Universal flu vaccine candidate protects against infection in mice

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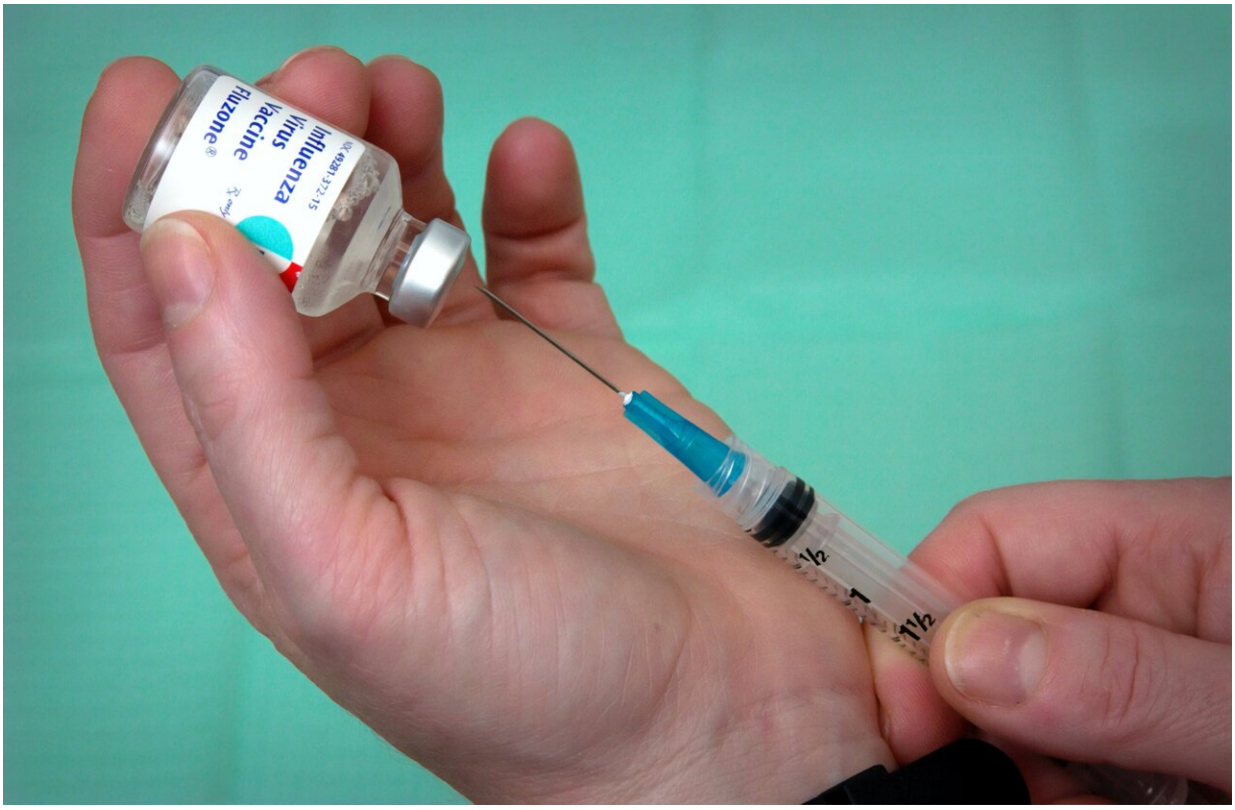

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Annual flu vaccines protect against severe infection, but they vary in efficacy and may not match the most virulent strains of the season. The reality of a universal flu vaccine, which would protect people from all strains, and ideally longer than a single season, remains elusive.

Findings published this week in the *Journal of Virology* suggest we're getting closer. Researchers at Cleveland Clinic's Lerner Research Institute have reported that their universal flu vaccine candidate, tested on animal models, elicited a strong immune response and provided protection against severe infection after viral exposure. The new work builds on previous, similarly promising preclinical studies on mice from the same group, led by Ted M. Ross, Ph.D., Director of Global Vaccine Development at Cleveland Clinic.

The researchers hope to launch human clinical trials within 1–3 years, said virologist Naoko Uno, Ph.D., who led the new study. "We want to make sure our vaccine can span multiple seasons, not just one, and protect against all the strains that affect humans," she said.

Scientists have identified 4 types of influenza virus, but 2 of them—Influenza A and Influenza B—pose the greatest risks to humans. Seasonal flu vaccines include proteins from 3 or 4 circulating subtypes of those viruses, which include H1N1, H3N2 and IBV. But because the virus mutates so quickly, predicting which strains will pose the biggest risk, and thus choosing which ingredients to include, is a guessing game.

Researchers in Ross' lab designed their new vaccine candidate using a methodology called COBRA, or Computationally Optimized Broadly Reactive Antigens. They began by downloading thousands of genetic sequences of pathogenic influenza strains, spanning multiple seasons, from an online database. Then they digitally analyzed those sequences to identify which amino acids—the building blocks of proteins—are conserved across viruses and seasons.

The researchers identified groups of proteins for different subtypes. To develop a wider-reaching vaccine, Uno said, the group identified 8 proteins from those previous studies associated with a sustained immune response.

"We've been able to whittle down this list, to say these are the best at spanning multiple seasons and eliciting a broadly reactive antibody response," she said. "It's like creating a greatest hits album. We want to put only the best ones back in the vaccine."

Those greatest hits included proteins from H1 and H3 types of influenza viruses, Uno said, but they also included proteins from H2, H5 and H7 viruses, which are strains against which most people don't have antibodies. Some of these have pandemic potential, Uno said.

Past outbreaks of bird flu, or H5N1, have led to a high rate of human mortality, and in March 2024 the virus was found in dairy cattle in Texas. Since then, 4 people who work with cattle have been diagnosed. In addition, it has spread to dozens of herds in multiple states, and in other species including sea lions, birds, cats and alpacas.

"We've shown that our H5 vaccine does cover many different clades," Uno said.

For the new work, the Cleveland Clinic researchers administered the vaccine candidate intranasally. Blood tests showed that 4 weeks later the animals had developed antibodies against the virus, and when the animals were exposed to the pathogen they were protected against developing infection.

Ross currently leads his group's efforts to advance testing of the candidate in the U.S., and Uno is collaborating with researchers in India and the European Union on an international effort.

Uno noted that the COBRA methodology isn't limited to finding and assembling recombinant proteins for the flu. It might be used to analyze mRNA or other biomolecules, she said, or explored for developing vaccines to viral diseases like dengue. "This can be used in a lot of

viruses," she said.

More information: *Journal of Virology* (2024). DOI: 10.1128/jvi.00354-24

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