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Covid shots may slightly increase risk of stroke in older adults, particularly when administered with certain flu vaccines

By Brenda Goodman, CNN

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the risk of strokes caused by blood clots in the brains of seniors, particularly when the two vaccines are given at the same time and when they are given to adults who are age 85 and older, according to a new study.

The safety signal was detected by experts at the US Food and Drug Administration who analyzed data from Medicare claims.

It is the second study to find an elevated risk of stroke for seniors after Covid-19 and flu vaccinations given together. The US Centers for Disease Control and FDA issued a public communication in January explaining that one of their near real-time vaccine safety monitoring studies — called the Vaccine Safety Datalink — had picked up a small and uncertain risk of stroke for older adults who received a dose of Pfizer's bivalent Covid-19 vaccine and a high-dose or adjuvanted flu shot on the same day. That study triggered the FDA's broader look at strokes after vaccination noted in the medical records of seniors on Medicare.

That said, the risk identified in the FDA's study appears to be very small — roughly 3 strokes or transient ischemic attacks for every 100,000 doses given — and the study found it may be primarily driven by the high-dose or adjuvanted flu vaccines, which are specially designed to rev up the immune system so it mounts a stronger response to the shot.



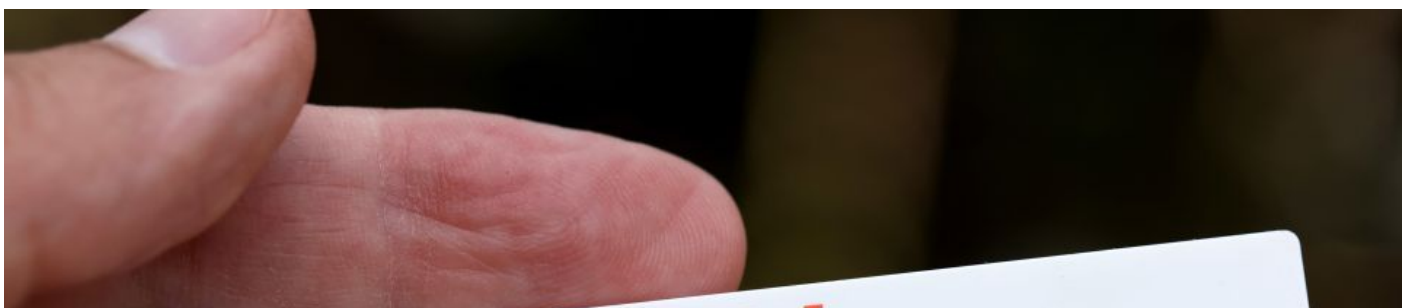
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In additional analysis of the Medicare claims data, the FDA researchers found a very slightly increased risk of stroke in adults ages 65 and older who'd only gotten a high dose flu shot. In absolute terms, the extra risk from high-dose flu shots amounted

“Available data do not provide clear and consistent evidence of a safety problem for ischemic stroke with bivalent mRNA Covid-19 vaccines when given alone or given simultaneously with influenza vaccines,” said Dr. Tom Shimabukuro, director of the Immunization Safety Office at the CDC in a public presentation of the data on Wednesday to the CDC’s Advisory Committee on Immunization Practices.

Researchers say they are continuing to probe the possible link, but in the meantime, they say everyone should still get vaccinated since any tiny increase in risk of a stroke after vaccination is dwarfed by the increased risk of stroke or other serious outcomes following either a flu or Covid-19 infection.



“The risk of serious disease associated with both influenza and Covid for the population at highest risk, which is of course, older persons, is so much greater than the potential increased risk associated with a vaccine,” said Dr. William Schaffner, an infectious disease expert at Vanderbilt University.

“That’s a hard equation for the average person to do,” Schaffner said.

Spread out your shots?

Schaffner said people who are worried could consider getting each shot at different times rather than together.

“That’s a reasonable thing to do,” he said.

Schaffner, who is in his mid-80s, said he got both his Covid and flu vaccines at the same time, in the same arm, and had very little reaction afterwards

Other experts said they hoped the information wouldn't confuse people or deter them from getting their vaccines, since the benefits of getting them still greatly outweigh the risks.

“The bottom line is that these are small signals. We’re not entirely sure whether they are valid, and they certainly do not lead themselves to any change in the recommendations for people getting either Covid or influenza vaccines at the present time,” Schaffner said.



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For the study, FDA investigators looked at the medical claims of more than 5.3 million adults ages 65 and older who were enrolled in Medicare and received a bivalent Covid-19 vaccine made by Pfizer or Moderna. They saw no increased risk of stroke in the overall group after Covid-19 vaccination.

ahead of peer review by outside experts and publication in a medical journal.

Study sees link to seizures in young kids

A separate FDA investigation of more than 4 million records from three large commercial insurance databases, found a very small and tenuous link between seizures in children between the ages of 2 and 5 and Covid-19 vaccination. Children this age appeared to be slightly more likely to have seizures after Covid-19 vaccination compared with background seizure rates in the general population in 2020 — a year when infectious diseases were lower in kids because of masks and social distancing.

The signal disappeared, however, when researchers compared it with background rates of seizures reported in US children in 2022, a year when infections in kids rebounded.


That study was also posted as a [preprint](#).

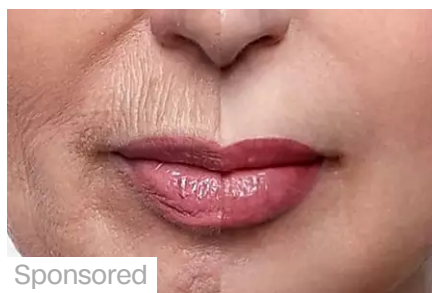
About 4% of children experience seizures triggered by fevers, according to the National Institute of Neurological Disorders and Stroke.

Dr. Phillip Yang, a cardiologist at Stanford Health Care, said the findings didn't look particularly concerning.

"It's not unusual after Covid vaccine that we have little bit of a fever that could trigger a seizure, and kids who are more susceptible to it. So again, it's not a surprising finding," Yang said.

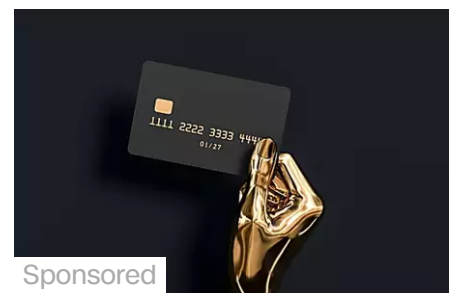
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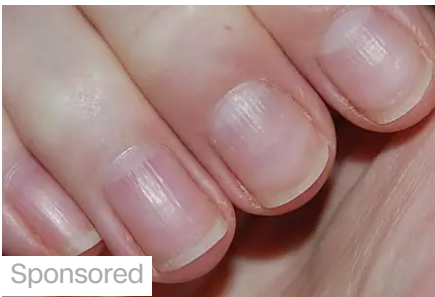


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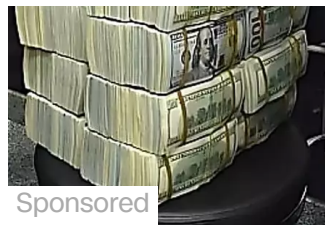
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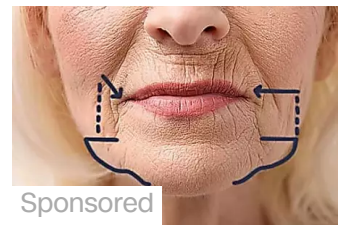
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