

CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older

January 13, 2023

Transparency and vaccine safety are top priorities for the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). U.S. government agencies use multiple, complementary safety monitoring systems to help detect possible safety signals for vaccines and other medical countermeasures as early as possible and to facilitate further investigation, as appropriate. Often these safety systems detect signals that could be due to factors other than the vaccine itself.

All signals require further investigation and confirmation from formal epidemiologic studies. When one system detects a signal, the other safety monitoring systems are checked to validate whether the signal represents an actual concern with the vaccine or if it can be determined to be of no clinical relevance.

Following the availability and use of the updated (bivalent) COVID-19 vaccines, CDC's Vaccine Safety Datalink (VSD), a near real-time surveillance system, met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Rapid-response investigation of the signal in the VSD raised a question of whether people 65 and older who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-42 following vaccination.

This preliminary signal has not been identified with the Moderna COVID-19 Vaccine, Bivalent. There also may be other confounding factors contributing to the signal identified in the VSD that merit further investigation. Furthermore, it is important to note that, to date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal:

- A large study of updated (bivalent) vaccines (from Pfizer-BioNTech and Moderna) using the Centers for Medicare and Medicaid Services database revealed no increased risk of ischemic stroke
- A preliminary study using the Veterans Affairs database did not indicate an increased risk of ischemic stroke following an updated (bivalent) vaccine
- The Vaccine Adverse Event Reporting System (VAERS) managed by CDC and FDA has not seen an increase in reporting of ischemic strokes following the updated (bivalent) vaccine
- Pfizer-BioNTech's global safety database has not indicated a signal for ischemic stroke with the updated (bivalent) vaccine
- Other countries have not observed an increased risk for ischemic stroke with updated (bivalent) vaccines

Although the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk, we believe it is important to share this information with the public, [as we have in the past \(/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older\)](#), when one of our safety monitoring systems detects a signal. CDC and FDA will continue to evaluate additional data from these and other vaccine safety systems. These data and additional analyses will be discussed at the upcoming [January 26 meeting \(/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-january-26-2023-meeting-announcement\)](#) of the FDA's Vaccines and Related Biological Products Advisory Committee.

No change in vaccination practice is recommended. CDC continues to recommend that everyone ages 6 months of age and older stay up-to-date with COVID-19 vaccination; this includes individuals who are currently eligible to receive an updated (bivalent) vaccine. Staying up-to-date with vaccines is the most effective tool we have for reducing death, hospitalization, and severe disease from COVID-19, as has now been demonstrated in multiple studies conducted in the United States and other countries:

- [Data \(https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions\)](https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions) have shown an updated COVID-19 vaccine reduces the risk of hospitalization from COVID-19 by nearly 3-fold compared to those who were previously vaccinated but have not yet received the updated vaccine.
- [Data \(https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status\)](https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status) have shown that the updated COVID-19 vaccine also reduces the risk of death from COVID-19 by nearly 19-fold compared to those who are unvaccinated.
- Other preliminary [data \(https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4314067\)](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4314067). [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) from outside the U.S. have demonstrated more than 80% protection against severe disease and death from the bivalent vaccine compared to those who have not received the bivalent vaccine.

Overall safety data for the bivalent COVID-19 vaccines are available [here](#).

[\(https://www.cdc.gov/mmwr/volumes/71/wr/mm7144a3.htm#:~:text=VAERS%20received%205%2C542%20reports%20of,and%204.5%25%20were%20](https://www.cdc.gov/mmwr/volumes/71/wr/mm7144a3.htm#:~:text=VAERS%20received%205%2C542%20reports%20of,and%204.5%25%20were%20) Once again, **no change is recommended in COVID-19 vaccination practice**, which can be found [here \(https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#:~:text=A%20bivalent%20vaccine%20is%20administered,bivalent%20Pfizer%2DBioNTech%20vaccine\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#:~:text=A%20bivalent%20vaccine%20is%20administered,bivalent%20Pfizer%2DBioNTech%20vaccine).

