

Nasal vaccines may be the next generation of protection against COVID

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Credit: Unsplash/CC0 Public Domain

Peter Palese pulls open the door of a 16th floor lab room at Mount Sinai's upper east side hospital.

Inside the unusually warm room, lie stacked sheets of chicken eggs, delivered fresh every Tuesday.

Palese holds a flashlight against one to show how these eggs differ from those typically eaten for breakfast. Red veins appear.

In the lab across the hall, researchers carefully infect each egg with a bird virus that is harmless to people. As this Newcastle disease virus replicates, it also makes copies of its payload: the spike protein from the coronavirus that has upended the world for more than two years.

Each egg can grow enough for about 10-100 doses of an experimental [vaccine](#) meant to combat COVID-19. Instead of being stabbed into someone's shoulder, the vaccine these researchers are developing is designed to be dripped into someone's upturned nose.

Current vaccines are great at stopping severe disease. But people can still catch COVID-19, even after two, three or more shots.

Researchers hope a different delivery system will make for a vaccine that is better at preventing transmission and infections. By putting the vaccine directly into the nose, it might prevent the virus from taking hold in the mucus membranes, where it first enters the body.

Studies are still underway to prove whether this approach will work. And even if it does, the vaccines are likely to take another year to become widely available.

But scientists are excited about their possibilities.

"I don't want to overstate it because no one has proven their efficacy, but their potential is extremely high," said Dr. Paul Spearman, director of infectious diseases at Cincinnati Children's in Ohio, who is developing a

different nasal vaccine that isn't grown in eggs. "I'm really excited."

From flu to COVID

Palese and Florian Krammer, both at the Icahn School of Medicine at Mount Sinai, have been working for years to develop universal flu vaccines that could be given once every few decades instead of once a year.

Krammer is the expert in antibodies, Palese in making the actual vaccine constructs. A colleague Adolfo Garcia-Sastre leads the research in animal models and Dr. Sean Liu runs the [human trials](#).

When the pandemic started, they all redirected their research to a COVID-19 vaccine.

Krammer said the team chose to grow their vaccine in chicken eggs because flu vaccines are essentially made the same way (but with a different virus). The new vaccine, technically called NDV-HXP-S, could be manufactured using the existing flu vaccine infrastructure that generates millions of doses every year worldwide.

"We could make a lot of vaccine quickly," Krammer said.

Four countries already have started to manufacture the vaccine—Vietnam, Thailand, Brazil and Mexico—and two of them are getting ready to test it in large, phase 3 trials. They're testing it both as an injectable and as an intranasal vaccine, which would be extremely useful in countries where there aren't a lot of people trained to deliver shots.

The vaccine also can be stored in a regular refrigerator rather than being kept frozen, which will make it cheaper and easier to provide to low- and middle-income countries. "We can probably make this for 30-cents a

dose versus \$30" for an mRNA vaccine like Pfizer-BioNTech or Moderna's, Palese said.

In the U.S., the vaccine would be used as a booster. In a current early-phase trial at Mount Sinai, researchers are trying it on volunteers, measuring antibody levels in blood as with other COVID-19 vaccines, but also in their nose and saliva to see if the vaccine might trigger a protective immune response there, too.

The team uses the Newcastle disease virus because very few people have ever encountered before, which means their immune system won't clear it before it has a chance to work.

"Except if you're a chicken farmer, there's basically no chance you've ever been exposed," Krammer said.

They've also tried going after different variants and found much broader protection when they use three variants in a cocktail rather than just one.

Other nasal vaccines are under development, each using a slightly different approach.

The World Health Organization is studying another potential nasal vaccine made by New York-based Codagenix. The WHO selected this vaccine as one of 4 to run through late-stage [clinical trials](#), considering them the most promising out of 194 candidates.

The Codagenix vaccine, like the others, would be used to prevent disease in countries that haven't had ready vaccine access. "There's still demand for vaccine in places that have very low vaccination rates," Codagenix cofounder and CEO Rob Coleman said.

It's also being tested as a booster for people who've already been

vaccinated, and is aimed at the U.S. market as well.

This vaccine consists of a live-attenuated virus, meaning it includes the whole SARS-CoV-2 virus that causes COVID-19. The virus is manipulated so it cannot cause infection. Theoretically, by including the whole virus, it can provide broader protection than just the spike protein.

In a small early-phase trial, two doses of the vaccine provided everyone with broad immunity, including against the omicron variant, Coleman said.

"The key value add here is not only are we breaking the transmission cycle, but we're providing all the proteins of the virus," he said.

A different approach

Spearman, at Cincinnati Children's, uses a canine flu virus to deliver his spike payload. It's never been used in humans before, but is believed to be harmless.

"The animal data was very promising," he said.

Like the other vaccines, it is intended as a booster dose in the U.S., though it might be useful as a standalone vaccine in parts of the world that haven't yet seen vaccines.

Having already shown in early trials that the vaccine is safe, the next challenge is deciding which of two doses is most effective, Spearman said.

He hopes it will provide longer-lasting protection than current vaccines, which have required booster doses to remain effective. Theoretically, vaccines like his and Palese's that replicate in the body, may last longer.

But "the proof will be in the immune response," Spearman said.

Right now, in collaboration with the Georgia company CyanVac, he's running a 22-person trial he hopes will look good enough to expand later this year. If the trial suggests it's as promising in people as it was in animals "then we'll really have something we want to move forward," he said.

Dan Wagner of Cincinnati, volunteered for Spearman's vaccine trial, because he worries he might infect someone else with COVID-19.

At 33, extremely fit and able to work from home, Wagner put off getting a shot in his arm, because he wasn't concerned about getting infected himself. But he does worry about his parents and others who are more vulnerable.

"I wanted a vaccine that protects other people, too, not just myself," Wagner said.

Though some people prefer nasal vaccines as a way to avoid shots, Wagner said he doesn't have a problem with needles. The trial included a number of blood draws, which didn't bother him.

Back in January when he got the vaccine, he had to sit down and tip his head back. "You could feel it going down your throat," he said. "It didn't hurt or anything. It just felt kind of weird."

He had no side effects at all—none of the headaches or chills or fatigue that many people complain of after the other COVID-19 vaccines.

Spearman is still working out the most effective dose of his vaccine and it's not clear whether Wagner is protected against either catching or passing on COVID-19, though he has managed to avoid infection so far.

Wagner, who sells car parts over the Internet, said he has been a little more willing to take risks since his vaccination, going out more often, getting back to his 5-day-a-week gym routine and feeling a bit safer.

Wagner said he's hopeful nasal vaccines work, so people who don't need it much for their own sake can still help protect others.

"Knowing so many people who've gotten other vaccines and tested positive, I do hope this is different," he said.

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