

Future of Health

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U.S. FDA, CDC see early signal of possible Pfizer bivalent COVID shot link to stroke

Reuters



Vials with a sticker reading, "COVID-19 / Coronavirus vaccine / Injection only" and a medical syringe are seen in front of a displayed Pfizer logo in this illustration taken October 31, 2020. REUTERS/Dado Ruvic/File Photo





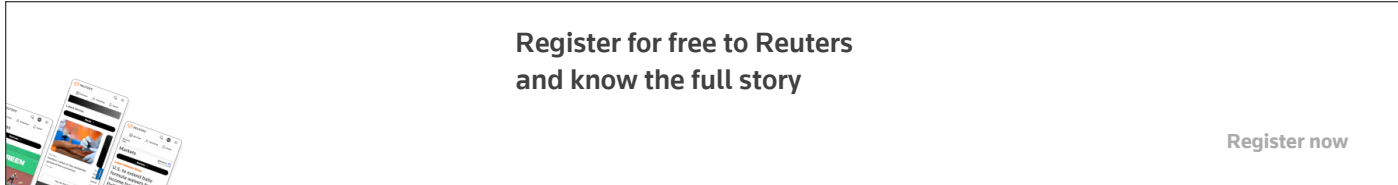




Jan 13 (Reuters) - (This Jan. 13 story has been refiled with an edited headline to clarify that the link to a stroke is possible, not definite.)

A safety monitoring system flagged that U.S. drugmaker Pfizer Inc ([PFE.N](#)) and German partner BioNTech's updated COVID-19 shot could be linked to a type of brain stroke in older adults, according to preliminary data analyzed by U.S. health authorities.

ischemic stroke 21 days after receiving the Pfizer/BioNTech bivalent shot, compared with days 22-44.



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An ischemic stroke, also known as brain ischemia, is caused by blockages in arteries that carry blood to the brain.

The FDA and CDC said that other large studies, the CDC's Vaccine Adverse Event Reporting System, other countries' databases and Pfizer-BioNTech's databases had not flagged this safety issue, adding that it requires more investigation.

"Although the totality of the data currently suggests that it is very unlikely that the signal in VSD (Vaccine Safety Datalink) represents a true clinical risk, we believe it is important to share this information with the public," the health authorities said.

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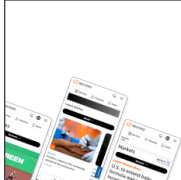
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Pfizer and BioNTech said in a statement that they have been made aware of limited reports of ischemic strokes in people 65 and older following vaccination with their updated shot.

COVID-19 vaccines," the companies added.

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This safety concern has not been identified with Moderna's (**MRNA.O**) bivalent shot and both the CDC and FDA continue to recommend that everyone aged 6 months and older stay up-to-date with their COVID-19 vaccination.



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U.S. FDA proposes shift to annual COVID vaccine shots

United States · January 23, 2023 · 2:56 PM PST

The U.S. health regulator on Monday proposed one dose of the latest updated COVID-19 shot annually for healthy adults, similar to the influenza immunization campaign, as it aims to simplify the country's COVID-vaccine strategy.

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