

HIV Impact

A Closing the Gap newsletter of the Office of Minority Health, U.S. Department of Health and Human Services

HIV Vaccines...Our Best Hope *OMH Talks to Dr. Anthony Fauci*

By Houkje Ross

Worldwide, over 20 million people have died from AIDS. Another 36 million are currently infected with HIV. And it continues to spread. Our best hope of controlling the epidemic is in the development of an HIV preventive vaccine. In 1997, then President Clinton challenged scientists and researchers to develop an AIDS vaccine within ten years.

To learn about the current status of research for an AIDS vaccine, the Office of Minority Health Resource Center turned to the lead agency in HIV vaccine research and development, the National Institutes of Health. OMHRC had the unique opportunity to ask Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID) about the current status of HIV vaccine development. Here's what Dr. Fauci told us:

Impact: We are nearly four years into former President Clinton's challenge to find a vaccine within ten years. Will we make that goal?

Dr. Fauci: We are hopeful. Progress toward the development of a vaccine to prevent HIV infection, or to slow the progression of disease if the vaccinated person does become infected is encouraging. Diverse approaches to vaccine design are actively being pursued, including advances and refinements of vaccines based on HIV surface proteins, DNA vaccines, vaccines using HIV functional proteins, combination vaccines, and novel vaccines that stimulate both components of the immune system (antibody and cell-mediated responses). The pipeline of innovative concepts continues to generate new possibilities for a preventive vaccine. Several experimental approaches have shown considerable promise in animal model tests; several of these candidates will soon move, or already have moved into Phase I safety trials in humans. In addition, expansion of trials of candidate vaccines that are already being tested in humans will be considered in the next few years.

Impact: What is the status of current efforts? How many clinical trials are currently being conducted in the United States and abroad?

Dr. Fauci: Since 1987, more than 3,700 non-HIV-infected volunteers have enrolled in 56 NIAID-sponsored HIV vaccine studies.

“...it is important that people understand that the candidate HIV vaccines that the NIH and others are developing will not cause anyone to become infected with HIV and *will not* cause AIDS.”

Currently, NIAID is sponsoring two Phase II trials. One is being conducted in the United States, and the other is being conducted at sites in Trinidad/Tobago and Haiti—and soon will expand to Brazil and possibly other countries in Latin America. If results of these studies are positive, NIAID will move forward with an efficacy trial enrolling thousands of volunteers. There are more than 18 products in the NIAID development pipeline; in addition, protocols are being developed to test the new products.

Impact: What is the NIH role in the development of an HIV vaccine? How much funding is available for vaccine research and development at NIH? Is it enough?

Dr. Fauci: The NIH supports basic research, preclinical evaluation, and human clinical testing of candidate HIV vaccines. Clinical trials of preventive HIV vaccines are conducted in the HIV Vaccine Trials Network (HVTN), an international network with sites currently located in the United States, South Africa, Haiti, Trinidad/Tobago, Peru, Brazil, India, Thailand, and China. Funding for HIV vaccine research at the NIH has significantly increased over the past several years. In fiscal year (FY) 1996, NIH spending on HIV vaccine research was just over \$100 million. In FY 2000, it was close to \$250 million and in FY 2002, NIH funding of HIV

...continued on page 2



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STAFF

Blake Crawford
Executive Editor

Brigette Settles Scott, MA
Senior Managing Editor

Matthew Murguia
Contributing Writer

Houkje Ross
Senior Editor/Writer

John I. West
Production Coordinator

Stephanie Singleton
Graphic Designer

I N S I D E

HIV Vaccines	1
Vaccine Development	4
Community Advisory Boards	6
Vaccine Legislation	7
Clinical Trial Participation	8-9
HIV/AIDS Services Update	10
Government Efforts	11
Funding	12
Quiz	13-14
Resources	15
Conferences	16



HIV Vaccines... from page 1

vaccine research is anticipated to be more than \$350 million. Significant progress will certainly be made at this level of funding.

Impact: What is it about HIV that is making vaccine development so difficult? What more do we need to learn?

Dr. Fauci: There are several obstacles in developing a vaccine to prevent AIDS. One obstacle is that HIV is genetically diverse in populations, and also mutates within infected individuals. This means that a vaccine will need to protect a person against many different strains of the virus. In addition, HIV infects helper T cells, the immune cells that orchestrate the immune response. It is very difficult to design a vaccine that, to be effective, must activate the very cells that are infected by the virus. Another obstacle is that HIV is transmitted both as free virus as well as by infected cells. This suggests that both arms of the immune system—antibodies that clear free virus, and cell-mediated responses that kill HIV-infected cells—may need to be stimulated to provide protection. Since the immune system of an HIV-infected individual does not spontaneously clear the virus from his/her body, the question of what constitutes an effective immune response to HIV is unknown. This is a critical gap in our knowledge that is being actively pursued. Furthermore, there is no ideal animal model available that exactly mimics the human immune response. More information on the immunology of HIV infection, and how to induce broadly reactive immune responses is needed.

Impact: Will a vaccine that works in the U.S. automatically work in other countries? If not, why not?

Dr. Fauci: We do not know at this point whether a vaccine that works in the United States will also work in other countries. That is why we have to do studies in different populations around the world, sometimes with the same candidate vaccines or strategies. For example, encouraging results regarding immune responses to a vaccine were obtained from a clinical trial conducted in Africa. The vaccine used in that trial was based on HIV strains found in the United States and Western Europe. This vaccine generated a broad-based immune response that could destroy cells infected with different strains of HIV. However, more clinical testing is needed in order to deter-

mine if these responses will ultimately be protective against African strains of HIV. NIAID also is aggressively working to develop HIV vaccines based on strains found in other countries, including those in Africa and Asia.

Impact: The same question could be asked about vaccines in different racial and ethnic populations in the United States. Since most HIV vaccine clinical trial volunteers are White, if a vaccine is developed that is efficacious, how will we know it will work in other races or ethnicities in the United States?

Dr. Fauci: NIAID-supported HIV clinical studies have included participants from different races and ethnicities reflective of the U.S. population. Recruitment efforts for an efficacy trial must include various racial and ethnic populations, including those people at an increased risk of becoming infected with HIV, so that we can definitively answer this question.

Impact: Do we have all the necessary systems in place to move this effort forward (i.e., the financial backing, collaboration, scientific technology, etc.)?

Dr. Fauci: NIAID is committed to the development of a safe and effective vaccine to prevent HIV infection and AIDS around the world. Programs have been developed that encourage collaborations between academic institutions and the private sector to accelerate HIV vaccine concepts through the development pipeline to human testing. With the formation of the HVTN, we are well poised to take candidate vaccines into human testing, both nationally and internationally. NIAID also has numerous resources that provide researchers around the world with the reagents and other tools needed to develop and test candidate HIV vaccines. Issues such as access to efficacious vaccines will be approached through discussions with pharmaceutical partners, international funders, government officials and other stakeholders.

Impact: How does NIH coordinate its efforts with other Federal agencies and other countries?

Dr. Fauci: Most currently available vaccines, as well as those in the development pipeline, have resulted from collaborations between the public and private sectors. NIH and other Federal agen-

...continued on page 3

cies actively pursue research portfolios that involve interaction with industry and academia, and the transfer of technology to the private sector for commercialization. Within the Federal government, NIH has the lead role in HIV vaccine research and development, and supports programs that span the spectrum from basic research to licensure of products. While NIH supports much of the basic and clinical research in fields such as virology, immunology and microbiology that leads to vaccine development, the Centers for Disease Control and Prevention conducts epidemiologic studies and surveillance needed to define health priorities, and develops recommendations for vaccine use. The Food and Drug Administration establishes standards for processes, facilities, and licensing studies to insure the safety and effectiveness of vaccines.

Impact: Is America ready for a vaccine? Will the systems be in place for educating people, for distribution, etc., when one is found?

Dr. Fauci: NIAID is working toward increasing the awareness of HIV vaccine research at the national and local levels, especially in those populations at greatest risk. NIAID recently awarded a contract to a health communications firm to

assist in the development of a national campaign to increase public awareness and support for preventive HIV vaccine clinical trials. This firm will work closely with NIAID, the NIAID-sponsored HIV Vaccine Trials Network, and the CDC to educate the public and to help create a supportive and sustainable environment for large-scale efficacy trials and for eventual implementation of strategies for vaccine distribution.

Impact: What does the public most need to know about HIV vaccines? What message would you like to leave the readers of *HIV Impact* about vaccines?

Dr. Fauci: A preventive HIV vaccine is the world's best hope of ending the AIDS pandemic. We believe that finding a safe and effective vaccine is now within our grasp. The studies needed to bring an HIV vaccine to market will require a spirit of trust and collaboration among researchers, affected communities, government officials, and private industry. As part of that trust-building, it is important that people understand that the candidate HIV vaccines that the NIH and others are developing will not cause anyone to become infected with HIV, and *will not* cause AIDS. 

Dr. Fauci first came to the National Institutes of Health (NIH) as a clinical associate in the Laboratory of Clinical Investigation (LCI) at the National Institute of Allergy and Infectious Diseases (NIAID).



In 1974, he became Head of the Clinical Physiology Section, LCI, and in 1980 was appointed Chief of the Laboratory of Immunoregulation, a position he still holds. Dr. Fauci became Director of NIAID in 1984.

Dr. Fauci has made seminal contributions to the understanding of how HIV destroys the body's defenses leading to its susceptibility to deadly infections. He has also been instrumental in developing strategies for the therapy, and immune reconstitution of patients with this serious disease, as well as for a vaccine to prevent HIV infection.

He continues to devote much of his research time to identifying the nature of the immunopathogenic mechanisms of HIV infection, and the scope of the body's immune responses to the AIDS retrovirus.

NIAID is a component of the National Institutes of Health (NIH). NIAID conducts and supports research to prevent, diagnose and treat illnesses such as HIV disease, and other sexually transmitted diseases, tuberculosis, malaria, asthma, and allergies. NIH is an agency of the U.S. Department of Health and Human Services. 

Other NIAID Information

Dr. Edmund C. Tramont was recently named Director of the National Institute of Allergy and Infectious Disease's (NIAID's) Division of AIDS (DAIDS). Dr. Tramont, who assumed the new position on July 6, has many years of vaccine research—he was instrumental in creating the combined meningococcal vaccine; he designed and implemented vaccine trials for gonorrhea, shigella, and HIV; and worked for the Army, primarily to develop vaccines that would protect soldiers.

As director of DAIDS, one of four research divisions within NIAID, Dr. Tramont will oversee an estimated \$444 million global research program involving hundreds of clinical trials with the aim of treating, preventing and better understanding HIV/AIDS.

"The DAIDS program has been enormously successful," says Dr. Tramont. "...My challenge is to build on that legacy."

For more information, go to <http://www.niaid.nih.gov>. 

The Jordan Report 2000 addresses vaccine research aimed at preventing many other diseases, including food-borne bacterial infections, shingles, anthrax and dengue, and ongoing efforts to improve existing vaccines.

Diseases are organized according to type and name, and are introduced with a brief overview prior to a detailed description of relevant vaccine research. The report contains appendices providing the status of all vaccines in development, plus trade names and licensing information where appropriate. The current recommended childhood immunization schedule, and a list of more than 350 references are also included.

For more information, go to <http://www.niaid.nih.gov> or write to Jordan Report/NIAID OCPL; Bldg. 31, Rm. 7A50; 31 Center Dr., MSC 2520; Bethesda, MD 20892-2520. 

How Vaccines Work

Vaccines are designed to stimulate the immune system to protect the body against infection from microorganisms such as viruses. Scientists hope that an HIV vaccine will help a person's immune system prevent a person from becoming infected with HIV, and for those already infected, lessen how ill that person may become.

If a vaccine is found, it would stimulate the immune system to immediately react in a way that tells certain cells in the body to attack and destroy the virus as well as cells which may have already become infected.

To do this, two main types of cells go into to action: B cells and T cells. B cells make antibodies or molecules that attach themselves to, and neutralize or kill any virus that is floating free in the bloodstream, preventing them from infecting other cells. T cells, or helper cells or killer cells, organize the immune response into attack mode. Killer T cells (known as CTLs) attack cells already infected by viruses and kill them.

A virus may contain many molecules, or antigens, that are not recognized by the body. Both B cells and T cells are activated when they recognize these antigens. Once a T cell or B cell is activated, the B or T cell clones itself, making many duplicate copies of itself. Some of these cloned T cells attack and destroy cells infected by the invading virus. Other cloned B or T cells remain in the body as memory cells. If the body is re-invaded by the virus in the future, the memory cells will be reactivated and respond faster and more powerfully to destroy the virus.

For more information on how vaccines work, go to <http://www.niaid.nih.gov/daids/default.htm>.

Source: Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Disease (NIAID), National Institutes of Health (NIH)

How Scientists Develop Vaccines

By Houkje Ross

Scientists have been searching for an HIV vaccine since 1987, when the first clinical trial opened at the National Institutes of Health. But so far, researchers have been stumped. Nine subtypes of the virus, which mutate once they are inside the body, make it challenging to come up with a working vaccine.

Over 30 candidate HIV preventive vaccines have been tested in Phase I clinical trials since development began, but only one preventive AIDS vaccine has reached Phase III of the clinical trial process. The vaccine, AIDSVAX, is made from a synthetic protein by VaxGen, Inc. a California-based research and development company. Approximately 8,000 volunteers are participating in the AIDSVAX trial, which is being run in several cities across the U.S. and internationally. Here's a brief overview of how scientists approach the search for an HIV vaccine:

Before the Clinical Trial

Basic Science. Basic scientific research is done at universities, research institutions, and private companies. Scientists work to develop ideas for how an HIV vaccine could function. They examine cells from the human immune system and parts of the HIV virus for clues about what might work and how a vaccine might be designed. Hundreds of scientists all over the world are now contributing to this stage of HIV vaccine development. New ideas are generated all the time, but only a very few move to the pre-clinical development stage.

Pre-clinical Development. During this stage scientists test vaccine candidates in cell-cultures. If the results are promising, the vaccines are then tested on animals. Animals are used in this stage to see if the vaccine is safe and if it works the way scientists believed. Only a small percent of the vaccines that make it to the pre-clinical development stage are safe enough and promising enough to be evaluated in clinical trials with individuals.

Clinical Trial Process

What are Clinical Trials?

Clinical trials test the safety and effectiveness of a drug, vaccine, or medical device. Doctors and other health profes-

sionals run clinical trials according to strict rules set by the Food and Drug Administration (FDA). FDA rules ensure that the people who agree to participate in the studies are treated as safely as possible.

When it comes to HIV vaccine clinical trials, there are two types, therapeutic or preventative. Therapeutic vaccines are for people who are already infected with HIV. Therapeutic vaccines test to see if a vaccine will keep HIV from weakening the immune system of the person it resides in. A preventative vaccine would protect a person from becoming infected with the virus, even if the person was exposed to it. It should be noted that with many diseases, individuals can be exposed to the virus that causes the disease, but not become infected with the disease.

The Three Phases of Clinical Trials

Phase I Trials—Phase I trials of HIV vaccine candidates are conducted domestically and internationally with people who have a low risk of becoming infected with HIV. Phase I trials have a small number of participants—usually under 50 people. These studies test vaccines for safety and ability to stimulate an immune response, and provide data that will assist in determining which vaccines should be advanced into larger Phase II trials. Phase I trials usually last 12 to 18 months.

Phase II Trials—Phase II trials usually

...continued on page 5

have hundreds of participants (both low and high risk individuals), and are conducted at a larger number of U.S. and international sites. Phase II trials expand upon testing in Phase I trials to include people who engage in behaviors that put them at high risk for acquiring HIV—may include injection drug users, and people who have unprotected sex and/or multiple sex partners. Phase II trials usually last about two years.

Phase III Trials — Phase III trials are conducted on a large scale with thousands of participants at many sites. Participants include people who engage in high-risk behaviors. The purpose of Phase III trials is to determine efficacy (how well or efficiently a vaccine works), and what type of immune response occurs. Phase III trials usually last 3 to 4 years.

Clinical Trial Participants

Who can join a study?

That depends on the trial and its phase. Each has different guidelines about who can be enrolled. Most studies however, require that participants be in good health and between the ages of 18 and 60 years. A history of serious allergic reactions or some medical conditions may exclude a participant, as well as certain prescription medications.

Informed Consent

Before joining a clinical trial a potential volunteer must be informed of all the risks, and their responsibilities as a participant (e.g., number of visits required, medical procedures). Informed consent requires the participant's *signed agree-*

ment to participate in the trial. Before they sign any documents, participants are asked if they understand and agree with everything about the trial. A written description of the study, along with opportunities to ask questions, is always provided to a potential volunteer before the trial begins. A volunteer may say no to participating at any time, and may drop out of the trial at any time.

What's involved in participating?

Joining a clinical trial involves agreeing to meet the schedule and requirements of the study. Based on the study protocol or plan, a series of vaccinations will usually be given to a participant over a period of time. Usually they are given by injection, but they can also be given orally.

Volunteers are asked to record any physical reactions that may occur after the vaccination, and to report them to the clinic. Commonly, these include sore arms, minor fevers or headaches.

During a participant's screening visit, they'll be informed of the specific vaccine or vaccines being tested in the study. Neither the participant nor the clinician knows whether the participant's receiving a vaccine or a placebo. This is called a "double blind" study and guarantees that all participants are studied the same way. After the trial is over, participants and clinicians are told if they received the vaccine or the placebo, or "unblinded."

Ways volunteers are protected

Institutional Review Boards (IRBs). Scientists, doctors, and others from the local community serve on IRBs to review and monitor their hospital's or research

institution's medical research involving people. They monitor studies to help make sure that there is the least possible risk to volunteers, and that the risks are reasonable in relation to the expected benefits. IRBs make sure volunteer selection is fair, and that informed consent is done correctly.

Data Monitoring Committees. These committees are used mainly when one treatment is being compared with another, and in studies where treatments are selected for patients at random. These committees are particularly important in tests of treatments for serious or life-threatening diseases. These experts review information from studies to make sure they are being done in a way that is safest for the volunteers. During a study, if the committee finds that the treatment is harmful or of no benefit, it will stop the study. If there is evidence that one treatment gives a greater benefit than another, the committee stops the study, and all volunteers are offered the better treatment.

FDA Inspections. The Food and Drug Administration routinely inspects the records of various scientists, clinics, and other research sites involved in a study. It aims to make sure volunteers are being protected and studies are being done correctly, and from time to time such inspections are done in response to complaints.

Community Advisory Boards (CAB). Almost every clinical trial site has a CAB, which is a voluntary organization of individuals who are participating in a clinical trial, or are members of the local community who are interested in HIV clinical trials. CABs serve as the eyes and ears of the community, providing education and serving as the liaison between vaccine volunteers and the staff at the trial site. Issues that CABs may deal with include: ensuring that volunteers understand research protocols, the informed consent procedures, ensuring ease in scheduling appointments, etc.🔗

ClinicalTrials.gov

The U.S. National Institutes of Health, through its National Library of Medicine, has developed *ClinicalTrials.gov* to provide patients, family members and members of the public current information about clinical research studies.

For more information, go to <http://www.ClinicalTrials.gov> to learn about clinical trials, trial updates, vaccines, and more.🔗

Community Advisory Boards Taking Science to the Community

By Houkje Ross

H*IV antigenic variability...phylogenetic analysis...nucleotide sequences of the envelope (env) and core (gag) genes...* The language researchers use to describe the science behind the search for an HIV vaccine reads like a foreign language. Even for the college-educated person who works in health care, obtaining a clear understanding of HIV, AIDS, clinical trials, and vaccines can be an arduous task, admits Barbara Nasir.

Talking about Science

“I have an entire glossary of terminology that the researchers use when talking about HIV vaccines and clinical trials. I still feel like I have a lot to learn before I can teach someone else,” said Nasir, a nurse who works as an HIV case manager with the Baltimore City Health Department. Nasir is also the co-chair of the Baltimore HIV/AIDS Community Advisory Board (CAB). The CAB is affiliated with Johns Hopkins University, which receives its funding from NIH.

CABs—required by any government-sponsored clinical trial site—act as the voice for clinical trial participants and the community. The roles of CAB members include:

Serving as the liaison between trial participants and trial staff.

Trial participants can go to CABs to voice concerns about any aspect of the trial. CABs also assist with recruitment efforts by advising sites where they should place advertisements, what radio stations to work with, what languages to use, and what visuals (photos, posters, etc.) are most likely to work with specific communities.

Help to build trust between researchers and the community.

Key to building trust is being able to communicate the science of HIV vaccine trials. For this reason, CABs often focus on what messages and information are shared with the community, and through what vehicles and languages.

CABs are independent of the clinical trial. They provide advice to the trial staff, but do not have to answer to them. Their role is to ensure that the trial is meeting the needs of the volunteers, and that the volunteers’ best interest is maintained. Most CABs have strong working relationships with the sites, but disagreements can and do occur.

CAB membership—which is open to anyone interested, regardless of whether or not they are in a clinical trial—can range from 5 to 50 people. Members are volunteers and like any group of volunteers, membership fluctuates.

Members of the Baltimore Alliance for the AIDS Effort (BRAVE)—a CAB affiliated with the University of Maryland’s

Institute of Human Virology (IHV)—also struggles to communicate the science behind HIV vaccines. “We have a lot of work ahead of us in terms of educating the community,” said Sandra Wearins, director of Community Education and Recruitment at IHV, and a member of the BRAVE CAB.

Building Trust

CAB members are not responsible for recruiting participants into clinical trials, but they are there to help bridge the gap between researchers and the community. Because most of the clinical research in the past has been conducted on non-minority males, scientists now must make a concerted effort to ensure that all racial and ethnic groups and genders are included in research. This is important because drugs can work differently among diverse groups.

“As scientists, we need the community more than they need us,” said Wearins. But scientists can’t just walk into a community and expect willing trial participants, especially in the African American community. Many are still very suspicious of government-sponsored research because they have heard or read about the Tuskegee syphilis experiments. And a suspicious community means collaboration can’t exist,” she said.

Johns Hopkins University researchers have one of the highest recruitment rates of African American clinical trial participants (almost 30 percent), but still there is a huge barrier of distrust among Baltimore residents. At a recent town hall meeting sponsored by both IHV and the Hopkins CAB, community distrust was evident, noted many CAB members at a joint meeting of the two CABs.

Some of the questions asked at the town hall meeting: Why do you want to recruit so many African Americans into clinical trials? Are we being used as guinea pigs? How do I know you are telling me the truth? How do I know that what you are injecting me with is what you say it is?

“Good or bad, the community has started to talk about HIV vaccine clinical trials,” noted William Blattner, MD, associate director at IHV. Dr. Blattner said that the scientific community must become more aware of and address the trust issue. In an effort to establish and maintain a connection to the Baltimore community, BRAVE has created a logo—Imagine a World without HIV—and designed a brochure, all with the advice and input of the local community.

Both CABs mentioned in this article are part of a network created by the National Institutes of Health (NIH) called the HIV Vaccine Trials Network (HVTN). The HVTN is sponsoring 9 other university sites in the U.S. and abroad.

For more information about the HVTN and CABs, call HTVN at 206-667-6705. 

Does Private Industry Need A Push? Vaccine Act Could Provide a Nudge in the Right Direction

By Houkje Ross

Nearly four years ago former President Clinton challenged scientists to develop a vaccine by the year 2007. With only 6 years left, many think that scientists are moving too slow. Last year, the Washington, D.C.-based AIDS Vaccine Advocacy Coalition (AVAC), noted in its report, *7 Years and Counting... How can we overcome obstacles to an AIDS vaccine?*, that it was “impatient” with the progress of the development of a HIV vaccine. AVAC’s May 2001 report—*6 Years and Counting...*—notes that “the where-withal and expertise to develop an effective vaccine most clearly resides in industry. Yet industry has been a fitful contributor to the search.”

Sporadic Funding in Vaccine Research

The private industry does face some challenging obstacles when facing the task of developing an HIV vaccine. According to a April 2001 report by Chris Collins and Stephen F. Morin, Ph.D, *The Policy of AIDS Vaccines: Exploring Legislative Options for Advancing AIDS Vac-*

cine Research and Delivery, there are a number of obstacles that work to dissuade private pharmaceutical companies from investing in the research and development of an HIV vaccine. Some of these include:

High research expenses. The newest technology is often needed to develop HIV vaccines, which makes investing in research and development of an HIV vaccine expensive.

Uncertain payoff. Scientists are still unclear what approach to take in vaccine design, or if any approach at all will prove protective in humans. This makes it risky, and less likely that investors and pharmaceutical companies will want to commit to HIV vaccine development.

Long timeline. The timeline from initial product development to marketing a product, if the research proves successful, is many years. Many other drugs—like those for depression or heart problems—can be made quicker and cheaper.

The Collins and Morin report was

produced by the AIDS Policy Research Center & Center for AIDS Prevention Studies. The authors suggest that an “unprecedented partnership between the public and private sectors is needed to accomplish the timely delivery of an AIDS vaccine. This partnership will have to recognize the right of industry to seek profits, and the responsibility of government and philanthropies to expect real outcomes for public health when they provide funding and incentives.”

Congress Steps Up

Two bills were introduced to Congress this past Spring that would provide incentives for pharmaceutical and biotechnical companies to speed up research and development of HIV vaccines. ‘Vaccines for the new Millennium Act of 2001’, introduced in the House of Representatives in April would amend the Internal Revenue Service Code of 1986. The bill (H.R. 1504) would allow for a limited business credit for the costs of medical research related to developing vaccines against widespread diseases. Widespread diseases would include only those that according to the World Health Organization, cause more than one million deaths per year—such as tuberculosis, malaria, and HIV.

The Senate also introduced its own ‘Vaccines for the New Millennium Act of 2001’ in May (S. 895), which would help pharmaceutical and other biotech companies justify the hundreds of millions of dollars necessary to develop and license an HIV vaccine. The bill would provide a 30 percent tax credit for research and development expenses for vaccines for malaria, TB, and AIDS. It would also provide a refundable tax credit to biotech companies that are doing innovative research but are not yet making a profit, and

International Economics

Global spending on AIDS vaccine research and development is “pitifully small,” according to the International AIDS Economics Network, (IAEN), a non-profit organization that provides data, tools, and analyses on the economics of HIV/AIDS prevention and treatment in developing countries. IAEN estimates global spending to be between \$300 and \$600 million per year. (NIH alone spent nearly \$250 million in FY 2000). But most of those infected, approximately 90 percent according to NIAID, reside in the developing world.

The International AIDS Vaccine Initiative, a nonprofit organization based in New York, wants to make sure that any vaccine capable of stopping or slowing the AIDS epidemic is available and affordable to developing nations. In the past, it has taken approximately 10 to 15 years for a newly introduced vaccine (e.g. polio in the 1950s) to widely reach developing countries.

In response to these concerns, IAEN recently came out with recommendations for how the World Bank could accelerate an AIDS vaccine that would be effective and affordable for developing countries. *Accelerating an AIDS vaccine for developing countries: Recommendations for the World Bank*, can be found on IAEN’s web site at <http://www.iaen.org/vacc/>

...continued on page 12

Up Close and Personal: *One Man's Decision to Help Find A Cure*

By Houkje Ross

*Lamarr doesn't particularly like needles, but that hasn't stopped him from donating blood—he's even made it to the gallon club of the American Red Cross. He knew that participating in a clinical trial for an HIV vaccine would mean more needles, but, he signed up anyway.

Thousands of people volunteer to test AIDS vaccines. Some see it as their responsibility or duty in the fight to find a cure. Others like the idea of supporting research. Some do it because they want to set a good example for their children, or simply because they see it as a way they can help others.

The Shoe could be On the Other Foot

"I believe a vaccine is just waiting to be discovered and I want to help find it," said the 40-year-old Lamarr, who is a life-long D.C. resident. He was born at Columbia Hospital in Washington D.C. He has a daughter, Halah. She is six. He would like to see a HIV vaccine developed in her lifetime. But his daughter isn't the only reason Lamarr decided to become a clinical trial participant. Although he is HIV

negative, Lamarr has seen many people with the disease.

"In 1981, I worked with a guy who got sick. But the doctors didn't know what was causing his illness or how to treat it. I didn't see him for the last six months of his life...his illness was kept pretty hush hush. I think, looking back, that he died of AIDS. Then, about 1986 or '87, my uncle was in George Washington University Hospital. In the bed next to him was a man who was dying of AIDS. His family and lover were there...it was very sad."

"I just keep thinking that all these people are dying unnecessarily. Fifty years ago we didn't have AIDS. We should be able to come up with the technology to solve this," he said. "I'm just not the type of person who can sit back and do nothing. The shoe could very well be on the other foot," he said of his reason to participate in the clinical trial.

Lamarr was keenly aware of his own risk of getting infected and in 1998 after a relationship ended, he got tested. "I told myself if I tested negative I would participate in a clinical trial," said Lamarr. The test came back negative. Lamarr kept his word and signed up to participate in a

clinical trial being conducted by Johns Hopkins University's Center for Immunization Research. His family and friends were supportive. "They considered the goal, prayed for me, and congratulated my efforts," he said.

The Phase I clinical trial began in March 1999. The study aimed to test the safety and tolerance of a combination of 2 different vaccines. Sixty-four people participated in the trial. A team from Hopkins educated Lamarr about the clinical trial process and answered any questions he had. He wouldn't know if he was one of the 8 participants that received the placebo until the trial ended. Every month, Lamarr would go to either D.C. General Hospital or Johns Hopkins University, where he would be examined by clinical nurses. They would take his blood pressure, draw blood and monitor him closely for physical reactions. He got shots four times, and received a combination of 2 different vaccines. *Lamarr and the other participants know they cannot become infected with HIV from the vaccine.*

In April 2001, Lamarr was told in the un-blinding phase that he had received the vaccine, not the placebo. "Because I received the vaccine, I know that I will test false positive for a while. But this doesn't mean that I'm HIV positive. It just means that my body produced antibodies against the HIV proteins in the vaccine. The staff at Johns Hopkins was really good about explaining this to me before I started the trial. After a period of time I will revert back to negative," said Lamarr. He didn't experience any side effects from the vaccine and has no regrets. Well, maybe one. "I can't donate blood anymore because it might test positive for HIV. They keep calling me and I feel really bad about it," he said. &

*Names have been changed to protect privacy.

Where do I find a Clinical Trial to Join?

The AIDS Clinical Trials Information Service (ACTIS) is a free resource from HHS that provides information on clinical trials, vaccines, drug treatments and therapies, and international resources. ACTIS also has a database of current trials that are recruiting volunteers for HIV vaccines. If you or someone you know would like to participate in a clinical trial, call ACTIS at 800-874-2572. The web site, <http://www.actis.org> includes links to related HHS web sites that contain information on the clinical trial process.

Other resources for finding out about HIV vaccine trials include the *ClinicalTrials.gov* web site at <http://www.clinicaltrials.gov>. Part of the National Institutes of Health's National Library of Medicine, *ClinicalTrials.gov* provides patients, family members and members of the public current information about clinical research studies. &

In Her Own Voice: An American Indian Tells Why She is Participating in a Clinical Trial

By Houkje Ross

Sandra Wearins is a Native American woman from the Lumbee tribe. Originally from Pembroke, North Carolina, her family moved to Baltimore, Maryland, when she was nine. Wearins, a long-time public health professional, is currently the director of community education and recruitment at the Institute of Human Virology at the University of Maryland at Baltimore.

She is also a clinical trial participant in a Phase II trial that is testing safety and immunogenicity, or the ability of the vaccine to stimulate an immune response. Here, in Wearins own words, are the reasons why she decided to become a trial participant:

This was an ethical decision for me—what felt right inside. I have never known a Native American woman who has participated in a clinical trial in Baltimore City. We spend too much time blaming the White man for our plight. I don't believe that. And I don't believe that the scientists are the 'bad guys' we once

said they were. But, if it is true, then we have to stand up and do something about it. We need to have a voice. I want to be one Native American woman with a voice. But we also have to be a body because we are all genetically different... the vaccine that works in a White man might not work in a Native American woman.

When it comes to HIV and AIDS, I've seen too many people get sick and die over the years. Ten years ago, I would not have done this. I was one of those who was afraid. Even my son and daughter asked me, Are you sure you aren't going to get HIV from the vaccine? But I have learned a lot in the last 10 years and I know people who have participated in clinical trials and I know that they did not get HIV from a vaccine trial. To those who are still afraid: Yes, you have good reason to be afraid, if you are uninformed. The best way to alleviate fear is to have information and to become educated. 📌

Think you want to participate in a clinical trial?

Here are some things to ask:

The Clinical Trial.

What is the study about? Why are you doing the study? What will you do with the results?

Study Sponsors.

Who is running the study? Who are the researchers? Are they doctors or scientists? Who do they work for? Is the government a part of this study? Who is paying for the study?

Your Community.

How will the study be explained in my community? Is there a Community Advisory Board I can talk to? How are you finding people for this study? Is transportation or daycare provided for people in the study? Are you trying to recruit minorities?

Health Care Services.

Will I get free health care or other services if I participate? For how long? What are the benefits to participating?

Safety.

Is there a chance I may be harmed by participating in the study? Will I experience any side effects? If I get harmed, who will take care of me? Who is responsible? If I get harmed, will I need treatment? Who pays for treatment?

Privacy.

Who is going to see the information I give? Will my name be used with the information? What happens to the information I gave, if I quit the study? Is there a written guarantee of privacy?

Responsibilities.

How long will the study last? What are my responsibilities? How many times will I have to come to the clinic? Will I know if I am getting a placebo or a real vaccine?

After the Study.

What will happen to the information and results of the study? How will it be kept? How will the public learn about the results? Are you going to send me a copy of the results? When? What other studies are you planning to do here? 📌

OMHRC HIV/AIDS Services Focuses Efforts on Six Regions

By Houkje Ross

Over the last year, the Office of Minority Health Resource Center's (OMHRCs) division of HIV/AIDS Services has been providing technical assistance (TA) to six regions in the United States that have some of the highest incidences of HIV/AIDS. OMHRCs *Building Healthy Organizations: A Skills-Building Training*, which ran from the Spring of 2000 to Fall 2000, began with town hall meetings held in six cities—New Orleans, San Francisco, Houston, Washington, D.C., Chicago, and Miami.

The town hall meetings were the start of what Oscar Lopez, director of HIV/AIDS Services at OMHRC, hopes will be a continuing dialogue between OMHRC and community-based organizations (CBOs) and AIDS service organizations (ASOs). The meetings gave representatives from more than 150 CBOs and ASOs the opportunity to discuss the challenges and needs in providing HIV/AIDS services to communities of color.

Starting a Dialogue

“This isn’t the typical government approach of the past that came into a community and told it how to solve its problems. What makes OMHRC’s efforts unique is that we wanted to hear from representatives of each region what they needed in order to better serve their communities. We went with open ears and really listened to what each community was telling us. We wanted them to teach us how we could best help them,” said Lopez.

“What we learned was that many of the communities expressed anxiety about ‘cookie cutter’ approaches to trainings that many national AIDS organizations take on the road. These trainings often don’t leave room to consider the subtleties that make each city and community unique,” said Lopez.

To increase its impact in the six regions, OMHRC developed a two-step process that is more intimate and hands on, said Lopez. This is important when working with minority communities, many of which still harbor deep resentment and distrust of government agencies. First, OMHRC collaborated with the community and conducted the needs assessment. “Other Federal agencies have conducted similar needs assessments in these same six cities but never shared the results of their findings with the communities they interviewed. It only added to the resentment of government entities,” noted Lopez.

Secondly, results of the needs assessments were then used to tailor TA for each region. For example, a high influx of recent Haitian immigrants in Miami created a gap in services for this population. CBOs and ASOs wanted to know how to work with and reach out to the Haitian community. TA from OMHRC in Miami included a training with experts on Haitian communi-

ties. OMHRC continues to follow up in Miami with one-on-one support for the development of an HIV Haitian Coalition, which is now on its way to becoming an official 501(c)(3) organization.

Other cities like Washington, D.C., and Houston—which both have large populations of African Americans—were more interested in building faith-based communities that could address HIV/AIDS problems. Leaders in Chicago wanted broad training in cultural competency. Other regions wanted help in dealing with stress and burnout of its health care workers. OMHRC pulled together the resources, experts, and information to assist each region with its unique needs. Although the *Building Healthy Organizations* initiative has formally ended, OMHRC continues to support several CBOs and ASOs with on-going technical assistance.

OMHRC is also working on a second initiative targeted for the same six regions. Collaborating with the National Library of Medicine, part of the National Institutes of Health, OMHRC has developed a *Meet the Experts* series of two-day trainings on accessing HIV/AIDS health information and resources via the Internet. Some of the specifics include: learning the language of the Internet; discovering better ways to search for information; and recognizing reliable web sites. Those targeted for the *Meet the Experts Series* include executive directors, program managers, and staff who need to improve or sharpen their Internet searching skills. The second component of the series will focus on learning how to write grant proposals.

“Our first initiative taught us that one of the most important things to these communities is that they feel that they matter, that what they are doing is important and valued. Continuing our efforts with the same regions is an important step OMHRC can take to keep the dialogue going, and to recognize valuable work at the community level,” said Lopez. “It is also a testing ground for us to see what kind of impact we can have if we continually focus a lot of time, energy, and commitment to the same six areas,” said Lopez.

Both OMHRC initiatives are a part of a larger effort OMHRC has initiated to expand information services on HIV/AIDS through the Resource Center. The expansion was made possible with Congressional funding in support of a partnership between HHS and the Congressional Black Caucus. OMHRCs long-term goal is to help strengthen CBOs and ASOs by connecting them to the tools, training, and information needed to build strong organizations that can have an impact in each community.

To learn more about OMHRC’s HIV/AIDS Services, go to <http://www.hiv.omhrc.gov> or call 800-444-6472 and ask to speak to an information specialist. 

A Multi-Agency Effort

By Stephanie Singleton

While spending on vaccine research by the U.S. Department of Health and Human Services' National Institutes of Health (NIH) is projected to be nearly \$300 million this year, there are other Federal efforts being made in the vaccine research arena.

Federal, private, and public sectors are now all working together as HIV/AIDS has become a global epidemic with far reaching ramifications—economic hardship, scarce medical resources, diminished social conditions, and the staggering loss of human life.

Here's a thumbnail sketch of what just some Federal agencies are doing to find an HIV vaccine:

The National Institute of Allergy and Infectious Disease (NIAID) has been instrumental in forming partnerships between private and public sectors in HIV vaccine research and development. Some of these efforts include evaluating Phase I, II, and III vaccine clinical trials, both internationally and in the U.S.; program funding; training research investigators from developing countries; phase support of pre-clinical and clinical vaccine development; and assisting developing countries with building a foundation for potential clinical trials.

The Centers for Disease Control and Prevention (CDC) works with both private and public sector entities to develop links between communities and scientists related to the field of vaccine and other research. The agency assists those working on HIV vaccines by providing principal investigators with vaccine experience and help oversee evaluations of vaccine trials. The CDC helps communities design and evaluate HIV prevention strategies including doing research on why fear of vaccine/clinical trials exist in certain communities.

The U.S. Department of Defense's (DoD) U.S. Army Medical Research and Materiel Command (USAMRMC) conducts HIV vaccine research as this virus can present military-specific problems—troops are deployed to HIV endemic countries; the military's blood supply and new recruits have to be screened for HIV; and

there are 300-400 new HIV infections in the U.S. military per year. Efforts have resulted in developing diagnostic criteria for early stages of HIV, an accurate and low-cost blood test, and international research.

USAMRMC's U.S. Military HIV Research Program is involved with HIV-related activities in the U.S., Africa, Europe, South America, and Southeast Asia. Some projects include vaccine development targeted towards HIV strains found primarily in Africa and a Phase III HIV vaccine trial in Thailand.

The Walter Reed Army Institute for Research (WRAIR), within the USAMRMC, also conducts research on different types of drugs and vaccines against infectious diseases, including malaria and other tropical diseases, hepatitis, and HIV/AIDS.

WRAIR has partnered with the private sector to research vaccine development, support pre-clinical research, and conduct primate clinical trials.

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) does not conduct direct vaccine research but is responsible for ensuring the safety and efficacy of all vaccines developed. CBER and the CDC jointly manage the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety. VAERS collects information about side effects from vaccines licensed in the United States. 

Agency Web Sites

Contact the agencies listed below for more information on the vaccine research each is conducting.

For more information on what other Federal agencies are doing in vaccine research, contact the Office of Minority Health Resource Center at 800-444-6472.

Center for Biologics Evaluation and Research (CBER)

<http://www.fda.gov/cber/index.html>

Centers for Disease Control and Prevention (CDC)

<http://www.cdc.gov>

The Food and Drug Administration (FDA)

<http://www.fda.gov/>

National Institutes of Allergy and Infectious Disease (NIAID)

<http://www.niaid.nih.gov>

Division of Acquired Immunodeficiency Syndrome (DAIDS) at NIAID

<http://www.niaid.nih.gov/daids/>

U.S. Army Medical Research and Materiel Command (USAMRMC)

<http://mrmc-www.army.mil/>

U.S. Department of Defense (DoD)

<http://www.defenselink.mil/>

U.S. Military HIV Research Program

<http://www.hivresearch.org/>

Vaccine Adverse Event Reporting System (VAERS)

<http://www.fda.gov/cber/vaers/vaers.htm>

Walter Reed Army Institute of Research (WRAIR)

<http://wrair-www.army.mil/>

The Collaborative HIV Prevention Research in Minority Communities grant is designed to assist scientists/researchers improve their programs of research and obtain additional funding for their work.

Designed to increase the numbers of ethnic/racial minorities among principal investigators at NIH, CDC, and other equivalent agencies, investigators from the UCSF Center for AIDS Prevention Studies will assist developing an ethnic minority-focused HIV prevention research project.

Participants will spend six weeks in San Francisco for three consecutive summers (2002, 2003, and 2004) and will receive a stipend. The deadline is January 25, 2002.

For more information, contact Barbara Marin, Ph.D., Program Director, Center for AIDS Prevention Studies, 74 New Montgomery, Suite 600, San Francisco, CA 94105, bmarin@psg.ucsf.edu, 415-597-9162

Or, go to <http://www.caps.ucsf.edu/capsweb/projects/minorityindex.html>

Drug Abuse Aspects of HIV/AIDS and Other Infections is sponsored by the National Institute on Drug Abuse (NIDA). NIDA supports research on the natural history, epidemiology, etiology, pathogenesis, prevention, and treatment of drug abuse and drug abuse aspects of HIV/AIDS and other infectious agents for example, hepatitis B virus, hepatitis C virus, and other sexually transmitted diseases and tuberculosis. Applications are due September 1, 2001, and January 2, 2002.

For more information, go to <http://grants.nih.gov/grants/guide/pa-files/PA-01-023.html>

Vaccine Legislation...from page 7

it would provide a 100 percent credit on sales of vaccines for TB, malaria, and AIDS to poor countries.

To learn more about the proposed legislation, go to <http://thomas.loc.gov> and type in S. 895 or H.R. 1504 in the search field.

HIV/AIDS Clinical Research Grants are being offered by the Campbell Foundation, which supports alternative clinical approaches to the treatment and prevention of HIV/AIDS.

Although the grants initially provide support for only one year, the foundation will consider extending the grant for an additional year if there is evidence of progress, says Campbell Foundation program officer Ken Rapkin. Typically, between ten and twelve proposals, representing about half of the applications received, are funded each year.

Rapkin cautions, however, that the foundation only supports clinical laboratory research, and he urges potential applicants to check out the foundation's summary of previously funded projects before they apply to ensure that their proposals fit with the foundation's priorities. Deadline: Applications are accepted at any time.

For more information: Visit the Campbell Foundation web site at: <http://members.aol.com/campfound/index.html>

HHS Awards \$17.1 Million in Abstinence-Only Education Grants, announced HHS Secretary Tommy G. Thompson in July 2001. The award is for new grants to help 49 communities develop and implement abstinence-only education programs for young people age 12 to 18.

The new awards, called Community-Based Abstinence Education Grants, come in two categories: three-year implementation grants totaling \$15.6 million, and one-year planning grants worth nearly \$1.5 million that support training and community assessment activities.

Administered by the Health Resources and Services Administration (HRSA), a list of the community-based abstinence-only program grantees and their awards is available at: <http://www.hrsa.gov/Newsroom/releases/2001%20Releases/abstinenceonlygrants.htm>

A "Micro-Grant" Initiative, from the Department of Health and Human Services (HHS), plans to award hundreds of "micro-grants" to community organizations for activities that support the goals of Healthy People 2010, announced HHS Secretary Tommy G. Thompson recently.

The "micro-grants" are worth up to \$2,010 each. Grantees could use the money for such activities as developing anti-smoking campaign materials for local students, coordinating substance abuse prevention forums for parents in local schools, or other specific projects designed to promote prevention and improve health locally.

The funds will be distributed to local, nonprofit organizations in different geographic areas to support programs designed to increase the quality and years of healthy life of residents and to eliminate health disparities.

HHS will launch the new micro-grant initiative with a two-year pilot project. If all goes well, the approach could be expanded nationally. HHS will commit between \$500,000 to \$700,000 to a pilot project this year in order to study the potential of the micro-grant approach to further the goals of Healthy People 2010.

For more information about Healthy People 2010, including a copy of the Federal Register notice, is available at <http://www.health.gov/healthypeople>

Call the Office of Minority Health

Resource Center today at

800-444-6472

for additional funding information.

Or, go to the

OMHRC HIV/AIDS Services web site

at <http://www.hiv.omhrc.gov>

and click on Funding for the latest on

HIV/AIDS funding.

What is Your HIV Vaccine I.Q.?

Before you make any judgements about HIV/AIDS vaccine trials, take this quiz and learn your HIV Vaccine I.Q. Quiz answers are on the back, on page 14.

1. Scientists have already developed a vaccine that prevents AIDS?
True False
2. Only men who have sex with men or people who use drugs should be concerned about an HIV vaccine.
True False
3. You can get AIDS from participating in a clinical trial.
True False
4. You have to be infected with HIV to participate in an AIDS vaccine clinical trial.
True False
5. If I am in a vaccine trial, I don't have to worry about practicing safe sex or using injection drugs because the vaccine will protect me.
True False
6. If I am in a vaccine trial, no one will know unless I tell them.
True False
7. Most HIV vaccine trial participants are men.
True False
8. A vaccine that works in Africa will automatically work in the United States.
True False
9. If I participate in a vaccine trial, I will automatically test HIV positive.
True False
10. Before I volunteer for a vaccine trial, I will be told about all of the possible side effects that may occur.
True False
11. A vaccine is our only real hope of ending the AIDS epidemic.
True False
12. In the U.S., more than 60 percent of all new HIV infections are in racial and ethnic minorities.
True False
13. In the U.S., more than 50 percent of all new HIV infections are in young people under the age of 25.
True False
14. In the U.S., some 30 percent of young black gay men are already infected with HIV.
True False
15. People like me don't need to worry about AIDS.
True False
16. I want to learn more about HIV vaccine clinical trials.
True False

Answers to What is Your HIV Vaccine I.Q.?

1. **False.**
Scientists are still looking for an HIV vaccine and clinical trials are occurring in the U.S. and the world. Scientists estimate that we are still many years away from an effective vaccine.
2. **False.**
Some 20 percent of all AIDS cases in the U.S. and more than 50 percent worldwide are in women. Worldwide, 90 percent of all AIDS cases are transmitted heterosexually.
3. **False.**
All AIDS vaccines are man-made and cannot infect someone with HIV/AIDS. Because the virus mimics HIV, someone may test positive but in reality be HIV negative. Special tests can tell the difference.
4. **False.**
HIV prevention vaccine clinical trials only enroll HIV negative volunteers. HIV therapeutic clinical trials enroll HIV positive people. Prevention trials aim to prevent new infections. Therapeutic trials aim to keep people from getting sick once already infected.
5. **False.**
HIV vaccine trials try to determine whether a specific vaccine works. There is no guarantee that it will, so all participants are regularly counseled to continue to practice safer sex and not share needles.
6. **True.**
Unless you tell people yourself, only you and the vaccine team will know you are in a trial. Your participation is strictly confidential.
7. **True.**
Almost 95 percent of all vaccine trial participants are men, despite the fact that more than 25 percent of all new HIV infections are in women.
8. **False.**
Because there are different strains or types of HIV, a vaccine that works in Africa may not work in the United States. That's why there are clinical trials both in the U.S. and overseas to make sure we find a vaccine that works everywhere.
9. **False.**
Since the purpose of a vaccine is to stimulate antibody development, you *may* test HIV antibody positive. However, you will not be infected with HIV. There are special tests which are used to distinguish between vaccine produced antibodies and antibodies from actual infection. No vaccine causes AIDS.
10. **True.**
All volunteers go through an informed consent process, where the potential side effects are explained in detail and you are allowed to ask questions. In fact, before you are allowed to be a volunteer, you must sign a form that says you understand all potential side effects.
11. **True.**
Right now, some 16,000 people are infected everyday in the world. Approximately 40,000 are infected in the U.S. every year. A vaccine is our best hope of ending the epidemic.
12. **True.**
Blacks and Hispanics account for the majority of new HIV infections, unlike at the very beginning of the epidemic. Racial and ethnic minorities comprise about 27 percent of the U.S. population, but more than 60 percent of all new HIV infections.
13. **True.**
In fact, more than 25 percent of all new HIV infections are in young people under the age of 24 years old. Young black women and young black gay men are being particularly hard hit with HIV infection.
14. **True.**
In a survey of several large U.S. cities, 30 percent of young black gay men ages 24 to 29 were already infected. In Hispanics, 17 percent were already infected.
15. **False.**
Everyone is at risk for HIV infection. It is not who you are, but rather what you do that places you at risk for infection.
16. To learn more about HIV vaccine clinical trials, you can go to <http://www.nih.niaids.gov/vaccines>, the National Institutes of Health web page.

Publications

The HIV/AIDS Epidemic in the United States Fact Sheet presents an overview of the HIV/AIDS epidemic in the U.S., including trends over time, a current profile of AIDS cases, and the impact of the epidemic on particular populations. The fact sheet was released by the Kaiser Family Foundation and the Ford Foundation to mark the 20th year of the AIDS epidemic.

For more information, go to <http://www.kff.org/content/2001/3029> &

HIV Vaccine Handbook: Community Perspectives on Participating in Research, Advocacy, and Progress provides an overview of AIDS vaccine activism; vaccine vs. cure; clinical trials; participant rights issues; and vaccine trials and minorities. Also has a vaccine glossary and a list of publications and organizations for further information.

For more information, go to <http://www.avac.org> or call 202-387-5517. &

The “Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention” summary was released in July 2001 after a special review panel led by HHS' National Institutes of Health (NIH) met to examine the efficacy of condom use in HIV/AIDS transmissions prevention.

The panel, comprised of professionals from the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the U.S. Agency for International Development, concluded that male latex condoms can effectively reduce transmission of HIV/AIDS.

However, the panel's report also found that there is inconclusive evidence to determine the effectiveness of condoms in actual use for preventing most other sexually transmitted diseases (STDs).

For more information on the summary, go to <http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>. &

Organizations

AIDS Clinical Trials Information Service (ACTIS)

P.O. Box 6421
Rockville, MD 20849-6421
800-874-2572
<http://www.actis.org>

AIDS Vaccine Advocacy Coalition (AVAC)

1875 Connecticut Avenue, NW
Suite 700
Washington, DC 20009
202-387-5517
<http://www.avac.org>

The American Foundation for AIDS Research (AmFAR)

120 Wall Street 13th Floor
New York, NY 10005
800-39-amFAR (800-392-6327)
212-806-1600
<http://www.amfar.org>

Center for AIDS Prevention Studies

74 New Montgomery
Suite 600
San Francisco, CA 94105
415-597-9100
<http://www.caps.ucsf.edu/>

The Center for Immunization Research

Johns Hopkins University
School of Public Health
Hampton House
624 North Broadway
Baltimore, MD 21205
877-863-1374
<http://ih.jhsph.edu/cir/>

Six Years and Counting: Can a Shifting Landscape Accelerate an AIDS Vaccine?

discusses economic and industry issues regarding research and development of an HIV vaccine; tax incentives for vaccine R&D; public-private collaborations; role of NIH, media, and foundations.

For more information, go to <http://www.avac.org> or call 202-387-5517. &

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road, NE
Atlanta, GA 30333
800-311-3435
404-639-3534
<http://www.cdc.gov>

HIV Vaccine Trials Network (HVTN)

1100 Fairview Avenue, North
P. O. Box 191014
Mailstop D3-100
Seattle, WA 98109-1024
206-667-6705
<http://www.hvtn.org>

The Institute of Human Virology

The University of Maryland
at Baltimore
725 West Lombard Street
Baltimore, MD 21201
866-IHV-4HIV (866-448-4448)
<http://www.ihv.org>

International AIDS Vaccine Initiative

110 William Street
New York, NY 10038-3901
212-847-1111
<http://www.iavi.org/>

National Institute of Allergy and Infectious Disease (NIAID)

Building 31, Room 7a-50
31 Center Drive, MSC 2520
Bethesda, MD 20892-0031
301-496-5717
<http://www.niaid.nih.gov>

Understanding Vaccines provides information on how vaccines were discovered, a list of current diseases that are prevented by vaccines, how the immune system works and antibodies are created; naturally and artificially acquired immunity; types of vaccines; research and development of a vaccine; and a complete glossary of scientific terms related to vaccines.

For more information, go to <http://www.niaid.nih.gov/publications/vaccine/undvacc.htm> &

DEPARTMENT OF
HEALTH & HUMAN SERVICES
Office of Public Health and Science
Office of Minority Health Resource Center
P.O. Box 37337
Washington DC 20013-7337

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HIV Impact

Upcoming Conferences

September

Sept 5-8: AIDS Vaccine 2001 Meeting, Philadelphia. Philadelphia Marriott. Sponsored by the Foundation for AIDS Vaccine Research and Development. A biennial conference that presents the latest basic, clinical, and public health data relevant to AIDS vaccine development. For more information contact: Office of the Conference Secretariat, 703-535-6863 or go to <http://www.AIDSvaccine2001.org>

Sept 10-11: SIDA Esperanza Vida: 7th Annual Spanish Conference on HIV/AIDS. Miami. Sponsored by the Community AIDS Resource (Care Resource). Major topics covered at this conference include: mental health; nutrition; public policies; spirituality; treatment and prevention. For more information, contact Care Resource at 305-667-9296 or e-mail caidsedu@aol.com

Sept 13-16: United States Conference on AIDS 2001. Miami. Sponsored by the National Minority AIDS Council. Contact: Paul Woods 202-483-6622, ext. 343 or go to <http://www.nmac.org/usca2001/home.htm>

October

Oct 4-5: Growing Up with HIV/AIDS: Issues. Sponsored by St. Jude Children's Research Hospital. University of Tennessee Boling Center for Developmental Disabilities. Major topics covered at this conference include: adolescents and children with HIV/AIDS; community health planning; cultural factors; ethical issues, quality of life. For more information, call 901-448-2660 or go to <http://www.utmem.edu/bcdd>

October 19: Testing Advocacy Network Regional Meeting. New Orleans, LA. Sponsored by the National Association of People with AIDS as part of the National HIV Testing Campaign. Contact Catina Perkins-Gibson at 202-898-0414, ext. 111 or go to <http://www.nhtd.org/> or to <http://www.NAPWA.org>

November

Nov 30- Dec 2: Infected or Affected by the HIV/AIDS Epidemic? Empower Your Life. Bayshore, New York. Sponsored by the Gateway Center, Inc. Workshops on death and dying; emotions; families of persons with HIV/AIDS; and grief. For more information, contact: The Gateway Center, Inc. 613-968-4677, or go to <http://www.thegatewaycenter.com>