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wise words

hiv/aids treatment information & advocacy by and for women

Vaccine basics

We often think only about how vaccines might protect us from infection, however, they can also protect those around us from getting sick. Researchers have found that vaccines are one of the safest and least expensive ways of reducing illness and death in a community. Some of the most important public health triumphs have been in vaccine development, such as the small pox and polio vaccines. This is an introduction to vaccines, how they work in our body and the different kinds of vaccines available today.

The immune system is our defense system for recognizing and eliminating infections or "foreign invaders." It is made up of a network of specialized cells and organs. When the immune system is functioning properly, it can tell the difference between foreign invaders and the body's own cells and will create a response to eliminate or neutralize the invader. There are different types of immune responses, those we were born with (*innate* immunity) and those we learn (*acquired* immunity).

When we get sick, some of the symptoms we experience such as fever or rashes are actually caused by our immune system's attack on the invader. The time it takes for our body to recognize and respond to a new infection generally takes several days. Once a robust and effective response has been learned, the immune system will attack and control the infection. If our body confronts that specific infection again the learned (acquired) responses swiftly kick into high gear and contain it before it causes a problem. This immunologic memory of how to fight a disease is stored in what are called memory B cells and/or memory T cells. In general, once a specific (HIV or other) immune response has been mounted, that response becomes part of our immunologic memory.

A vaccine is a substance that teaches the immune system how to recognize and defend against bacteria and viruses that cause disease. Vaccines are made by using the same components that are found in the natural virus or bacteria, using made man materials, or a combination of both. A vaccine is not a cure, but can prevent infection or slow disease progression.

One example is the flu (influenza) vaccine. Just before flu season comes around many people get a flu shot (vaccine). This is a severely weakened form of the flu virus, or a man-made flu virus particle that prompts an immune response without causing disease. The weakened or man-made particle is mixed in with something that helps to stimulate our cells to respond. Sometimes this response causes a mild fever, swollen joints or stiffness, which are common signs that the immune system is doing something. When flu season arrives, the flu vaccine should have armed your immune system to respond to the new flu virus so that it is controlled and you will not experience symptoms of the flu. Once an immune response has been learned, it can be a swift and potent first line of defense against disease.

WHAT'S WISE INSIDE

Greetings Wise Women!!

Welcome to the first issue of Wise Words for 2004! As we move forward in research and developing new technologies to treat HIV, vaccines are increasingly becoming an interest to many communities. While the world of vaccine research can be complex and overwhelming, understanding the basics can help you to grasp what would otherwise be very confusing.

This issue of Wise Words provides some basic information about vaccines (both preventive and therapeutic HIV vaccines) and a useful tool that you can take with you to your doctor. In our policy section, we talk about the decreased funding for the AIDS Drug Assistance Program and one woman's journey to advocacy.

As always, your feedback is crucial. Please continue to email or call with your comments and suggestions.

Shalini Eddens
Women's Program Manager

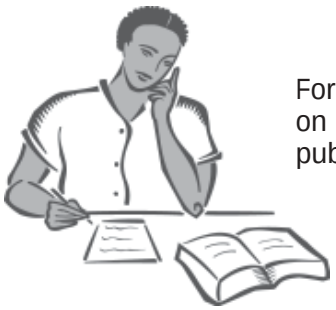
Wise Words is a program of PROJECT inform

Types of vaccines

The chart below is a list of some vaccines and the diseases they protect against. The remaining articles in this issue provide a deeper understanding of several specific vaccines and the types of vaccinations most critical for people living with HIV. Vaccines protect not only you but also everyone around you.

the various types of common vaccines

vaccine type	disease	advantage	disadvantage
Live, weakened vaccines	measles, mumps, rubella (German measles), polio (Sabin vaccine) and chicken pox	Produces a strong immune response so can provide life-long immunity with 1–2 doses.	Not safe for people with compromised immune systems. Needs refrigeration to stay potent.
Inactivated or "killed" vaccines	Cholera, flu, hepatitis A, rabies, polio (Salk vaccine)	Safe for people with compromised immune systems. Easily stored and transported; does not require refrigeration.	Usually requires booster shots every few years to remain effective.
Subunit Vaccines	Hepatitis B	Lower chance of adverse reaction.	Research can be time-consuming and difficult.
Conjugate Vaccines	Haemophilus influenzae B (or Hib) and pneumococcal vaccine	Safe for people with immune compromised systems.	Usually requires booster shots every few years to remain effective.



For more information on vaccines, read Project Inform's publication, *Vaccines*.

1 = 2 ?

Two-for-one vaccination for hepatitis A and B

Hepatitis A and hepatitis B are the two most frequently reported diseases that can be prevented by vaccines. The combination vaccine called Twinrix® combines two vaccines—Havrix® for hepatitis A and Engerix-B® for hepatitis B.

This combination vaccine is recommended for those at risk of exposure to hepatitis A and hepatitis B viruses. People at risk include those living with HIV. The Twinrix® vaccination is a series of at least three shots, the second shot follows the first by about a month and the third shot should happen between six months to one year after the first shot. Once you complete the vaccination series, you are protected from both diseases.

An anti-body titer is a blood test to check whether your immune system mounted a protective response (made enough antibodies) to the two viruses to guard against both diseases. If your antibody titer is not high enough, another vaccination and blood titer are usually recommended.

Some people with HIV may need more than three shots to stimulate the immune system to make enough antibodies to guard against hepatitis A and B. Others, particularly those with very low CD4+ cell counts, may not be able to make enough antibodies to be considered successfully vaccinated. If you have not been vaccinated for hepatitis A and/or Hepatitis B—talk to your doctor about getting vaccinated. (For more information about hepatitis, read Project Inform's publications, *Hepatitis, Hepatitis C,* and *Wise Words #12.*)

Numerous therapeutic HIV vaccine studies have taken place over the years. Though, none have produced impressive results, there continues to be interest in this type of approach. Theoretically, a therapeutic vaccine might offer the potential for a monthly injection with few side effects as a way to treat HIV, prevent or delay the need for anti-HIV medications and/or allow for prolonged periods of time off of anti-HIV medications. This potential is what keeps research in this area going despite disappointing study results.

The goal of a therapeutic vaccine is to bolster immune responses against HIV in hopes of boosting the body's ability to control HIV replication. For most people, natural immune responses against HIV are not enough to control HIV disease for the long-term. It is hoped that by boosting immune responses artificially that HIV disease progression could be prevented or significantly delayed.

Who participates in therapeutic HIV vaccine studies?

Studies of therapeutic vaccines focus on people with HIV who are healthy with relatively intact immune systems. Most studies have included people with CD4+ cell counts above 250 at study entry. Many studies require people to have even higher CD4+ cell counts at study entry, above 300 or 500, and also require that a person never had a CD4+ cell count below 250. Most studies of therapeutic HIV vaccines will require people to take anti-HIV medications while they are receiving the experimental vaccine.

People with lower CD4+ cell counts are generally not included in studies of therapeutic HIV vaccines because the effectiveness of a vaccine is dependent on immune function. If a person has poor immune status, vaccines are unable to induce new immune responses or bolster existing responses. Thus, therapeutic HIV vaccines will likely never prove useful for people with advanced-stage HIV disease and low CD4+ cell counts.

Many therapeutic HIV vaccine studies currently ongoing include some period of time off all therapy. Taking people off all therapy after they have received a therapeutic HIV vaccine might show if the new immune responses are able to prevent HIV from reproducing without the help of anti-HIV medicines.

Are there side effects of therapeutic HIV vaccines?

Each product will carry its own unique risk of side effects. In general, however, side effects associated with experimental therapeutic HIV vaccines have been similar to side effects of commonly available vaccines. That is redness, swelling and/or pain at the site of the injection and sometimes mild flu-like symptoms.

Side effects could be more serious than mild pain or flu symptoms, however. They could include more severe pain and/or ulceration at the site of injection.

If the vaccine was made out of whole-killed or live-crippled HIV, it's possible that the virus in the vaccine could combine with a person's HIV and potentially become infectious. One therapeutic vaccine, HIV-Immunogen (Remune), is a whole-crippled form of HIV. In studies to date there is no evidence that it worsened anyone's HIV infection. There is also no evidence to date, however, that it has benefited anyone.

Are there other risks of participating in a therapeutic vaccine study?

It is possible that an experimental therapeutic HIV vaccine could stimulate HIV replication and increase the risk of HIV disease progression. Vaccination stimulates and activates the immune system and this has been associated with increases in HIV replication. Also, immune responses brought about by vaccination could possibly enhance the ability of HIV to infect cells.

It is possible that people who receive an *experimental* therapeutic HIV vaccine that doesn't work will not benefit from an *effective* therapeutic HIV vaccine. It is very likely that people who participate in a study of a therapeutic HIV vaccine and receive the experimental vaccine (rather than the placebo) will not be eligible to participate in studies of other therapeutic HIV vaccines and other experimental anti-HIV and immune-based approaches.

Are there possible benefits to participating in these studies?

It is possible, by participating in an experimental therapeutic HIV vaccine study, that the vaccine will be effective in slowing or preventing HIV disease progression. People who received the vaccine (rather than the placebo) will have gained earlier access to an effective therapy.

Conclusion

Ultimately the decision to participate in an experimental drug study is a very personal decision. Products tested so far have had relatively few side effects, but results from studies aren't very encouraging. New products that boost the immune system differently and/or more potently are constantly entering small studies. Currently most (if not all) studies of therapeutic vaccines require that people be on anti-HIV therapy, and most studies include some period of time off all therapy following vaccination.

Vaccine recommendations for adults living with HIV disease in the United States

Based on recommendations from the Centers for Disease Control (CDC)

Vaccine	Recommended for people with HIV?	Number of vaccinations	Additional information
Influenza	Yes	One vaccination per year.	FluMist®, a live attenuated influenza vaccine (LAIV) inhaled through the nose, should not be used by people with HIV.
Pneumococcal	Yes	One vaccination with a booster vaccination after five years.	Vaccination is recommended soon after you find out you have HIV disease.The vaccine protects from pneumococcal infections in the lungs only.
Hepatitis B virus (HBV)	Yes	Three vaccinations.	A blood test (HBV antibody test) can tell if you have been exposed to HBV. After completing the series, a blood test (antibody titer) will tell you if you need another booster shot for protection. (Note: Twinrix® is a three-shot hepatitis A/B combination vaccination.)
Hepatitis A (HAV)	Yes	Two vaccinations.	A blood test (HAV antibody test) can tell if you have been exposed to HAV. Most doctors recommend an HAV vaccination for people living with HIV. (Note: Twinrix® is a three-shot hepatitis A/B combination vaccination.)
Tetanus/ Diphtheria (Td)	Yes	Three childhood vaccinations followed by one booster vaccination every 10 years.	
Measles, Mumps and Rubella (MMR)	Depends	MMR is two vaccinations. Rubella alone is one booster vaccination.	Check your childhood and young adult medical history. • If you *have* already been fully vaccinated for MMR, you may not need another vaccination. • If you do not know or *have not* been completely vaccinated, talk with your doctor about whether or not the MMR vaccination series would be right for you. People with no symptoms of HIV and CD4+ cells above 200, especially women planning on getting pregnant, should talk with their doctors about the rubella vaccination. The CDC does NOT recommend the MMR vaccination, or other measles containing vaccines, for people living with HIV whose CD4+ cell count is either below 200 cells/mm3 or whose CD4+ cell percentage is below 14% of their total lymphocytes.
Varicella (the virus that causes chicken pox *and* shingles)	No	One to two doses depending on age.	The Varicella vaccine is currently NOT recommended for people living with HIV.If you have NOT had Varicella, avoid contact with children and adults who currently have either active chickenpox or shingles.

Talking to my doctor about vaccinations

People living with HIV see their doctor multiple times a year for HIV specific monitoring and care issues. In addition to HIV-specific medical care, keeping up to date with vaccinations is important for maintaining overall health and well-being. The checklist below can help you identify specific questions or issues about vaccinations that you would like to discuss with your doctor.

I would like to talk about ...

☐ **The influenza vaccination ("flu shot") because:**

- o I have questions about the flu vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I would like to talk about your thoughts, recommendations or concerns about the flu shot.
- o It is the time of the year for a flu shot (fall/winter).

☐ **The pneumococcal vaccination because:**

- o I have questions about the pneumococcal vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I do not remember if I have had a pneumococcal vaccination.
- o It has been at least 5 years since my pneumococcal vaccination.

☐ **Hepatitis B vaccination because:**

- o I have questions about the HBV vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I'm not sure if I have ever been infected with HBV.
- o I'm not sure if I have been vaccinated against HBV.
- o I'm pregnant or planning on getting pregnant.

☐ **Hepatitis A Virus (HAV) vaccination because:**

- o I have questions about the HAV vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I'm not sure if I have ever been infected with HAV.
- o I'm not sure if I have been vaccinated against HAV.

☐ **Tetanus-Diptheria (Td) because:**

- o I have questions about the Td vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I do not remember if I have received at least 3 Td shots in my lifetime.
- o I do not remember when my last Td shot was, but it may have been more than 10 years ago.
- o I know that my last Td shot was 10 or more years ago.

☐ **Measles, Mumps and Rubella (MMR) vaccination because:**

- o I have questions about the MMR vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I'm thinking about becoming pregnant and do not know if I'm immune to rubella, so I need to be tested and we need to talk about whether the rubella vaccine/booster would be right for me.
- o Given my health, I would like to understand what the potential risks and benefits of the MMR vaccine might be for me?

☐ **Varicella virus vaccination (the virus that causes chicken pox and shingles) because:**

- o I have questions about the Varicella vaccination, specifically:
  - ▶ _____
  - ▶ _____
- o I'm not sure if I have been vaccinated for Varicella virus.
- o My children or children that I work with have been or are being vaccinated for the Varicella virus.
- o I have or am around children, and would like to better understand what can I do to minimize risk of exposure to Varicella?

Adapated from the Immunization Action Coalition (www.immunize.org).

Though several studies are completed or underway, we are years away from an effective preventive HIV vaccine. These studies recruit people who are HIV-negative. The vaccines are being evaluated first for their safety and ability to induce an immune response (in Phase I and Phase II studies) and later for their ability to prevent the establishment of HIV infection and/or disease (in Phase III studies).

There are 5 mid-sized and nearly 30 small studies of other experimental preventive HIV vaccine candidates ongoing. Several products and combinations of products are being evaluated for safety and their ability to promote immune responses.

Results from the first large study to evaluate the effectiveness of a vaccine, called AIDSVax, showed that it did not work. HIV infection rates were similar among those who received vaccine and placebo, meaning that receiving the vaccine did not protect people from HIV infection.

Who participates in preventive HIV vaccine studies?

Small studies of HIV vaccines typically include HIV-negative people who are at very low risk for HIV infection. Mid-sized studies typically include HIV-negative people who are at higher risk for HIV infection. Large studies include HIV-negative people who are at very high risk for HIV infection (such as current injection drug users and sex workers).

Why do large studies only include people at very high risk for HIV infection?

Large studies target people at very high risk for HIV infection in communities with known HIV infection rates. Certainly, this doesn't' mean other groups aren't at risk—everyone is at risk for HIV infection. However, researchers can get better data on infection rates among groups where infection rates are known to be high. The higher the number of infections in a given population, the fewer people needed in a study to determine if a vaccine works.

Are there side effects of experimental preventive HIV vaccines?

Each product will carry its own unique risk of side effects. In general, however, side effects associated with experimental preventive HIV vaccines have been similar to side effects of commonly available vaccines: redness, swelling and/or pain at the site of the injection and sometimes mild flu-like symptoms. Side effects could be more severe than mild pain or flu symptoms, however. They could include more severe pain and/or ulceration at the site of injection.

If the vaccine was made out of whole-killed or live-crippled HIV, then it's possible there could be a risk of HIV infection from the vaccine itself. However, that there have been no studies of whole-killed or live-crippled preventive HIV vaccines in the United States.

Are there other risks of participating in a preventive vaccine study?

It is possible that receiving an experimental preventive HIV vaccine could increase the likelihood of HIV infection should someone become "naturally" exposed to HIV.

It is possible that if someone received an experimental preventive HIV vaccine and became infected with HIV (because the vaccine didn't work) that the vaccine could increase the rate of HIV disease progression.

It is also possible that an experimental preventive HIV vaccine could cause a later effective preventive HIV vaccine not to work. It is very likely that people who participate in a study of a preventive HIV vaccine and receive the experimental

Putting prevention in women's hands

Ideally a highly effective and accessible preventive HIV vaccine would best serve the HIV prevention needs of women. If such a vaccine existed, ideally women would be protected from HIV infection by a series of shots. This offers women a discrete option, requiring little advanced planning and relies far less on the acceptance of a sex partner in order to be effective. Ideally both girls and boys would be vaccinated in childhood, leading to protection against HIV infection for many years. Optimally periodic booster shots spanning years or decades would be all that is required to maintain effective HIV immunity late into life. The drawbacks of a preventive HIV vaccine is that it would not protect against other sexually transmitted infections or offer birth control protection.

vaccine (as opposed to the placebo) will not be eligible to participate in studies of other preventive HIV vaccines and other HIV prevention approaches (like microbicides studies).

Are there possible benefits to participating in these studies?

The most important benefit to participating in these studies is the benefit to community and science, called altruism. Whether or not a vaccine succeeds or fails, if the experiment is well designed, the results bring us one step closer to an effective preventive HIV vaccine. Getting closer to an effective HIV prevention is an important benefit to us and future generations.

It is possible, by participating in an experimental preventive HIV vaccine study, that the vaccine will be effective. Participants who received the vaccine (as opposed to the placebo) will have gained earlier access to an effective preventive HIV vaccine. It is also possible that an experimental preventive HIV vaccine will not prevent HIV infection, but may prevent HIV disease progression among those who do become infected with HIV. While these outcomes are theoretically possible, it is vital to remember before entering a trial that they are merely that—theory.

Ultimately the decision to participate in a study of an experimental preventive HIV vaccine is a personal decision. It's important to remember that the very fact that an HIV vaccine is being researched means that we don't know if it works. The worst outcome of these studies may be that people believe that they're getting an effective product, increase HIV risk behaviors and increase HIV infection rates overall among study participants. The best outcome is that we move toward identifying an effective HIV preventive vaccine.

ADAP crisis reaches a new level

The crisis in providing treatment access to all who need it reached a new peak in early April when it was announced that the number of people on waiting lists for the AIDS Drug Assistance Program (ADAP) has gone from 791 to 1,263. ADAPs provide HIV treatment to low income, uninsured and underinsured people with HIV/AIDS.

The program has faced a financial crisis for the past few years, with more states unable to meet the needs of those it serves. According to the National Alliance of State and Territorial AIDS Directors (NASTAD), there are currently nine state ADAPs with waiting lists (Alabama, Alaska, Colorado, Idaho, Kentucky, Montana, North Carolina, South Dakota, and West Virginia). Ten other states have indicated that they may need to have some kind of new or additional restrictions to their current ADAPs in the coming year. Those states include Alabama, California, Iowa, Missouri, New Hampshire, New Jersey, New Mexico, Oregon, South Carolina, and Texas.

Advocates around the country are working hard to save this important program. In California, rallies have been held in San Francisco and at the State Capitol in Sacramento fighting a proposal to create a waiting list for the state's ADAP. Other grassroots efforts such as lobby days, letter-writing campaigns, and public testimony have been organized in many other states.

The story below is just one example of positive women advocating for ADAP. If you're interested in learning more about ways to get involved in ADAP advocacy, contact Ryan Clary at *rclary@projectinform.org* or call 415-558-8669 x224.

Women speaking up: Advocating for ADAP

One of my first experiences as an activist took place on Saturday, March 27, 1999, when a committed group of women, men and children took to the streets to let HIV-positive women and the people who love them know, "You are not alone!" For me, it was the beginning of fulfilling a fantasy of being part of the 60s. A time of rallies, marches, and protests. I like the idea of people working together for a cause. It has always appealed to me. Before the day even happened, I was excited by the idea of being surrounded by so many women. It was great. There were about 75 of us. We were from a lot of different places spiritually, emotionally, and physically, but we could still support each other and together build community for even more women. You would have had a difficult time finding anyone who didn't consider it a success, including me. Listening to the comments of women who participated, there was a feeling of sisterhood, community, and wanting to communicate to everyone about AIDS.

continued next page

Women speaking up, continued

Then in February of 2000, I reluctantly went to an advocacy training sponsored by Project Inform, Mothers Organizing Mothers (MOMs), and Women Organized in Response to Life-threatening Diseases (WORLD). I say *reluctantly* because at that time I had never done or thought about doing advocacy of any kind and the idea of it seemed very intimidating. But, I went anyway. At the training you could fill out an application to go to AIDSWatch, the national HIV/AIDS lobby days in Washington, D.C. I had no intention of applying ... me in D.C. ... crazy. But, I did anyway. About a week later I got a call ... I had been chosen to go to D.C. I was excited and terrified ... excited to have been chosen and terrified to have been chosen. I had about three weeks to prepare and panic for the trip and I did panic. But, I got on that plane and my life changed. I know that sounds dramatic but it's absolutely true. As terrifying as it was to fly alone across country and arrange for my transportation to the hotel in a city that I had never been, it was also the most empowering, confidence-building and rewarding experience of my life.

> *And I will always know that whatever happens I stood up, spoke up, and was heard.*

On the plane ride home I felt noticeably different. Not only had I conquered my fears but I had actively participated in one of the, if not the most important decision making systems in our country, the legislative process. I was fortunate enough to recognize that I was not the same person as when I left. After I returned home, I channeled the confidence I had gained from that experience into my personal life. The empowerment and strength I received from the advocacy training and my experiences lobbying in Sacramento and Washington, D.C. for the needs of people with HIV/AIDS has given me the courage and confidence to take charge of my life.

Since then I have used the skills I learned to advocate for the needs of positive women, including myself, in many ways. I joined my local Ryan White Planning Council, I co-chair a positive women's committee and I recently joined with Project Inform and the San Francisco AIDS Foundation to bring representatives from Santa Clara County to Sacramento to persuade the State Legislature to preserve the AIDS Drug Assistance Program (ADAP). When I first heard about the rally in Sacramento I knew I was going. I began mentioning it to my friends hoping to find someone to make the over two-hour trip with me. But, I began to see more and more people becoming interested. It was exciting. I really wanted to get as many women involved as I could. Having experienced the empowerment that comes from advocacy and knowing the impact it had on me I wanted to give other women the same opportunity. I also think that women bring strength, compassion and commitment that is so important.

It was a challenge to get women to attend. After all, women have families that always come first. I encouraged the women to bring their children. I felt it would be a wonderful opportunity for families to support the person who has given so much of herself for them, and we did have one woman who brought her son.

For me the experience was exciting. I was asked to testify before the Senate Budget Subcommittee. I was very nervous. I had never done that before. As I was waiting my turn to speak I was listening to the other speakers and furiously rewriting my speech. I wanted to say just the right thing and there was a moment where I wanted to turn around and run very fast in the other direction. But I didn't. When the time came I approached the podium and said what I wanted to say. Afterwards, I felt very proud of myself. I conquered my fear and spoke from my heart. And I will always know that whatever happens I stood up, spoke up, and was heard.

Other vaccine resources

1. International AIDS Vaccine Initiative (IAVI)
   www.iavi.org
2. AIDS Vaccine Advocacy Coalition (AVAC)
   www.avac.org

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