UCSF Center for AIDS Prevention Studies
AIDS Research Institute

can an HIV vaccine make a difference?

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why do we need an HIV vaccine?

Vaccines are among the most powerful and cost-effective disease prevention tools available. A vaccine that could prevent HIV infection or stop progression of the disease would greatly help in the fight against the AIDS pandemic. Vaccines have been pivotal in worldwide smallpox elimination efforts, have nearly eliminated polio and have drastically reduced the incidence of infectious diseases like measles and pertussis in the US.

A crucial question is whether a vaccine based on one strain of HIV would be effective for populations in which a different strain is predominant. There are also questions about how an HIV vaccine would protect individuals: the vaccine might not be able to actually prevent infection, but could prevent or delay progression to disease, or simply reduce the infectiousness of people who do become infected with HIV.

HIV prevention education and counseling are important components of vaccine programs. Even after the release of a vaccine, there will be an ongoing need for effective behavioral prevention programs. An HIV vaccine will not be a "magic bullet" but it could play an extremely powerful role as part of a package of prevention interventions.

has progress been made?

Twenty-two years into the epidemic, researchers are still struggling with the daunting scientific challenges involved in HIV vaccine research: 1) traditional approaches to vaccine design (i.e. use of inactivated or attenuated viruses) are considered too dangerous with HIV; 2) the virus is highly variable and mutates rapidly; 3) the viral infection is permanent, full recovery from HIV has not been documented, and thus, it is unclear how the body could mount an effective immune response and 4) there is no perfect animal model for use in AIDS vaccine research.[1]

There is still no HIV vaccine that has been tested and found to be effective. There have been over 70 small-scale human clinical trials of over 35 different candidate HIV vaccines, but only one product, AIDSVAX, produced by VaxGen, has been tested in a large-scale (Phase III) trial. Unfortunately, two separate trials of AIDSVAX conducted in 1) North America, Puerto Rico and the Netherlands[2] and 2) Thailand, found that the vaccine did not prevent HIV infection in the overall study populations and did not slow progression of disease among participants who became HIV-infected during the trial.[3]

A successful HIV vaccine would train the immune system to recognize HIV before it does extensive damage. Vaccine concepts now in development use a variety of methods to train the immune system to recognize parts of HIV without exposing people to HIV itself. Early AIDS vaccine research focused on developing bio-engineered vaccines that represent a portion of HIV's outer surface (envelope) protein. Different vaccine approaches are currently in development, none of which include the actual virus (HIV) and none of which can cause a recipient to acquire HIV from the vaccine itself.

what is the impact on HIV prevention?

An effective HIV vaccine cannot take the place of HIV prevention efforts, any more than prevention efforts can take the place of a vaccine. The best way to address the HIV pandemic is using multiple interventions at multiple levels, and the protective power of a vaccine could one day be of enormous benefit in HIV prevention.

There have been increases in sexual risk behavior in men who have sex with men (MSM) since the advent of ART (antiretroviral treatment).[4] There is concern that when a vaccine becomes available there could be similar increases in risk behavior among people who receive the HIV vaccine because they feel they can't become infected with HIV.

In the VaxGen efficacy trial in North America, younger participants and MSM who believed they had received the actual vaccine rather than a placebo were more likely to report unprotected anal intercourse during the trial. Overall, self-reported risk behavior did not increase throughout the trial.[5] In the VaxGen efficacy trial in Thailand, injecting drug users reported decreases in injection drug use and needle sharing during the first 12 months of the trial.[6] This may have been due to the prevention education and risk-reduction counseling received.

Says who?

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what are the ethical issues?

HIV vaccines can only be tested for safety and effectiveness if thousands of individuals are willing to participate in clinical trials. These trials raise concerns about the potential harm to trial participants. Certain HIV vaccines may cause trial volunteers to test HIV+ on standard HIV antibody tests, even though they are not infected with the virus. A positive HIV test result could expose individuals to discrimination in health insurance, employment and immigration, or lead to social stigma. The simple act of participating in an HIV vaccine trial may result in someone being labeled as a "high risk" individual, a gay person or a drug user, and discrimination against these and other groups is a very real issue in many places. It is the responsibility of researchers to ensure that vaccine trial participants receive assistance to alleviate the risks of discrimination or other harm that may result.[7] Communities must be closely involved in clinical trial design and implementation.

Researchers also need to ensure that true informed consent is acquired before individuals are enrolled in a vaccine trial. Community members and potential volunteers need to be fully informed about the vaccine trial process and must understand such concepts as "placebo," "randomization" and "blinding" to be able to truly evaluate whether participation is right for them. Using community educators and peers to help with the community education that accompanies HIV vaccine research will also help increase participants' understanding and acceptance of vaccine trials.[8]

what are barriers?

Much of the expertise to develop and manufacture HIV vaccines rests in private-sector pharmaceutical and biotechnology companies. Yet industry commitment to HIV vaccines has not matched the enormity of the public health need.[9,10] An HIV vaccine will only bring the pandemic under control if it is widely available in the developing world, where more than 95% of new HIV infections are occurring. People in resource-poor countries have often had to wait a decade or more for vaccines after they have been licensed for use in industrialized nations.[11,12]

There are numerous challenges to HIV vaccine access in addition to price. Marginal health care infrastructures in some developing countries may make it difficult to distribute a vaccine. Even countries that can afford vaccines may not see them as a high priority and may not allocate adequate resources to fund research or vaccine purchase.

Vaccination programs generally focus on children. With HIV, it is sexually active adolescents and adults who will need a vaccine most immediately, necessitating new approaches to immunization. Vaccine acceptance may be problematic in communities where there is a distrust of government or stigma in being associated with HIV/AIDS.

what needs to be done?

Public sector funding for research on HIV vaccines has increased in recent years, and additional resources are needed. The private sector must be encouraged to invest in HIV and other priority vaccines through a range of incentives, including direct funding, public support for clinical research infrastructure and product manufacture, and through public/private partnerships.[9] Wealthy governments should commit in advance to purchase AIDS vaccines for people in the developing world. Continued political leadership is needed to prioritize resources for vaccines.

Vaccine trials conducted to date have included HIV prevention education and risk reduction counseling. Vaccine trials can further benefit participants by offering drug treatment services and STD screening and treatment. Combining medical, behavioral and psychological efforts as part of a vaccine initiative can be a powerful tool for combatting the HIV pandemic.

Vaccines are an integral part of an effective disease prevention strategy, and vaccine development is critical in arresting the spread of HIV. Yet, a vaccine alone will not eliminate the social and structural conditions that created and fuel the epidemic. Even when HIV vaccines are available, communities will continue to need quality behavioral interventions to control the HIV epidemic and policies that ensure access to vaccines.

PREPARED BY CHRIS COLLINS, MPP, AIDS VACCINE ADVOCACY COALITION

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Resources

AIDS Vaccine Advocacy Coalition (AVAC)
101 West 23rd St. #2227
New York, NY 10011
212/367-1021
www.avac.org

HIV InSite: Vaccine Overview
http://hivinsite.ucsf.edu/InSite?page=kb-08-01-11

HIV Vaccine Trials Network
http://www.hvtn.org

International AIDS Vaccine Initiative (IAVI)
110 William Street
New York, NY 10038-3901
212/847-1111
www.iavi.org

IAVI vaccine trials database
www.iavi.org/trialsdb/basicsearchform.asp

National Institute of Allergy and Infectious Diseases (NIAID)
Division of AIDS Vaccines
www.niaid.nih.gov/aidsvaccine

NIAID Vaccine Research Center
www.vrc.nih.gov