

Nasal spray flu vaccine candidate shows promise when administered alongside high dose annual shot

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A unique influenza vaccine candidate that's inhaled and based on technology developed by University of Wisconsin–Madison researchers is safe and could bolster protection against seasonal and pandemic influenza for people vulnerable to severe disease when they receive it in

addition to the annual flu shot.

Those are the results of a randomized, controlled trial of the [vaccine candidate](#), administered in [nasal spray](#) form in conjunction with the annual shot to a group of 65- to 85-year-olds in 2022. The findings were [recently reported](#) in the journal *Lancet Infectious Diseases*.

A different kind of influenza vaccine

The vaccine candidate tested in this study, FluGen's M2SR, is based on technology developed by UW–Madison researchers Yoshihiro Kawaoka and Gabriele Neumann more than a decade ago. It differs in a few ways from seasonal flu shots, which for decades have provided suboptimal protection against [severe disease](#) for [vulnerable people](#).

Typical flu vaccines use inactivated influenza virus administered via a shot in muscle tissue, prompting the immune system to create antibodies that can recognize and combat the virus. The candidate vaccine M2SR relies instead on live virus with an essential replication gene deleted from its DNA. The vaccine is administered directly into the upper respiratory system with a nasal spray.

The gene deletion means "it can't continue replicating and make you sick, but it stimulates the immune system just like a natural virus infection," says Pamuk Bilsel, who led the study as chief scientific officer for FluGen, a spinoff company founded by Kawaoka, Neumann and FluGen CEO Paul Radspinner.

A safety study with promising results

In 2022, FluGen tested the vaccine candidate among more than 300 people in the United States between the ages of 65 and 85, assessing its

safety and the [immune response](#) it elicited.

Some participants received only the [annual flu shot](#) formulated for people in this high-risk age group, while others received only the nasal spray candidate vaccine. A third group received both, and a fourth group received the regular shot and a nasal spray placebo.

Participants who received the nasal spray vaccine candidate tolerated it well, with a minority reporting minor side effects including [runny nose](#) and nasal congestion.

Blood and nasal swab samples taken one day and again 2–4 weeks following vaccination showed that participants who received both the nasal spray vaccine and flu shot had significantly more protective antibodies along with other protective immune responses not seen in participants who received the flu shot alone.

Those participants "got not just the antibodies that those normal flu shots give you, but also the local immunity, mucosal immunity and T-cell immunity," says Bilsel. "It's a multifaceted, broad spectrum response."

Better protection against annual influenza and possibly pandemics

While the study was focused on assessing the vaccine candidate's safety, data on the immune responses it elicited suggests that vulnerable seniors would be better protected from influenza if they receive both the flu shot and nasal spray vaccine.

A more protective immune response possibly offered by administering both vaccines could apply to both seasonal influenza and potential pandemic strains, since current vaccines are the first line of defense

should a strain like the currently circulating H5N1 avian influenza become widely transmissible in humans. While the vaccine candidate shows promise, larger studies are planned to confirm that it's safe and provides protection. Those studies will take a couple years to complete.

"Older adults deserve better alternatives to prevent infection, illness and hospitalization from influenza and finally we believe we have one," says Radspinner. "We hope existing manufacturers agree and will be working with them to find ways to make this a reality for patients sooner rather than later."

More information: Joseph Eiden et al, Safety and immunogenicity of the intranasal H3N2 M2-deficient single-replication influenza vaccine alone or coadministered with an inactivated influenza vaccine (Fluzone High-Dose Quadrivalent) in adults aged 65–85 years in the USA: a multicentre, randomised, double-blind, double-dummy, phase 1b trial, *The Lancet Infectious Diseases* (2024). [DOI: 10.1016/S1473-3099\(24\)00351-7](https://doi.org/10.1016/S1473-3099(24)00351-7)

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