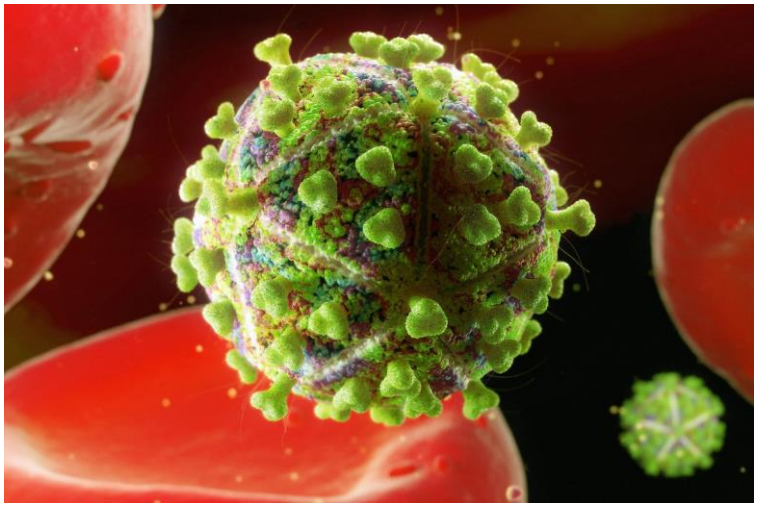
There's a promising new HIV vaccine candidate in the pipeline



Developing a vaccine to stop HIV is thought to be among the most daunting challenges in medicine for one big reason: The virus is extraordinarily genetically diverse, even more so than the flu. So it's difficult to think about how a single shot might work against all the different HIV subtypes circulating around the world.

But scientists may be inching toward a vaccine that could tackle HIV's genetic diversity and prevent the virus from taking hold in people.

Researchers from the National Institutes of Health and Johnson & Johnson at the International AIDS Society conference in Paris Monday morning presented data on a clinical trial of what's called the "Ad26-env mosaic vaccine."

The mosaic vaccine was developed using a computer algorithm to analyze HIV data from around the world and select a range of HIV sequences to include in a shot. It's called a "mosaic" because it involves taking pieces of different viruses and sticking them together to generate immune responses that can cover a broad range of HIV subtypes.

"One of the great challenges for development of HIV vaccine is viral diversity," said Dan Barouch, a lead researcher on the vaccine and director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center in Boston. "The mosaic strategy is one way to attempt to deal with the global virus diversity."

A word of caution, though: We're only in the early phase of human testing, and the vaccine could ultimately fail to prevent the virus from spreading among people. But so far, the HIV community is carefully watching the Ad26 vaccine research because the approach seems quite promising.

The mosaic approach seems promising in very early clinical research

In the 35 years of the HIV epidemic, only four HIV vaccine concepts have been tested in humans. The mosaic strategy is the fifth concept, and one of only two HIV vaccines that's currently part of clinical trials of efficacy in humans. (The other is the HVTN 702 HIV vaccine candidate, now underway in Thailand.)

In the study of the Ad26 mosaic vaccine, called the APPROACH trial, 393 volunteers in the United States, Rwanda, Uganda, South Africa, and Thailand were randomly assigned to receive one of seven experimental

vaccines or a placebo. The mosaic vaccine was the best tolerated and also capable of generating anti-HIV immune responses in all the people who received the shots.

Before this, studies of the mosaic vaccine in rhesus monkeys showed a 66 percent efficacy rate, meaning 66 percent of monkeys that got the shot were protected from the virus. (With HIV, 50 to 60 percent is about the efficacy range researchers hope for.) Interestingly, in the early human study, the immune response was comparable to the rhesus monkey one, which gave the researchers hope that the vaccine might be similarly effective in people.

We need more human studies of this HIV vaccine

But we still don't know if the vaccine will protect humans from the virus, since the studies so far have only looked at safety and immune responses, not efficacy. And many medicines that look promising in animals, and safe in humans, don't pan out in clinical trials focused on efficacy.

"I wouldn't use the word excited too much," said Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases. "It's a step forward toward getting another candidate into trial that could have some promise." It's too soon to say if and when the mosaic vaccine might work to prevent the virus from spreading in humans, he added. As for next steps, if the researchers continue to see promising data on the mosaic vaccine from another ongoing study, a larger human efficacy trial will move forward toward the end of the year in southern Africa, involving some 2,600 healthy, HIV-negative women.

Deaths from AIDS have halved since 2005 — but there's still a ton of work to be done

We've made remarkable progress against HIV around the world. In 1996, as HIV prevalence was peaking around the world, the United Nations established UNAIDS, the first global health body focused on a single disease. In 2000, the UN Security Council convened an unprecedented meeting to address the out-of-control AIDS crisis. This led to a massive concentration of resources into HIV/AIDS research, and triggered global and coordinated efforts to stem the disease.

Researchers and doctors figured out how to get people tested and diagnosed quickly, and uncovered effective treatments that allowed those with HIV to live long, relatively healthy lives. Public health officials also waged awareness campaigns about prevention, reminding people to practice safe sex with condoms and get tested, and that early HIV treatment can save lives. Recently, researchers even discovered a pill to prevent HIV. Deaths from AIDS have halved to 1 million since 2005, and UNAIDS estimates almost 20 million people now have access to treatment. (Some of that access is now in jeopardy, however, given that President Donald Trump has proposed cutting $800 million from a key US government AIDS program called PEPFAR in the 2018 budget.)

An HIV vaccine has long been elusive. The other HIV vaccine in human testing, the HVTN 702 candidate, is a newer version of the only other HIV vaccine to show any efficacy in humans, called RV144. In a trial on the RV144, 31 percent of people who got the vaccine did not develop HIV — too small a number to be useful. But with the new HVTN trial, researchers hope some tweaks to the vaccine might boost the efficacy rate.

"A safe and effective HIV vaccine would be a powerful tool to reduce new HIV infections worldwide and help bring about a durable end to the HIV/AIDS pandemic," Fauci said in a statement. "By exploring multiple promising avenues of vaccine development research, we expand our opportunities to achieve these goals."