

Clinical Update

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Preliminary COVID-19 Vaccine Safety Signal for Strokes in Persons Aged 65 Years and Older

- On January 13, 2023, [CDC and FDA posted a joint statement](#)
 - As part of routine, detailed surveillance of COVID-19 vaccine safety, they detected a preliminary indication in one monitoring system (Vaccine Safety Datalink-VSD) of a possible increase in the risk of stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 bivalent mRNA vaccine
- Notably, no increased risk of stroke has been noted in
 - Any safety monitoring systems worldwide after use of monovalent mRNA Covid-19 vaccines as initial series or booster doses over the last two years
 - For bivalent boosters, in any other safety monitoring system besides the VSD
 - In VSD system, for persons receiving Moderna rather than Pfizer mRNA bivalent booster mRNA vaccine

Preliminary COVID-19 Vaccine Safety Signal for Strokes in Persons Aged 65 Years and Older

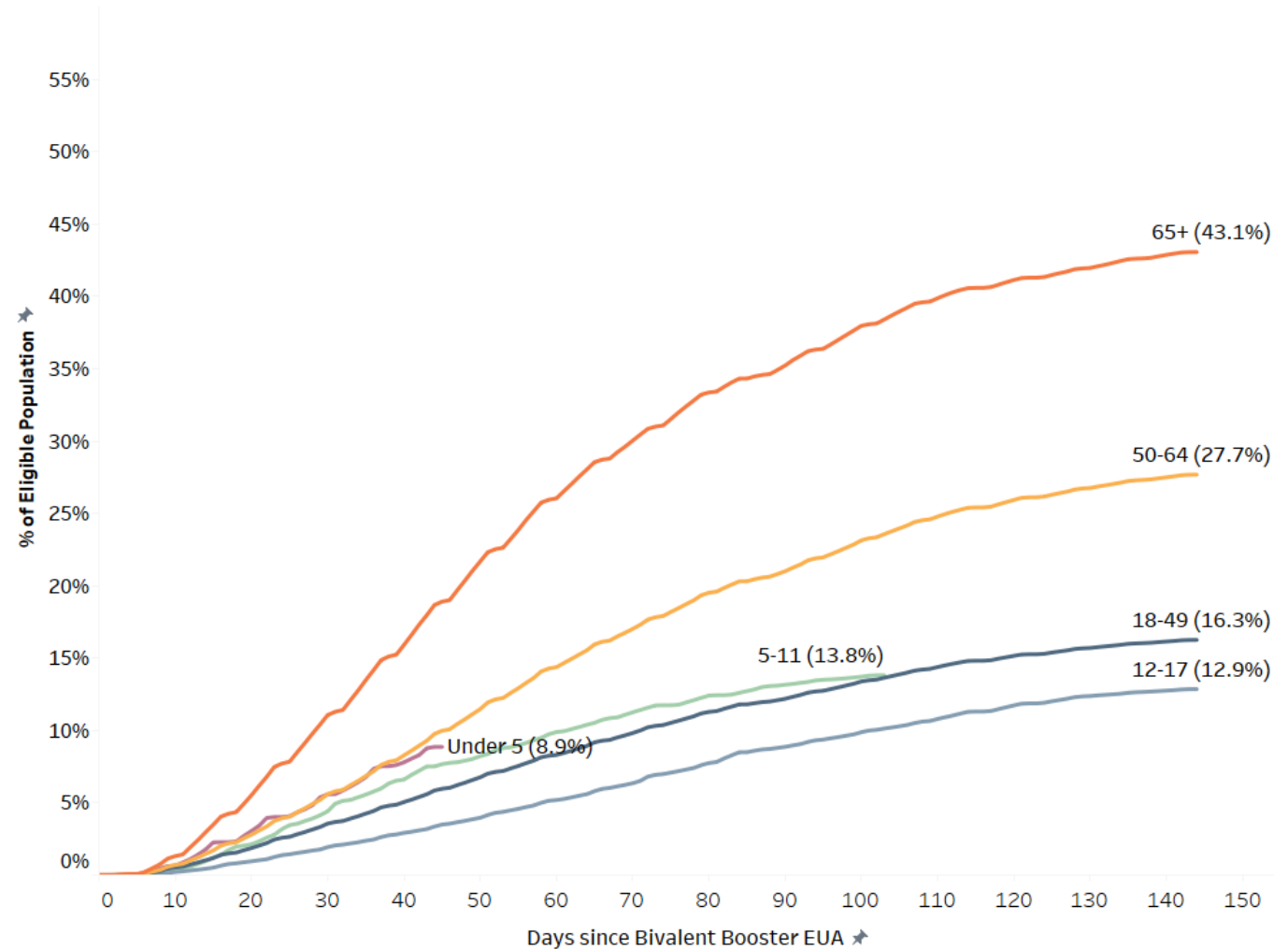
- **The totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk.**
- **No changes in vaccine administration are recommended.**
- An update on the ongoing investigation is scheduled for the [FDA advisory Committee meeting](#) on January 26, 2023.

Booster Uptake Trends

as of January 23, 2023

- Statewide 23.6% of the eligible population has received a bivalent booster
- Faster uptake among eligible 65+ population compared to other age groups

Bivalent Booster Uptake Trends



CDC COVID-19 Vaccination Program: 90 Day Initiative

- Single dose vials are available for all LTCF – ask your pharmacy
 - If you don't have a pharmacy and are not already a COVID-19 provider, then consider the CDC-sub provider agreement
- Sub-provider agreement
 - For LTCF that wish to access single dose vial COVID-19 vaccine through enrolled pharmacy providers for direct administration by the LTCF to their residents and staff.
 - Pfizer-BioNTech COVID-19 Vaccine for people 12 years of age and older in single-dose vials is the ONLY vaccine product/presentation available in this program.
 - To qualify for this program, the LTCF:
 - Must partner with a designated pharmacy enrolled as a COVID-19 Vaccine Provider
 - Facility cannot be a regular fully enrolled COVID-19 Vaccine Provider
 - The enrolled parent pharmacy partner organization is primarily responsible for making sure the LTCFs have proper storage and handling in place.
 - State jurisdictions are not required to visit facilities receiving vaccine under this initiative.
 - Pharmacy partners and enrollees should be aware of state-specific data reporting requirements. [AB1797](#) requires LTCFs in CA to report doses administered.

CDC COVID-19 Vaccination Program: 90 Day Initiative

- Update on utilization of sub-provider agreement
 - As of 1/20/23:
 - 104 LTCFs across the country have enrolled, but only one LTCF has been confirmed by its parent pharmacy partner organization
 - Confirmation is when they place the first order for single dose vial from the pharmacy
 - No LTCFs located in California have enrolled in the program
 - The program only began in mid-December. Most enrollments came after the holidays and only one LTCF has been confirmed, so that would be the only possible example of success thus far.
 - CDC sends to jurisdictions data on the facilities that sign up every week (Thursday or Friday)

Long-term Care Facility COVID-19 Vaccine Toolkit

Long-Term Care Facility (LTCF)

COVID-19 Vaccine Toolkit

The **LTCF COVID-19 Vaccine Toolkit** has been developed as a resource to ensure that Long-Term Care (LTC) residents and staff have continued access to primary series and booster doses of COVID-19 vaccine. The following are vaccine access options, vaccination resources, and staff and resident education resources.

- LTCFs are encouraged to reach out to their regular or contract pharmacy to inquire about meeting the facility's ongoing needs of COVID-19 vaccination, including on-site clinics.
- LTC residents and staff who can travel to a vaccine site are encouraged to utilize vaccination sites in their local community (i.e., nearby pharmacies or healthcare provider offices); this may be the fastest way to get vaccinated.
- If an on-site vaccination clinic is the best option to meet your LTC residents' needs, facilities can contact LTC or retail pharmacies directly for support. When planning, LTCFs should take into consideration how many residents and staff will need primary and booster vaccines.
- Consider planning coadministration of both flu and COVID-19 vaccine at the same time. COVID-19 vaccines can be administered at the same time as flu and other vaccines.

CDPH Influenza (Flu), RSV, and Other Respiratory Viruses Report (Week 2: January 8, 2023 – January 14, 2023)

Influenza Highlights



▼ **3.5%**
Laboratory
flu positivity



▼ **3.9%**
Outpatient
ILI activity



▼ **0.5%**
Hospital
flu admissions



477
Deaths
since 10/2/2022



81
Outbreaks
since 10/2/2022

Influenza Activity Levels⁺



Geographic Area	Activity Level
California Statewide	Low
Northern Region	Low
Bay Area Region	Low
Central Region	Low
Upper Southern Region	Low
Lower Southern Region	Low

Influenza Resource

THE IMPORTANCE OF PREVENTING INFLUENZA DURING A PANDEMIC

As the world faces coronavirus disease 2019 (COVID-19), it is more important than ever that older adults get vaccinated against influenza (flu).

UNDERSTANDING COVID-19 AND ITS IMPACT ON OLDER ADULTS

In 2019, a new coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged that had not previously been seen in humans. In February 2020, the World Health Organization announced an official name for the novel disease caused by infection with SARS-CoV-2: coronavirus disease 2019, often abbreviated as COVID-19.¹

Though everyone is at risk for getting COVID-19 if they are exposed to the virus, this risk increases with age, as does the potential for severe illness, including hospitalization, intensive care, the use of a ventilator to facilitate breathing, and death.²



Current studies show that **8** out of **10** COVID-19-related deaths in the United States have been among adults age 65 years and older.²

Preliminary studies also suggest coinfection with influenza B and COVID-19 disease can elevate risk of death and increase the chance of a poorer prognosis.²

FLU VACCINATION AMIDST COVID-19 FOR ADULTS AGE 65 AND OLDER

As new information about the disease and how it relates to other viruses emerges each day, your patients may have questions about flu and flu vaccination as it relates to COVID-19. Following are a series of questions your older adult patients may ask, with suggested evidence-based responses to help guide your discussion with them on the increased importance of flu vaccination during this time.

How do I know if I have the flu, or if it's COVID-19?

Flu and COVID-19 are both contagious respiratory illnesses that share many characteristics, but they are caused by different viruses. Because some of the symptoms are similar, it can be hard to tell the difference between the two diseases, but there are some clues that can aid the differential diagnosis. For example, COVID-19 may include a change in or loss of taste or smell, and, after someone has been exposed, COVID-19 symptoms typically take several days longer to appear than those related to flu. Testing will likely be needed to confirm a disease diagnosis.⁴

Upcoming FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting

Discussion Topics: [Meeting agenda](#)

- Update on Original COVID-19 Vaccine and COVID-19 Vaccine Bivalent Effectiveness and Safety
- Presentations by Moderna, Pfizer, and Novavax
- FDA Considerations for Potential Changes to COVID-19 Vaccine Strain Composition

Date: Thursday, January 26, 2023

Time: 8:30 AM - 5:30 PM ET

YouTube Link: <https://youtu.be/ZjULNuSYfd0>

Upcoming FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting

Voting Question

Simplification of current COVID-19 vaccine use:

- *Vaccine composition:* Does the committee recommend harmonizing the vaccine strain composition of primary series and booster doses in the U.S. to a single composition, e.g., the composition for all vaccines administered currently would be a bivalent vaccine (Original plus Omicron BA.4/BA.5)?