HIV Vaccines—Key Messages

HIV Vaccine Awareness Day (HVAD)

May 2017

An HIV vaccine is both possible and essential. **Existing options for prevention and treatment must be scaled up to bring down rates of new infections, but a vaccine is an essential component of a long-term end to the HIV epidemic.**

- Global coverage of HIV treatment, care and existing prevention options has increased dramatically. If coverage of prevention and treatment continues to expand, new HIV infections and deaths from AIDS will continue to decrease.
- Many of today's HIV prevention methods require daily use or regular adherence. Sustained control of the epidemic will likely depend on methods that provide long-lasting protection, work in combination with existing methods, and offer a variety options to meet people's diverse needs for HIV prevention. A vaccine is a critical part of such a comprehensive, integrated and sustained strategy.
- Underway for more than 30 years, HIV vaccine research is a long-term endeavor; the vaccines for other diseases that are in use today took decades to develop.
- In 2009, a clinical trial known as RV144 achieved proof-of-concept that a preventive HIV vaccine is possible, and, since then, researchers have continued to build on the results of that trial.

There is tremendous progress and new vaccine concepts are being tested. **Vaccine development is always a long-term process, but we've seen unprecedented advances in recent years.**

- For the first time ever, three different approaches are in, or moving to, large-scale efficacy trials simultaneously. These include two vaccine candidates and one vaccine-related approach:
  - A study known as HVTN 702, ongoing in South Africa since late 2016, is building on the RV144 trial, which tested the only vaccine regimen to date to demonstrate efficacy in a human clinical trial.
  - A novel "mosaic" candidate, so-called because it is designed to work across many HIV subtypes, delivered via an Ad26 vector in combination with HIV envelope proteins through a prime-boost regimen, will be tested for proof of concept. This trial is expected to begin in late 2017 or early 2018 in sub-Saharan Africa and is being led by Janssen in partnership with a number of global vaccine development partners.
  - In 2016, two antibody-mediated prevention (AMP) efficacy studies began in the Americas, Europe, and Africa, testing a broadly neutralizing antibody (bNAb), called VRC01. These studies are testing whether direct intraveneous infusions of the bNAb into the bloodstream can prevent HIV infection. This new strategy, known as passive immunization, will explore the potential of this strategy as a prevention option while also providing insights that can be applied to vaccine development.
- A pipeline of trials and early-stage research is focusing on improving existing concepts for a successful vaccine and testing new ones, including: improved pox-protein candidates; DNA-based vaccines alone and in combination with vectors such as MVA; adenovirus-based vectors; as well as newer concepts such as a gp145-based candidate and the use of replicating vectors such as VSV and CMV.

- In addition, progress in broadly neutralizing antibody (bNAb) research is contributing to HIV vaccine research. These antibodies have the ability to neutralize, or block, many strains of HIV, and potentially prevent the virus from establishing a lasting infection. By blocking many different strains of HIV, bNAbs may help address one of the greatest challenges in HIV vaccine development: the virus's ability to mutate rapidly.
  - Researchers continue to discover additional bNAbs that are able to block multiple strains of HIV.
  - Future clinical trials will test additional and modified bNAbs, as well as bNAb combinations.
  - Understanding how bNAbs block HIV infection when delivered by intravenous drip (passive immunization) could inform the development of preventive vaccines. Additionally, understanding how much antibody is required to achieve protection provides a target for future vaccines.
  - If researchers can identify individual bNAbs, or combinations of them, that provide protection against infection in small enough doses that last long enough in the body, passive immunization with bNAbs could become a prevention intervention itself.
  - Many of the concepts pursued in HIV vaccine R&D have broader benefits for prevention as well as vaccines for other diseases.
- As large-scale vaccine efficacy trials move forward, researchers, advocates and communities must work together to ensure that trials are well-conducted, conform to Good Participatory Practice Guidelines and adapt to the changing realities of the HIV response. This entails the inclusion of new options as part of the standard of HIV prevention in ongoing and planned trials.

Global partnerships are moving the science forward. Success in HIV vaccine development and eventual delivery depends on global partnerships, sustained funding, political will and continued community support.

- After more than 35 years, we know that developing an HIV vaccine is not easy. Success depends on maintaining momentum and working together. We've seen unprecedented global cooperation among governments, industry and academic researchers working to find an HIV vaccine. As the field evolves, researchers and funders must prioritize evidence, information-sharing and rational decision-making about which candidates get tested.
  - The current large-scale clinical trials have all been designed and implemented by international groups involving funders, trial sites, trial networks, academic researchers, industry partners, government officials and communities from countries around the world.
  - Innovative partnerships have developed vaccine candidates through basic research and moved them efficiently to clinical testing. These efforts made a positive impact on the HIV vaccine field and set new standards for R&D generally.
- HIV vaccine development and eventual rollout of a successful vaccine requires sustained financial support. Developing a successful vaccine is not cheap, but an HIV vaccine will pay huge dividends in lives saved. Modeling research estimates that in some parts of the world, an effective HIV vaccine could reduce new annual HIV infections by nearly half in its first 10 years, averting tens of millions of infections. We can't afford to slow down promising and urgently needed research.
- Funding product development and clinical trials is not enough. It will take many partners working together to develop and deliver an effective HIV vaccine, and to ensure that plans for success are in place before the efficacy trial results are in.
- Researchers, advocates, donors, policy makers, regulators, funders and communities all have a role to play in the successful development, testing and rollout of a safe, effective, licensed and accessible HIV vaccine.

For more on the state of HIV vaccine research and advocacy visit: *www.avac.org/hvad*.