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9
8
7
6
5
4
3
2
1

8 Years and Counting...

What Will Speed Development of an AIDS Vaccine?

AIDS Vaccine Advocacy Coalition

May 1999

AIDS VACCINE ADVOCACY COALITION

May 18, 1999

Dear Colleague:

Enclosed is a copy of AVAC's newest advocacy report, *"8 Years and Counting: What Will Speed Development of an AIDS Vaccine?"*

This annual report chronicles events during the past year, with an emphasis on the major obstacles and opportunities in HIV vaccine development. We hope this report inspires you with ideas for advocacy. We encourage you to do more:

- Go to the AVAC web site (www.avac.org) and other HIV vaccine web sites (see this report p. 57) and read more of the latest news on HIV vaccine research and development. Find out how you can be involved in local and national vaccine advocacy efforts. Consider writing an article or essay for the AVAC web site or for your local community newspaper.
- Contact your local vaccine trial site, and ask about how you can get involved in their Community Advisory Board and the trials that they are currently running.
- If you can afford it, send a donation to AVAC, or to other not-for-profit organizations that work to speed progress toward an effective preventive HIV vaccine.
- Above all, get involved in the effort to end the AIDS epidemic. While work is being done for a preventive HIV vaccine, more is needed here in the US and internationally to advance HIV prevention programs, treatment research, and access to life-saving drugs and healthcare.

In our effort to promote well-informed and honest dialogue about HIV vaccine research, we have made this report available for free on the AVAC web site (www.avac.org). If you would like additional copies to be mailed to you, please send your mailing address, the quantity of reports that you would like, and a check or money order for the cost of postage ($2.00/report) to us in the envelope provided.

AVAC's mission is to speed the development of preventive HIV vaccines by analyzing obstacles to HIV vaccine development and advocating to remove those obstacles. AVAC is committed to achieving this mission without taking resources away from basic HIV research, drug development, or other prevention efforts. We hope that this report is useful to you, and supports your involvement in the effort to research and develop a preventive HIV vaccine.

Sincerely,

Sam Avrett, Executive Director

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PHONE: 202-387-5517 • FAX: 202-986-1345

AIDS VACCINE ADVOCACY COALITION

Controversy over clinical trials of short-course AZT in Africa foretells similar ethical debates for HIV vaccine trials. The Joint United Nations Programme on HIV/AIDS (UNAIDS) conducted a series of regional consultations on ethical issues of HIV vaccine trials in 1998, and is presently completing guidelines for ethically conducting preventive HIV vaccine trials. The UNAIDS recommendations will go to the Council for International Organizations of Medical Sciences (CIOMS) that sets international ethical guidelines for all biomedical research. AVAC participated in the UNAIDS process and made the following statement to UNAIDS in response to a November 1998 draft of the UNAIDS guidelines:

February 25, 1999

José Esparza, Team Leader, Vaccine Development
Department of Policy, Strategy, and Research
Joint United Nations Programme on HIV/AIDS (UNAIDS)

Re: Guidance Document on Ethical Considerations in International Trials of HIV Preventive Vaccines (November 1998 Draft)

Dear Dr. Esparza:

We are responding on behalf of the AIDS Vaccine Advocacy Coalition (AVAC) to the currently circulating draft of your Ethics Guidance Document. As you know, AVAC is a coalition of U.S. advocates formed in 1995 with the mission to speed development of preventive HIV vaccines. We work to analyze obstacles to HIV vaccine research and advocate to overcome those obstacles, our goal being an enhanced HIV vaccine effort without a loss of effort for basic HIV research, drug development, or other prevention research. As a citizen group, we have a particular interest in helping protect the rights of trial participants in our country and abroad.

Thanks to UNAIDS hospitality, several of our members attended the UNAIDS Geneva and Washington, D.C. ethics meetings and six of our members were able to attend one of the three regional ethics consultations, in Brazil, Uganda, and Thailand. Since then we have discussed these issues and your draft extensively. We believe that there is little, if any, disagreement that the general ethical principles of the Declaration of Helsinki, the Belmont Report, and CIOMS Guidelines must still apply to all medical research: respect for persons (autonomy), beneficence (doing no harm, maximizing possible benefits, and minimizing possible harms), and justice (equitable distribution of risks and benefits).

We believe that the most important finding in your recommendations is the consensus position that host countries should have the right to conduct Phase 1 and 2 trials without these having been preceded by trials in the sponsor country. Given the diversity of viruses and local needs, this change itself justifies the UNAIDS efforts to develop a Guidance Document...

...We would also like to comment on four crucial and debated topics:

I. Treatment of HIV Infection Acquired During Conduct of a Preventive HIV Vaccine Trial

We believe international ethical guidelines require that all participants in a medical study be assured that interventions provided are likely to be at least as advantageous to the individual as any available alternative. In a prevention trial, AVAC interprets this as a requirement to provide all volunteers a proven means of reducing the risk of getting infected. Specifically, an HIV vaccine study must provide all participants with health education and behavioral risk-reduction

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counseling that is proven effective, STD treatment, condoms, and clean needles. Moreover, if proven methods for preventing HIV infection change during the course of the study, the changes must be incorporated into the trial as soon as possible.

There is no universal consensus on whether participants who develop infection with HIV while participating in a vaccine trial are entitled to the 'best proven' therapeutic methods of treating HIV and concurrent infections, the 'standard of care' in the country where the study is being held, or something in between. This lack of universal consensus must be noted in the guidance document. The document should clearly state the consensus that simple referral is not sufficient, and that sponsors, hosts, and investigators must ensure that these volunteers are connected with the appropriate facilities and services that are predetermined to be available and acceptable in their country.

It is conceivable that an HIV vaccine that lowers viral load or prevents further HIV transmission would be of less use and less easily testable in a region with full access to Highly Active Anti-Retroviral Therapy (HAART), yet very useful in a region where it is as yet unavailable or ineffective for some reason. We should all work to make the best proven HIV therapies and care available globally. But, given that there may be benefits of preventive HIV vaccines in settings where there is not yet full access to antiviral treatments and care, AVAC believes that countries can decide ethically to evaluate whether a vaccine has benefit in their population at the currently highest attainable standard of care, while they also work toward ensuring greater access to treatment and care.

While AVAC believes there is no ethical requirement to provide a level of treatment that is not generally available to participants who get infected in a preventive vaccine study, it is imperative UNAIDS include a statement in this section saying that all countries, including those planning to host HIV vaccine studies, have an ethical responsibility to make a serious effort to raise their standard of care for all the HIV infected population to the best proven standards. UNAIDS should also specify that this ethical responsibility must be shared by drug manufacturers, international agencies, local NGOs, and sponsoring countries.

II. Control Arm of a Phase 3 Vaccine Trial

Our understanding is that until an HIV vaccine is shown to be partially effective somewhere, the control arm of preventive HIV vaccine trials can ethically be a biological placebo, with all control and vaccine arms of the study receiving behavioral risk-reduction interventions. If an HIV vaccine is eventually shown to be partially effective, that HIV vaccine should be used as a placebo in future preventive HIV vaccine trials unless there is compelling rationale to believe that the partially effective vaccine could not be effective in the host country. Such rationale could be, for example, significant antigenic differences between the partially effective vaccine and the circulating strains of HIV in the new study site.

III. Increasing Availability and Access to Effective Preventive HIV Vaccines

As you state, an effort must be made to have plans in place before Phase 3 studies start, and UNAIDS should make every effort to press for, broker, and secure such plans. We recommend that this UNAIDS guidance document elaborate on the role of international agencies, drug manufacturers, sponsoring countries, and host countries in increasing availability and access. There have been initial efforts by the World Bank and others to ensure availability of HIV vaccines after licensure and similar efforts to resolve intellectual property barriers to vaccine development and distribution. AVAC is supportive and hopeful for the success of these efforts,

but we recommend that HIV vaccine development and Phase 3 testing not be delayed until these efforts are complete, as appears to be stated in the final paragraph of this section...

IV. Selection of Vaccine Constructs

The issue of vaccine design and testing for local viruses is a difficult one. Ideally, it would be preferable to begin development with a vaccine construct designed to be appropriate for the specific region and epidemic in which it will be tested and used. However, given rapidly changing scientific knowledge about the relative significance of genetic and antigenic diversity of HIV, testing of other vaccine constructs may be justified if they are expected to be efficacious against circulating viruses or if the scientific knowledge gained will guide the design of vaccines appropriate for the region...

In closing, we do not in any way want our opinions and recommendations to interfere with the ability of participants and their representatives in developing countries to decide these issues for themselves. In fact, we believe that a most important principle should be that trial design must be relevant to the host needs and situation, otherwise it is by its nature unethical. Community input, including consultation with potential research participants, is essential for a host country's trial design process and ethical review process. As UNAIDS provides guidance and support to countries in developing national vaccine research plans and capabilities, we strongly encourage UNAIDS to support meaningful participation by community in those countries.

We also encourage a degree of international oversight by groups such as UNAIDS, who are not directly participating in the research, to ensure a degree of uniformity world-wide in approaching ethical questions and to provide an objectivity that the host and sponsor may not have in efforts to protect vulnerable participants. UNAIDS should clearly, actively, and forcefully promote such interests while facilitating timely solution of problems as they arise so that vaccine research can proceed as swiftly and ethically as possible.

We are faced with the challenge of doing ethical vaccine trials in an unethical world. This UNAIDS-sponsored consultative process has been useful in promoting discussion and some resolution of difficult ethical questions. We hope UNAIDS continues its involvement by working with local communities and countries to ensure that there is increased local capacity not only to define but to meet the highest possible ethical standards in all HIV vaccine trials. We at AVAC would be very happy to support this effort.

Sincerely,

AIDS Vaccine Advocacy Coalition

Sam Avrett, Executive Director

David Gold, New York
Adrian Marinovich, New York
Luis Santiago, New York
Bill Snow, San Francisco
Jim Thomas, St. Louis
Steve Wakefield, Chicago

NEWS FROM . . .

Congresswoman Nancy Pelosi

2457 Rayburn Building, Washington, D.C. 20515 202-225-4965

FOR IMMEDIATE RELEASE
March 24, 1999

Contact: Doug Lea
(202) 225-4965

Pelosi Introduces Legislation to Fight Infectious Disease On World TB Day

Bill would provide Tax Credit for Research on Vaccines Targeted at the World's Most Deadly Diseases

Rep. Nancy Pelosi (D-CA) today introduced the Lifesaving Vaccine Technology Act, legislation that would provide a tax credit for research and development on vaccines for the world's most deadly infectious diseases. "Every year, TB, malaria and HIV/AIDS kill over seven million people," Pelosi said. "If Congress is going to provide tax credits, let us pass a credit that can accelerate the fight against infectious diseases at home and around the world."

The Lifesaving Vaccine Technology Act is cosponsored by Rep. Charles Rangel (D-NY), ranking Democratic member of the House Ways and Means Committee. Companion legislation will soon be introduced by Senator John Kerry (D-MA).

"Vaccines are our best hope to control the epidemics of TB, malaria, and HIV/AIDS, yet there are significant disincentives for private sector research and development investment in vaccines for these infectious diseases," Pelosi said. "The legislation I am introducing today will leverage private sector resources, and encourage the market to work more effectively to address the biggest public health opportunities."

The Lifesaving Vaccine Technology Act would provide a 30% tax credit on qualified R&D expenditures on vaccines for malaria, TB, HIV, and other diseases that kill one million or more people annually. The credit would also apply to R&D costs for microbicides to prevent these diseases. Small companies could choose to pass a portion of the credit to equity investors who finance their R&D for one of the priority vaccines. Companies using the credit to produce a licenced vaccine would be obligated to establish a good-faith plan for global access to the vaccine.

The Lifesaving Vaccine Technology Act is supported by the American Public Health Association, the Global Health Council, the International AIDS Vaccine Initiative, the AIDS Vaccine Advocacy Coalition, and the Reproductive Health Technologies Project.

Provisions of The Lifesaving Vaccine Technology Act
H.R. 1274

I. Tax Credit

- Provides a 30% tax credit for qualified research and development costs associated with research on vaccines for malaria, tuberculosis, HIV, or other diseases that kill 1 million or more people annually. The credit would also apply to R&D costs for microbicides to prevent these diseases. The tax credit is based on the successful Research and Experimentation Tax Credit created in 1981.

- Small companies could choose to pass a portion of the credit to equity investors who finance their R&D for one of the priority vaccines.

- Companies that use the credit to develop a licensed product would be obligated to establish a good faith plan for the widest possible global access to the vaccine. Companies would *not* waive any rights to pricing, patent ownership, or proprietary information.

II. Sense of Congress

- Expresses the Sense of Congress that the President and federal agencies should work together in support of the creation and funding of multi-lateral international efforts, such as a vaccine purchase fund, to accelerate the introduction of priority vaccines into the poorest countries in the world.

- Expresses the Sense of Congress that flexible pricing for vaccines is one of several valid strategies to accelerate the introduction of vaccines in developing countries.

AIDS Vaccine Advocacy Coalition
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9 Years and Counting

Will we have an HIV vaccine by 2007?

An Agenda for Action
for an HIV Vaccine

By the AIDS Vaccine Advocacy Coalition, May 1998

AIDS VACCINE ADVOCACY COALITION

The mission of AIDS Vaccine Advocacy Coalition (AVAC) is to speed the development of preventative HIV vaccines by analyzing obstacles to vaccine development and advocating/lobbying to remove these obstacles. AVAC is committed to achieving this mission without taking resources away from basic HIV research, drug development or prevention efforts.

March, 1998

Dear Community Advocate,

We wanted to write to give you a quick update on the AVAC's activities and the National AIDS Vaccine Advocate's Forum (NAVAF) in San Diego, and to give you advance notice of some of what's in the works with AVAC for the months to come.

With only one part-time staff person and a handful of volunteers, 1997 was a busy year for AVAC: We wrote a report on liability issues, about two dozen articles for local community papers, and began researching and writing our first Report Card on vaccine development. We presented at conferences and for community-based groups. We organized the first national vaccine advocates meeting and worked with community-based groups and coalitions to build informed advocacy on HIV vaccines. We also worked to set up dialogue between high-level government officials and industry representatives.

In 1998 AVAC plans to continue to build our network of advocates and to improve our ability to keep these advocates involved. We plan to organize the second national vaccine advocates meeting, and to contribute to the public and activist discussions. We will keep writing our reports and articles, and keep building the funding and infrastructure to support this advocacy.

Enclosed you'll find the NAVAF mailing list, a helpful outline of Mary Allen's NAVAF presentation on Vaccine Basic Science, and a job announcement for our Executive Director position.

We look forward to staying involved with you in our common vaccine advocacy efforts.

Sincerely,

AIDS Vaccine Advocacy Coalition

Report Card on Vaccine Development due out in May

Keep a look-out for the AVAC Report Card, *"Nine Years and Counting: Are we on course to develop an AIDS vaccine by 2007?"* which is due for release in mid-May. In this report, as in our December 1996 report *"Industry Investment in HIV Vaccine Research,"* AVAC seeks to provide an independent, honest, well informed critique of current efforts toward an HIV vaccine. We hope this report furthers both dialogue and progress in the many organizations whose missions relate to public health and eradication of disease throughout the world.

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NATIONAL AIDS VACCINE ADVOCATES FORUM

Vaccine Basic Science

Mary A. Allen, R.N, M.S.

November 8, 1997

This forum is focusing on the current status of a vaccine to prevent AIDS. We will be answering questions such as:

- What do scientists mean by basic, preclinical and clinical research?
- What is a vaccine?
- What are the strategies involved in designing a vaccine to prevent AIDS?
- How does a vaccine to prevent AIDS get developed, tested and licensed?
- What is the role of the NIH and the community in this process?

Vaccine

A vaccine is a substance that teaches the immune system to recognize and defend against a disease-causing microorganism

A vaccine is a substance that teaches the immune system to recognize and defend the body against a disease-causing organism.

Commonly Administered Vaccines

Live attenuated:	Measles, Mumps, Sabin Polio (oral)
Whole inactivated:	Influenza, Salk Polio
Toxin-based:	Tetanus (lockjaw), Diphtheria
Subunit:	Pertussis (whooping cough), Hepatitis B

The vaccinations given in childhood against measles, mumps, whooping cough, and polio are weakened or killed forms of the viruses or bacteria causing these diseases. In live attenuated vaccines, the microorganism in the vaccine is too weak to make the child sick but is strong enough to stimulate the immune system to produce memory cells to the virus or bacteria. When the child is later exposed to the wild virus or bacteria, these memory cells are activated and attack the wild virus or bacteria very quickly and prevent the child from becoming sick.

Challenges in Designing a Vaccine to Prevent AIDS

- HIV continually mutates and recombines.
- HIV infects helper T cells, the immune cells that orchestrate the immune response.
- HIV can be transmitted as both free virus and in infected cells.
- There is no clearly identified natural immunity to HIV.

- HIV continually mutates and recombines. This may mean that a vaccine would need to protect the person against many strains of the virus. Vaccines against other viruses have only had to protect the person against one or a limited number of strains. The NIAID funds scientists to analyze the genes of the different strains of HIV through the ***HIV Variation Project and the HIV Sequence Database and Analysis Unit.***
- 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, needs to activate the very cells that are infected by the virus.
- HIV can be transmitted as both free virus and in infected cells. This may mean that more than one form of immune response must be activated to protect the individual.
- Researchers do not know what constitutes an effective immune response to HIV. It might be antibodies, activated immune cells, perhaps a third immune response, or a combination of immune responses.

Possible Outcomes of a Vaccine to Prevent AIDS

- Completely prevent infection: sterilizing immunity
- Allow brief infection, but block continued infection and eliminate the virus
- Allow chronic infection, but delay onset of AIDS
- Reduce transmission to others

Scientists consider several possible favorable outcomes of a vaccine to prevent AIDS.

- A vaccine could prevent infection entirely- so-called sterilizing immunity. This is not achieved with any licensed vaccines in use.
- A vaccine could permit the person to become infected briefly, but would prepare the person's immune system to block continued infection and eliminate the virus. The childhood vaccines against measles, mumps, and polio work in this manner.
- A vaccine could delay the onset of AIDS for many years, perhaps by which time a more effective treatment could be available.
- A vaccine might not prevent AIDS in the infected person but could reduce the transmission of HIV to others.
- *It is also possible that the vaccine would have no effect at all, or even make HIV disease progress more quickly.*

Specific Immune Response

Humoral Immunity	Cellular Immunity
Neutralizing antibodies	*CTLs*

Overview of the Immune System

- One of the purposes of the immune system is to protect the body against micoorganisms such as viruses. When viruses enter the body, they invade individual cells, take over the cell and use the cell's own machinery to produce more viruses.
- The immune system activates immune cells to destroy the invader. This activation of the immune system involves two main types of cells: B cells and T cells. B cells make antibodies, molecules that attach to and neutralize viruses floating free in the bloodstream, thereby preventing the viruses from infecting other cells. T cells can be helper cells or killer cells. Helper T cells organize the immune response. Killer T cells (known as CTLs) attack cells infected by viruses.
- Microorganisms such as viruses contain many molecules that are seen as foreign to the body. These different molecular shapes are called antigens, or epitopes. The B cells and T cells are activated by recognizing these antigens. Each individual T cell or B cell will only recognize and respond to its individual "destiny antigen".
- Once a T cell or B cell is activated by its destiny antigen, 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. This is the principle behind vaccines, such as the vaccinations we received in childhood against measles or mumps.

Basic, Preclinical and Clinical Research

Medical research is divided into basic research in the laboratory preclinical research in animals and clinical research in people. Basic research involves testing ideas in test tubes and in cells. If the results are promising, preclinical research begins in small animals.

Preclinical Research

- Does the vaccine appear to be safe?
- Does the vaccine stimulate a promising immune response? (*Is it immunogenic?*)
- Does the vaccine protect the animal against the disease?

- The primary reason to conduct animal research is to determine if the test vaccine appears safe. If it makes animals very sick, it might be too dangerous to use in humans.
- Second, researchers use animals to look for an immune response to the test vaccine -- to see if the test vaccine protects the animal against the wild virus. Researchers also look to see what type of immune response is found in animals that are protected but is missing from those animals that get sick.
- Vaccines are first tested in many different small animals such as rats, rabbits, hamsters and guinea pigs. If the results of that research are favorable, vaccines to prevent AIDS are then tested in non-human primates such as monkeys and chimpanzees.
- Remember that before we ever get to the point of clinical trials in humans, the test vaccine will have undergone many years of development and testing in test tubes, cells, small animals and, finally, in non-human primates.
- Only when these results show a test vaccine that appears to be both safe and promising is it tried in people.

How Do You Design a Vaccine to Prevent AIDS?

You start with an idea.

To design a vaccine to prevent AIDS, researchers must start with an idea or strategy. This strategy is based on what the scientist believes would be an effective immune response to HIV.

Targeting HIV Vaccines

- HIV exists in the body in two forms: free viruses and virus-infected cells.
- Neutralizing antibodies may be required to eliminate free viruses.
- CTLs may be required to eliminate HIV-infected cells.
- A vaccine against HIV may need to stimulate both neutralizing antibodies and CTLs.
- A third immune response or combination of responses could be the key to an effective vaccine against HIV.

There are two major kinds of a specific immune response: humoral immunity uses antibodies to defend against free viruses, and cellular immunity uses activated immune cells to destroy cells infected by the virus.

Humoral Immunity and HIV Vaccines

- Neutralizing antibodies attach to and neutralize free viruses, preventing the viruses from infecting additional cells, and permitting the body to destroy these neutralized viruses.
- "Boosting" with vaccines containing HIV envelope proteins may stimulate the immune system to make neutralizing antibodies to these proteins.

- In the childhood diseases such as measles and tetanus, people who recover from the disease are immune to the disease and have high levels of neutralizing antibody to the virus or bacteria. So, to develop a vaccine against HIV, researchers might focus on designing a test vaccine that would stimulate the body to produce neutralizing antibodies. These antibodies would attach to and neutralize free viruses, thus preventing these viruses from infecting any more cells, and permitting the body to destroy these neutralized viruses.
- To design this test vaccine, the researchers make an educated guess at what will cause the body to produce neutralizing antibodies. Some research indicates that the proteins in the HIV envelope (or outer coat) may stimulate the body to produce neutralizing antibodies. So, researchers have developed test vaccines based on synthetic forms of the HIV envelope.

Cellular Immunity and HIV Vaccines

- Activated immune cells (CTLs) attack and destroy the cells that have been infected by HIV.
- "Priming" with recombinant live vector vaccines such as vaccinia or canarypox carrying synthetic HIV genes may stimulate the immune system to make CTLs to the HIV gene products.

- Another strategy is to destroy the cells that have been infected by the virus. To do this, scientists try to design products that would stimulate the body to produce immune cells called CTLs that will attack and destroy virus-infected cells.
- Unlike some other viruses, HIV can be transmitted and can exist in the body in two forms: free viruses and virus-infected cells. So, a vaccine against HIV may be required to stimulate both neutralizing antibodies and CTLs.
- It is difficult to design a single product that can do both, so scientists are also combining two or more different products in order to achieve this goal. Of course, it is also possible that a third immune response is the key to protection against HIV.

Non-Human Primate Research

- The NIH funds primate centers to test experimental vaccines against HIV, SIV and SHIV in chimpanzees and monkeys.
- Chimps can be "infected" with HIV, but usually do not become sick with AIDS.
- Monkeys can be infected with simian immunodeficiency virus (SIV), a relative of HIV, but not all strains of SIV make monkeys sick.

- Other primates such as monkeys and chimps are the closest relatives to humans, so these animal models are used in developing HIV vaccines. Unfortunately, there are many difficulties with conducting research in monkeys and chimpanzees. It is especially difficult to conduct HIV vaccine research in chimps because although they can be "infected" with HIV, HIV does not seem usually to make chimps sick. Some chimps have had drops in their CD4 counts, but only one chimp has died of AIDS, and it took 10 years of repeated injections with different strains of HIV before this chimp became sick. A second chimp was injected with blood from the first chimp; this second chimp now has a wasting illness.
- Because of these difficulties with chimps, researchers have focused on using monkeys. Monkeys can be infected with simian immunodeficiency virus (SIV), a relative of HIV. Some strains of SIV don't make monkeys sick, but other strains cause monkeys to die of an AIDS-like disease. These deadly strains of SIV are called "pathogenic" to monkeys.

Non-Human Primate Research: SHIV

- Scientists have produced SHIV, simian-human immunodeficiency virus, by putting the outer envelope of HIV onto an SIV core.
- The monkey is immunized with a promising test vaccine against the HIV envelope.
- Later, the monkey is challenged with an injection of SHIV.
- If the HIV envelope test vaccine is effective, it may protect the monkey against the SHIV.

- However, researchers want to test vaccines to HIV - not SIV- in monkeys. Therefore, scientists have combined a strain of SIV with a strain of HIV to produce SHIV- simian-human immunodeficiency virus. SHIV is a virus with an outer envelope of HIV but an SIV core.
- The monkey is vaccinated with a promising vaccine against HIV envelope. Some time later, the monkey is challenged with an injection of SHIV. If the HIV envelope vaccine is effective, it may protect the monkey against the SHIV.
- ***NIAID funds primate centers to test vaccines against HIV, SIV and SHIV in chimpanzees and monkeys.***

Mucosal Immunity

- Approximately 80% of HIV transmission in the world occurs sexually.
- To be effective, an HIV vaccine may need to stimulate mucosal immunity.
- NIAID funds scientists around the country to study how vaccines can best be designed to stimulate mucosal immune responses to HIV and SIV infection, and to design tests to measure these responses. [*Cooperative Mucosal Immunology Group*]
- NIAID funds the *Mucosal Immunology Lab* in Birmingham to conduct research on human mucosal immune responses to test HIV vaccines in clinical trials.

- Most viral infections are transmitted by the virus entering the mucous membranes of the body, such as your mouth, nose, lungs, or genitalia. Approximately 80% of HIV transmission in the world occurs sexually. So, to be effective, an HIV vaccine may need to stimulate mucosal immunity. Little is known about how the mucosal immune system protects against viral infections.
- NIAID funds scientists around the country (**Cooperative Mucosal Immunology Group)** to study how vaccines can be designed to best stimulate mucosal immune responses to HIV and SIV, and to design laboratory tests to measure these responses.
- In clinical research on humans, the NIAID funds the **Mucosal Immunology Laboratory in Birmingham** to conducts research on human mucosal immune responses to HIV vaccines. Study staff take samples of vaccine volunteers' saliva, semen, vaginal and rectal secretions to see if these substances contain antibodies to the vaccine and if they can neutralize or kill HIV in the test tube.

Conformational Epitopes

- Antigens are protein molecules formed by linking amino acids together to assume a particular shape that immune cells can recognize.
- Scientists can link amino acids together to try to form a protein molecule, but it is difficult to produce a protein molecule that assumes the proper shape (conformation).
- Researchers are designing new synthetic forms of the HIV envelope molecule that will assume the same shape as the molecule of the wild virus *(oligomeric gp120).*

Antigens are protein molecules in which amino acids are linked to form into a particular shape. Scientists can string amino acids together to try to make a protein molecule, but the challenge is to make the molecule form the proper shape (conformation). Only the proper shape will be recognized by immune cells. Researchers are designing new synthetic forms of the HIV envelope molecule, so that the synthetic molecule will be same shape as it is in the wild virus ***[oligomeric gp120].***

Adjuvants

- Adjuvants are substances that enhance the immune response to the vaccine; they make the vaccine more effective.
- The NIAID also funds the study of adjuvants.

Adjuvants are substances that enhance the immune response to the vaccine; they make the vaccine more effective. The NIAID also funds research into the development of adjuvants which can be used for HIV vaccines.

Cytokines

Cytokines are chemical messages that immune cells secrete to communicate with each other.
Some cytokines cause immune cells to become more activated or powerful.
Scientists are designing clinical trials using as adjuvants to help vaccines work better.

Cytokines are chemical messages that immune cells secrete to communicate with each other. Some cytokines cause immune cells to become more activated or powerful; others cause immune cells to decrease their response. Scientists are working at trying to use cytokines as adjuvants to help vaccines work better. For example, the cytokine GM-CSF stimulates immune cells to respond more effectively to an invader. So perhaps it would be useful to combine it with a vaccine. **[AVEG protocol 033: vCP205 + GM-CSF]**

NIH Funding of Basic Research in HIV Vaccines

- Researchers need purified products to use in the laboratory, to identify the components of HIV and SIV. *The Antibody Serologic Project* focuses on designing these products.
- Researchers also need standardized immunology tests to test for and measure responses to SIV and HIV vaccines. *The Immunology Laboratory Support for Assessment of AIDS Vaccines in Non-human Primates* develops such tests.
- NIH funds teams of scientists from government, universities and industry to develop and test novel experimental HIV vaccine concepts in laboratory and animal studies. These teams form the *National Cooperative Vaccine Development Groups* or *NCVDG.*

- There are many other basic and preclinical research projects funded by the NIAID that are critical to the development of a vaccine to prevent AIDS. For example, researchers need purified products to use in the laboratory to identify the components of HIV and SIV. The ***Antibody Serologic Project*** focuses on designing these products.
- Researchers also need standardized immunology tests to measure responses to SIV and HIV vaccines. The ***Immunology Laboratory Support for Assessment of AIDS Vaccines in Non-human Primates*** develops such tests.
- One of the key components of the HIV vaccine effort is the NIH funding of teams of scientists from government, universities and industry to develop and test novel experimental HIV vaccine concepts in laboratory and animal studies. These teams form the ***National Cooperative Vaccine Development Groups or NCVDG.***

NIAID Funding of Basic and Preclinical Research

In the fall of 1997, NIAID awarded $13.1 million in 58 grants to conduct basic and preclinical research on HIV vaccines.

AIDS Vaccine Advocacy Coalition (AVAC)

November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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November 8, 1997 National AIDS Vaccine Advocacy Forum

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9 Years and Counting

Will we have an HIV vaccine by 2007?

An Agenda for Action
for an HIV Vaccine

By the AIDS Vaccine Advocacy Coalition, May 1998

9 Years and Counting: Will we have an HIV vaccine by 2007?

An Agenda for Action for an HIV vaccine by the AIDS Vaccine Advocacy Coalition, May 1998

Principles

Agencies funded to conduct HIV vaccine research and development must establish clearer plans and goals to expand the HIV vaccine pipeline.

The U.S. Government must be clear about who should take responsibility and accountability to achieve these goals.

Increased commitment, funding, and courage is required from all sectors.

Agenda for Action

1. The logical answer to meeting a ten-year goal is to do many things at once in a clearly planned effort.

2. A far greater number of clinical trials will need to be initiated if there is to be any chance of reaching a ten-year goal for an HIV vaccine.

3. Within the U.S. government, clearer lines of responsibility and accountability must be defined to achieve progress.

4. The Director of the NIH should take ultimate responsibility in adequately managing the HIV vaccine effort. He should submit an annual report to the President and Congress on progress in meeting the ten-year goal.

5. The Director of the NIH must ensure that the new intramural NCI-NIAID Vaccine Research Center is a driving force in vaccine development, and not just a reorganization of researchers already on the payroll placed in a new building.

6. The NIH must continue to create new and innovative mechanisms to fund targeted HIV vaccine research.

7. The Directors of NIAID and NCI must ensure that well-designed, comparative studies of promising vaccines be conducted in primates on a systematic basis.

8. The Director of NIAID must challenge his division directors to make funding more available for product development.

9. The Director of NIAID and the clinical trial investigators should be more assertive in recommending clinical evaluation of vaccine concepts.

10. The Director of NIAID should outline a clear process for deciding whether and when to move into Phase III efficacy trials.

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11. U.S. agencies such as the CDC, USAID, and the State Department, and leaders of the G-8 countries, the World Bank, and the UNAIDS, should increase support for international clinical trial activities.

12. The CEO's of the world's major vaccine companies must be publicly called upon to invest in HIV vaccine development. Companies like SmithKline Beecham must begin to play a significant role in the effort.

13. The President must take a direct and personal role in encouraging private and public HIV vaccine development efforts. The directors of the NIH and the National AIDS Policy Office should use their influence to enlist President Clinton and Vice President Gore in these efforts.

14. Non-government-sponsored research efforts need to move more quickly in certain areas of HIV-vaccine development. These efforts must be encouraged and provided with broad-based support.

15. AIDS-related conferences must provide increased opportunities for exchange of scientific information among vaccine researchers, developers and affected communities.

16. An International HIV vaccine purchase fund must be created. IAVI's proposal to launch the fund, which would be managed by an international agency such as the World Bank, should be actively supported.

17. Community advocates and not-for-profit organizations must increase their commitment to HIV vaccines.

18. Community members should continue to push for resolution of several participant's rights issues as Phase III trials are being considered and planned.

19. Affected communities continually need to address justified fears that vaccine research may siphon off funding for HIV drug development and other prevention efforts.

Founded in December 1995, AVAC's mission is to speed the development of preventive HIV vaccines by analyzing obstacles to HIV vaccine development and advocating to remove these obstacles. AVAC is committed to achieving this mission without taking resources away from basic HIV research, drug development or prevention efforts.

In this report, as in our December 1996 report Industry Investment in HIV Vaccine Research, AVAC seeks to provide an independent, honest, well informed critique of current efforts toward developing an HIV vaccine. We hope this report furthers both dialogue and progress in the many organizations whose missions relate to public health and eradication of disease throughout the world.

To order copies of this report of other AVAC reports, contact AVAC at:

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Fact Sheet

May 15, 1998

HIV/AIDS VACCINE RESEARCH

Overview: Since the AIDS epidemic began in 1981, more than 630,000 Americans have been diagnosed with AIDS and nearly 400,000 men, women, and children have lost their lives to this disease. An estimated 650,000 to 900,000 Americans are believed to be living with HIV.

The Clinton Administration has responded aggressively to the significant public health threat posed by HIV/AIDS with increased attention to research, prevention, and treatment. Overall funding for AIDS programs within HHS has increased by 86 percent to $6.8 billion in FY 1998, with funding for AIDS care under the Ryan White CARE Act rising 230 percent and support for AIDS Drug Assistance Programs increasing by 449 percent. The Medicaid program, which covers an estimated 50 percent of all persons living with AIDS, is also a major source of AIDS treatment funding.

Support for AIDS research at the National Institutes of Health (NIH) now totals $1.6 billion, an increase of 50 percent since FY 1993. In one of his first acts in office, President Clinton signed the National Institutes of Health Revitalization Act of 1993, establishing a permanent Office of AIDS Research at NIH to coordinate all AIDS research. Today, NIH Director Harold Varmus, MD, announced the appointment of Neal Nathanson, MD, as the director of the NIH Office of AIDS Research. Dr. Nathanson has served as a member of the NIH AIDS Vaccine Research Committee.

Development of an HIV/AIDS vaccine is a major component of the Administration's comprehensive approach to the global HIV/AIDS epidemic. On May 18, 1997, President Clinton announced that development of a safe and effective AIDS vaccine is "a global health imperative." He announced a comprehensive AIDS vaccine research initiative and challenged scientists and

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pharmaceutical manufacturers to work together to develop an AIDS vaccine within 10 years.

To date, the National Institutes of Health has evaluated 23 vaccine candidates and 10 adjuvants (substances that might enhance the effect of a vaccine) in 49 Phase I and Phase II clinical trials to determine the safety of the vaccine candidates and their effect on the human immune system. These studies have been conducted with 2,900 volunteers. NIH currently is exploring a new concept in a study involving 420 volunteers. It tests the effect of two different substances (ALVAC-HIV vCP205 and HIV SF-2 rgp 120) given simultaneously to enhance the human immune response.

Other Actions Aimed At AIDS Vaccine Development:

- AIDS Vaccine Funding. Funding for AIDS vaccine research at the National Institutes of Health (NIH) has increased significantly. Total funding in FY 1998 is $153 million, a 17.5 percent increase over FY 1997 and a 53 percent increases since FY 1995. The President's fiscal year 1999 budget includes $180 million for AIDS vaccine research, an increase of 17.5 percent over FY 1998 and an 80 percent increase since FY 1995.

- AIDS Vaccine Coordination. An AIDS Vaccine Research Committee was created in 1997 to improve the coordination of NIH-supported vaccine activities. The Committee is chaired by Nobel Laureate Dr. David Baltimore of the California Institute of Technology. The AVRC has developed a comprehensive AIDS vaccine research program and advised the NIH on scientific opportunities, gaps in current knowledge, and future directions of AIDS vaccine research.

- Innovation Grants. The Innovation Grants Program for Approaches in HIV Vaccine Research was launched in 1997 to encourage and support creative and novel research with promise for improving and speeding vaccine development. The program also is aimed at attracting new researchers into the AIDS vaccine development field. So far, 58 grants have been awarded, including 28 grants to investigators new to AIDS research. Total funding for the program this year is $13.1 million.

- Vaccine Research Facility. Construction will begin this fall on a new vaccine research facility on the NIH campus in Bethesda, MD, to house the new Vaccine Research Center (VRC), which initially will focus on AIDS vaccines. The VRC will bring together scientists with expertise in immunology, virology, and HIV vaccine research. It will stimulate multidisciplinary research from basic and clinical immunology and virology to vaccine design and production.

Questions and Answers
AIDS Vaccine Development

Question: Is the President failing to provide leadership in AIDS vaccine research?

Answer: The President has provided unprecedented leadership on AIDS and on the effort to develop a safe and effective AIDS vaccine. In his five and a half years in office, the President has increased overall funding for AIDS research, prevention, and care by 86 percent. Funding for AIDS treatment under the Ryan White CARE Act has risen 230 percent and funding for AIDS drug assistance programs has jumped 449 percent.

One of the first actions the President took once he was in office was to sign the NIH Revitalization Act of 1993, creating a permanent Office of AIDS Research at NIH to coordinate all AIDS research. That office has provided tremendous leadership not only at NIH but throughout the research community.

The President also created the Office of National AIDS Policy at the White House, held the first-ever White House Conference on HIV and AIDS, and launched a comprehensive AIDS vaccine initiative. He also has been working with the leaders of the international community to assure a global effort. In fact, he plans to raise this issue again at the G-8 meeting.

It's important to recognize that scientific breakthroughs don't happen overnight, but the President is confident that we are on the right track and that we have the best minds in science at work. He is committed to working with the Congress to assure that there is enough funding in the budget to support these efforts and he will continue to work with private industry and nations around the globe on this matter.

Question: How do you respond to criticism that the President's AIDS vaccine initiative is a failure?

Answer: The President is very pleased with the progress to date on AIDS vaccine research. We have increased funding for AIDS vaccine research to $153 million in FY 1998, an increase of 53 percent since 1995. The President's FY 1999 budget includes $180 million for AIDS vaccine research. That would represent an 80 percent increase in just four years.

Nearly 40 AIDS vaccines are being evaluated in clinical trials worldwide, including 23 at the NIH. Additional studies are being conducted on substances that might enhance the effectiveness of an AIDS vaccine. Nearly 3,000 volunteers are participating in these trials, a remarkable commitment to saving lives.

But we all must recognize that research and development of an AIDS vaccine is not an easy task. HIV poses numerous scientific challenges unlike any other virus in history. The President recognizes that success in developing a safe and effective AIDS vaccine requires a long-term commitment and a long-term investment of resources and scientific brainpower. That is why the President has made a long-term commitment to this effort and has backed that up with added resources, coordination, and leadership.

Question: When will the director of the NIH vaccine research center be appointed?

Answer: Creation of the AIDS Vaccine Research Center is a critical component of the President's comprehensive strategy to develop an AIDS vaccine. Construction of the facility to house the center will begin this summer and is scheduled for completion in the Spring of 2000. Appointment of a director of the center is very important. NIH is conducting a national search for the most qualified candidates and we hope to have an appointment by the end of this year. Today, NIH Director Harold Varmus, MD, announced the appointment of Dr. Neal Nathanson, a distinguished scientist and a member of the AIDS Vaccine Research Committee, to serve as Director of the Office of AIDS Research. This is a critical leadership position in the global effort to end the epidemic.

NIH NEWS RELEASE

NATIONAL INSTITUTES OF HEALTH Office of the Director

NIH NAMES NEW DIRECTOR FOR AIDS RESEARCH

For Immediate Release
Friday, May 15, 1998

Contact: Anne Thomas
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NIH Director Harold Varmus, M.D., has named Neal Nathanson, M.D., to serve as the new Director of NIH's Office of AIDS Research (OAR). Dr. Nathanson, a world leader in viral pathogenesis, has a broad background in virology, epidemiology, and public health. He is an active member of the NIH AIDS Vaccine Research Committee, chaired by Dr. David Baltimore.

"Dr. Nathanson brings a powerful scientific intellect, great compassion, and long administrative experience to the task of leading the NIH AIDS research program at this critical time. He will have a central role in our continuing efforts to develop an effective vaccine, improve treatments for HIV disease, and prevent transmission of HIV," said Dr. Varmus. The previous OAR director, Dr. William E. Paul, returned last November to the Laboratory of Immunology at the National Institute of Allergy and Infectious Diseases, and has extended his activities to help search for an effective HIV vaccine. Dr. Jack Whitescarver has been serving in the interim as the OAR Acting Director.

The OAR, located within the Office of the Director of NIH, is responsible for coordinating the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program, as well as the promotion of collaborative research activities in domestic and international settings. OAR conducted the first comprehensive evaluation of the NIH AIDS research program. The final report, known as the "Levine Report," provided a blueprint for restructuring the NIH AIDS research program to streamline research, strengthen high-quality programs, eliminate inadequate programs, and ensure that the American people reap the full benefits of their substantial investment in AIDS research.

In implementing a key recommendation of that report, the OAR has made HIV vaccine development a high priority, restructuring and revitalizing the program, and providing significantly increased resources. Dr. Varmus also stated, "The recruitment of Dr. Nathanson to serve as OAR Director will further enhance our deep commitment to vaccine research."

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Dr. Nathanson was educated at Harvard University, where he received both a BS and an MD degree, followed by clinical training in internal medicine at the University of Chicago and postdoctoral training in virology at Johns Hopkins University. Early in his career, Dr. Nathanson spent two years at the Centers for Disease Control where he headed the Polio Surveillance Unit. Later he joined the faculty of the Johns Hopkins School of Hygiene and Public Health where he became Professor and Head of the Division of Infectious Diseases in the Department of Epidemiology. He then moved to the University of Pennsylvania Medical Center where he chaired the Department of Microbiology for 15 years, finally serving for two years as Vice Dean for Research and Research Training.

Dr. Nathanson is known particularly for his contributions to the field of viral epidemiology as the author of the definitive papers on the epidemiology of polio. During a research career spanning 35 years, he has worked with a large number of viruses and disease conditions, and has made many important contributions such as the clear delineation of the two major routes by which poliovirus could be disseminated in its host, the introduction of immunosuppression to understand the role of the immune response in recovery from primary viral infections, the demonstration that lymphocytic choriomeningitis could be prevented or enhanced by immune manipulation, and the detailed genetic analysis of bunyavirus virulence. He did some of the early studies of visna virus of sheep, the prototype of the lentiviruses, of which the AIDS virus is another member. In recent years, his NIH-sponsored work has included studies in the mechanisms by which HIV causes disease.

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