Safety of Pfizer's bivalent booster: Suggested talking points

- **Pfizer's bivalent booster has not been linked to increased risk of stroke in older adults, according to the CDC and FDA.**
  - In November, the CDC's Vaccine Safety Datalink (VSD), a vaccine safety monitoring system, detected a signal that Pfizer's bivalent booster may be linked to an increased risk of stroke in people ages 65 and older.
  - This signal prompted the CDC and FDA to conduct further investigation.
  - After reviewing several other large databases—including those from VAERS, other countries' regulators, and Pfizer-BioNTech—the CDC and FDA found no evidence of similar findings.
  - In an announcement last week, the CDC and FDA confirmed that "the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk."

- **This process is evidence that our vaccine safety systems work.**
  - Our vaccine safety systems are designed to be extremely sensitive and can detect risks that may not be caused by the vaccine itself. Through further investigation, scientists can determine whether a signal actually indicates a true safety risk.
  - The recent investigation around Pfizer's bivalent booster is evidence that our vaccine safety systems work.
  - The CDC and FDA say they will continue to evaluate additional data from vaccine safety systems.
  - Their findings and analyses will be discussed at the January 26 FDA advisory committee meeting.

- **Bivalent boosters remain critical for older adults.**
  - Data shows that bivalent boosters reduce the risk of COVID-19 hospitalization and death, especially for older adults.
  - Yet less than 40 percent of people ages 65 and older have received a bivalent booster.
  - News around the safety signal connected to Pfizer's bivalent booster could fuel vaccine misinformation and vaccine hesitancy among older adults.
  - The CDC and FDA continue to emphasize the safety of bivalent boosters and recommend staying up to date with COVID-19 vaccinations.

Safety of Pfizer's bivalent booster: Frequently asked questions

1. **Does Pfizer's bivalent booster cause an increased risk of stroke in older adults?**

The Vaccine Safety Datalink (one of the CDC's vaccine safety monitoring systems) detected a safety signal around Pfizer's bivalent booster and a potential increased risk of stroke in older adults, but upon further investigation, the CDC and FDA determined that this risk is "very unlikely." The regulatory agencies analyzed several large studies and vaccine safety databases—including those from VAERS, other countries' regulators, and Pfizer-BioNTech—to look for any other evidence around the increased risk of stroke related to bivalent vaccines. They found none.

2. **What is the difference between a safety signal and a true safety risk?**

It's important to distinguish between a safety signal and a true safety risk in the context of vaccines. We have several vaccine safety monitoring systems (including VAERS and the Vaccine Safety Datalink) that are designed to be extremely sensitive. They can detect "safety signals," or increased incidences of health risks, that may not be caused by the vaccine itself. Through further investigation, scientists can determine whether a safety signal actually indicates a true safety risk. In the recent case around Pfizer's bivalent booster and a potential increased risk of stroke, the CDC and FDA determined that "the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk." The agencies say they will continue to evaluate additional data from vaccine safety systems.

3. **Should older adults still get a bivalent booster?**

Yes. The CDC, FDA, and other health care experts all agree that bivalent boosters are crucial for older adults and other high-risk individuals. Data has shown that bivalent boosters reduce the risk of COVID-19 hospitalization and death compared to people who are unvaccinated as well as people who are vaccinated but have not received a bivalent booster. Both Pfizer's and Moderna's bivalent boosters are currently authorized for everyone ages 5 and older at least two months after their last shot. Some kids under age 5 are also eligible to receive a bivalent vaccine.