HIV vaccine presents unique challenges. For example, it is critical that no one (whether involved in the studies or not) abandon safer sexual and drug-related behaviors proven to prevent HIV infection. Overall, vaccine development must not endanger progress already made in HIV prevention.

Until a vaccine is available, and even afterwards, we must continue to reinforce the already proven methods of HIV prevention.

CDC's HIV vaccine research focuses on conducting and evaluating HIV vaccine trials in the United States and elsewhere. CDC played an important role in the world's first 2 efficacy trials of HIV vaccine candidates. Although the results indicated that the vaccines were not effective in reducing the risk for HIV infection, the trials

CDC is actively involved in research to identify and test potential HIV microbicides.

provided critical information that will guide future research on HIV vaccines. Through an agreement with the National Institutes of Health and through membership in the Partnership for AIDS Vaccine Evaluation, CDC is currently contributing to the US government's effort to develop a safe and effective HIV vaccine.

United States

CDC collaborated with a US vaccine developer, VaxGen, in the world's first efficacy trial of an HIV vaccine (AIDSVAX B/B gp 120). At 6 sites, CDC also sponsored extensive substudies on how the vaccine affected risk behavior.



Thailand

CDC collaborated with VaxGen, the Bangkok Metropolitan Administration, and Mahidol University to test the efficacy of a vaccine (AIDSVAX B/E gp 120) in Bangkok. CDC helped develop counseling, educational, and prevention materials. CDC and the Thai government also identified persons willing to participate and to be followed up to evaluate risk behaviors and infection. CDC also worked with the community to build the understanding and support necessary for such a trial. CDC, Thai health officials, and VaxGen ensured that participants received appropriate risk-reduction counseling and were fully informed about how the trial worked, the potential risks and benefits, and the importance of maintaining good risk-reduction behaviors during the trial. CDC also evaluated the clinical care and disease progression of participants who become HIV-infected during the trial.

Africa

Along with Emory University and the National Institutes of Health, CDC helped develop a prototype vaccine (HIV-1 subtype A/G DNA+MVA) for people in West/Central Africa. CDC is also helping with preparations for HIV vaccine clinical trials in West/Central and East Africa. In Cameroon and Kenya, CDC is collaborating with Ministries of Health to help develop the capacity to conduct HIV vaccine clinical trials.

Until a vaccine is available, and even afterwards, we must continue to reinforce the already proven methods of HIV prevention.