



Bivalent COVID-19 Vaccine and Stroke Risk

Let's Take a Closer Look

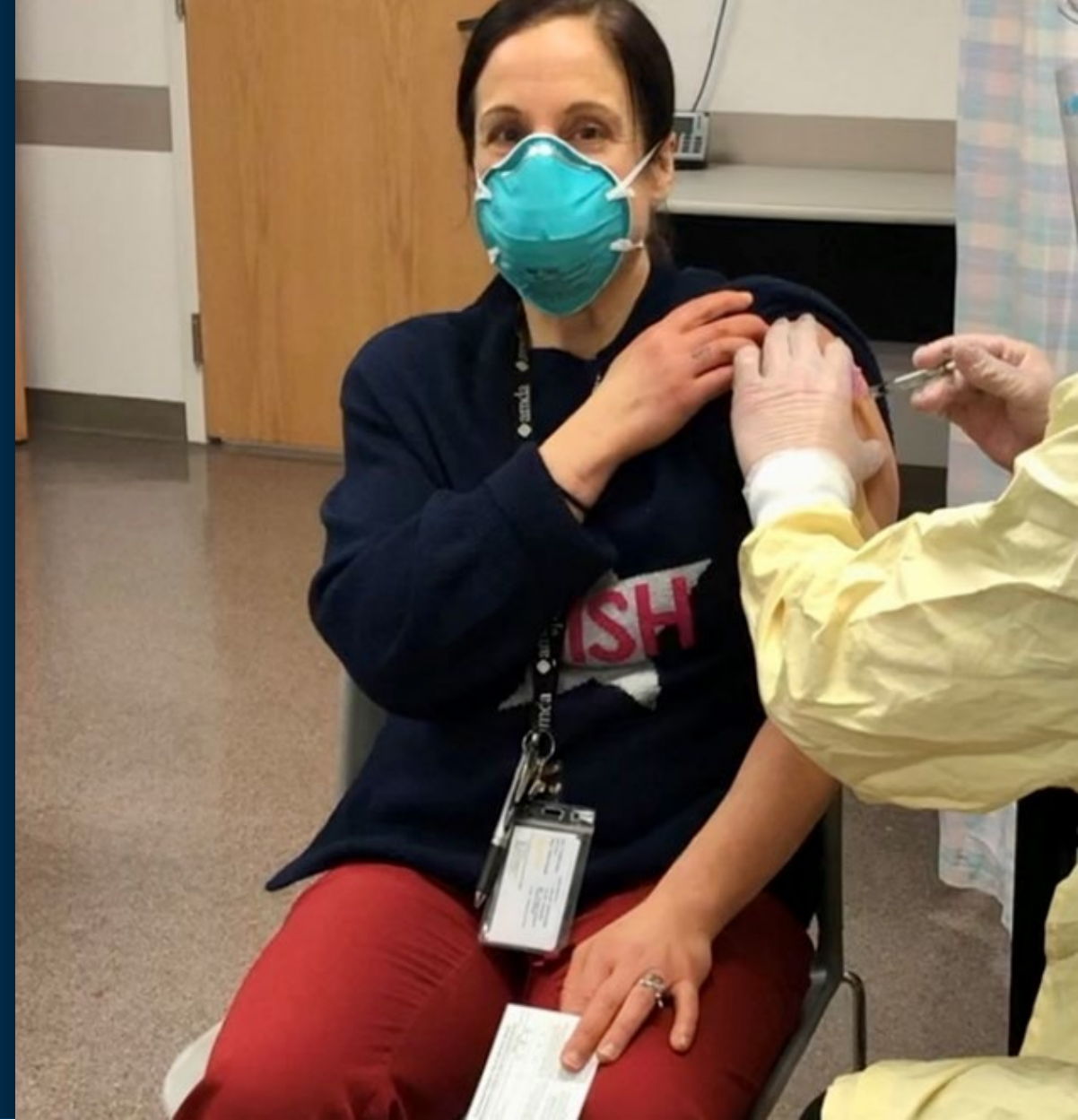
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What is the Bivalent Vaccine?

- These vaccines include mRNA encoding the spike protein from the original strain of the virus that causes COVID-19 combined with omicron variants.
- This vaccine provides better protection now because the virus that causes COVID changes over time (like all viruses).



FDA Has Authorized 2 Bivalent Vaccines

- BNT162b2 (Pfizer-BioNTech)
- mRNA-1273 (Moderna)



Most U.S. adults have not yet received an updated (bivalent) COVID-19 booster



An **updated booster** may reduce your risk of severe COVID-19 by 50% or more*



For the best protection, get an updated booster



*Vaccine effectiveness varied based on previous vaccination status of the control group and outcome studied

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Safety Monitoring

- Multiple safety monitoring systems are in place to ensure the Centers for Disease Control and Prevention (CDC) is aware of any potential side effects
- These safety monitoring systems include Vaccine Safety Data Link (VSD), Vaccine Adverse Event Reporting System (VAERS), and V-safe (self-reported), among others



Safety Signal

- Preliminary safety signal from VSD indicated a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer Bivalent vaccine
- The safety flag signaled need for rapid-response investigation of whether people 65 and older who have received the Pfizer bivalent vaccine were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-42 following vaccination.



Important Data



- A large study of bivalent vaccines using the Centers for Medicare & Medicaid Services (CMS) 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 a bivalent vaccine.
- The Vaccine Adverse Event Reporting System (VAERS) managed by CDC and the U.S. Food & Drug Administration (FDA) has not seen an increase in reporting of ischemic strokes following the bivalent vaccine.

Important Data



- 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 bivalent vaccines.
- No increased risk of stroke has been identified with the Moderna bivalent vaccine.

Transparency

- “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, when one of our safety monitoring systems detects a signal.”
- **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 a bivalent vaccine.



What Protection Does the Bivalent Vaccine Offer?

- Reduces the risk of hospitalization by nearly three-fold as compared to those previously vaccinated but not bivalently boosted
- Reduces risk of death by COVID by nearly 19-fold as compared to those who are unvaccinated
- Approximately only 39% of those over 65 have been bivalently boosted.





XBB.1.5

- Nicknamed “Kraken,” this variant is the latest omicron variant
- “XBB.1.5. does not carry any mutation known to be associated with potential change in severity,” according to a World Health Organization (WHO) risk assessment released January 11, 2023
- Bivalent boosters provide protection against XBB.1.5

Take Home Points

- The updated bivalent boosters protect against both the original virus that causes COVID-19 and the omicron variants
- CDC recommends one updated bivalent booster dose for everyone aged 5 years and older if it has been at least 2 months since your last dose
- The CDC will continue to keep the public updated on all important information regarding covid vaccines



Questions?

Contact Us

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