

# Clinical Update

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# FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting 1/26/2023

- Advisory committee unanimously voted yes (21/21 members) to harmonizing COVID-19 vaccine strain composition going forward
- Moving to the same vaccine strain composition for primary and booster vaccines would simplify the COVID-19 vaccination regimen
- No changes to FDA or CDC guidance have been made **at this time** but anticipate late spring/early summer annual target for review

# CDC/FDA Safety Data Support Continued Recommendation of COVID-19 Bivalent Boosters

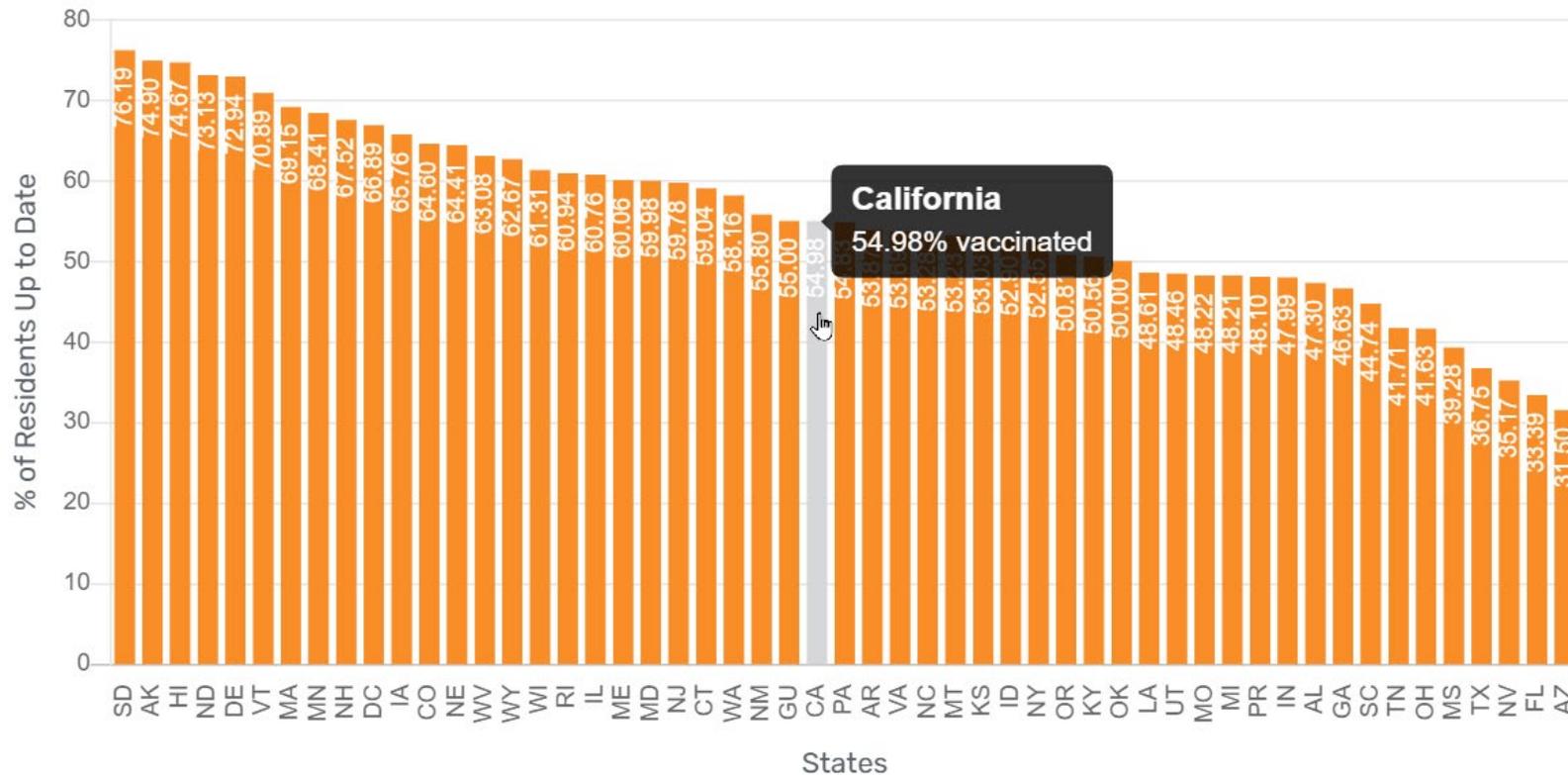
- Safety signal update: ischemic stroke following bivalent Pfizer COVID-19 mRNA booster vaccination in people 65+
- Additional analyses were completed by both the CDC and the FDA
  - Chart review: small subset, most confirmed cases had co-administered high-dose or adjuvanted flu vaccine – continue to further analysis on this
  - FDA data suggests no safety signal for ischemic stroke for the bivalent boosters in people aged 65 years and older
- CDC continues to recommend that everyone eligible for a COVID-19 mRNA bivalent booster or a flu vaccine get vaccinated

# COVID-19 Nursing Home Data - Residents

Data as of January 15, 2023

## Percentage of Current Residents Up to Date with COVID-19 Vaccines per Facility

This shows the average percentage among facilities who have reported vaccination data in the current or prior week.

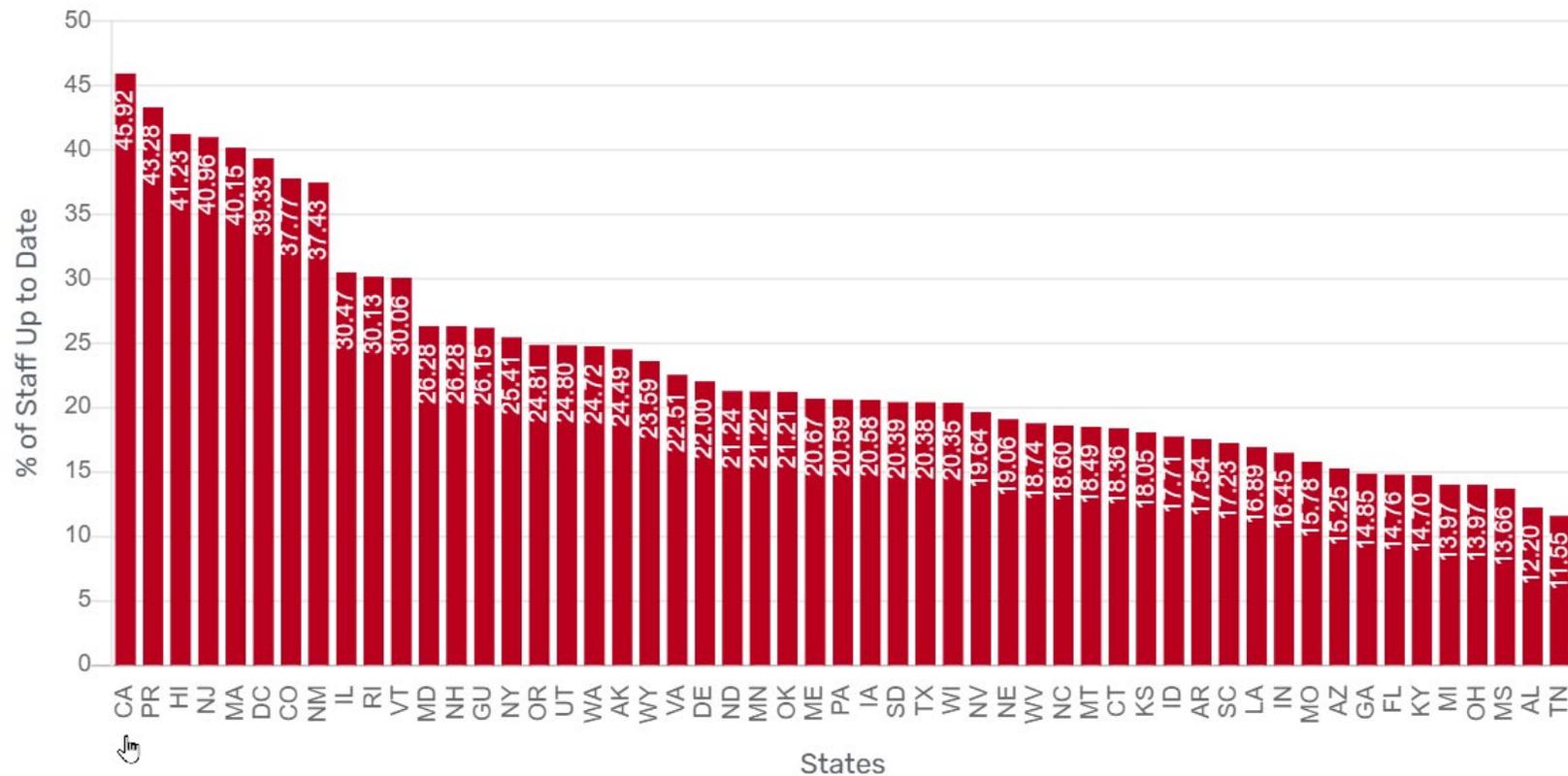


# COVID-19 Nursing Home Data - Staff

Data as of January 15, 2023

## Percentage of Current Staff Up to Date with COVID-19 Vaccines per Facility

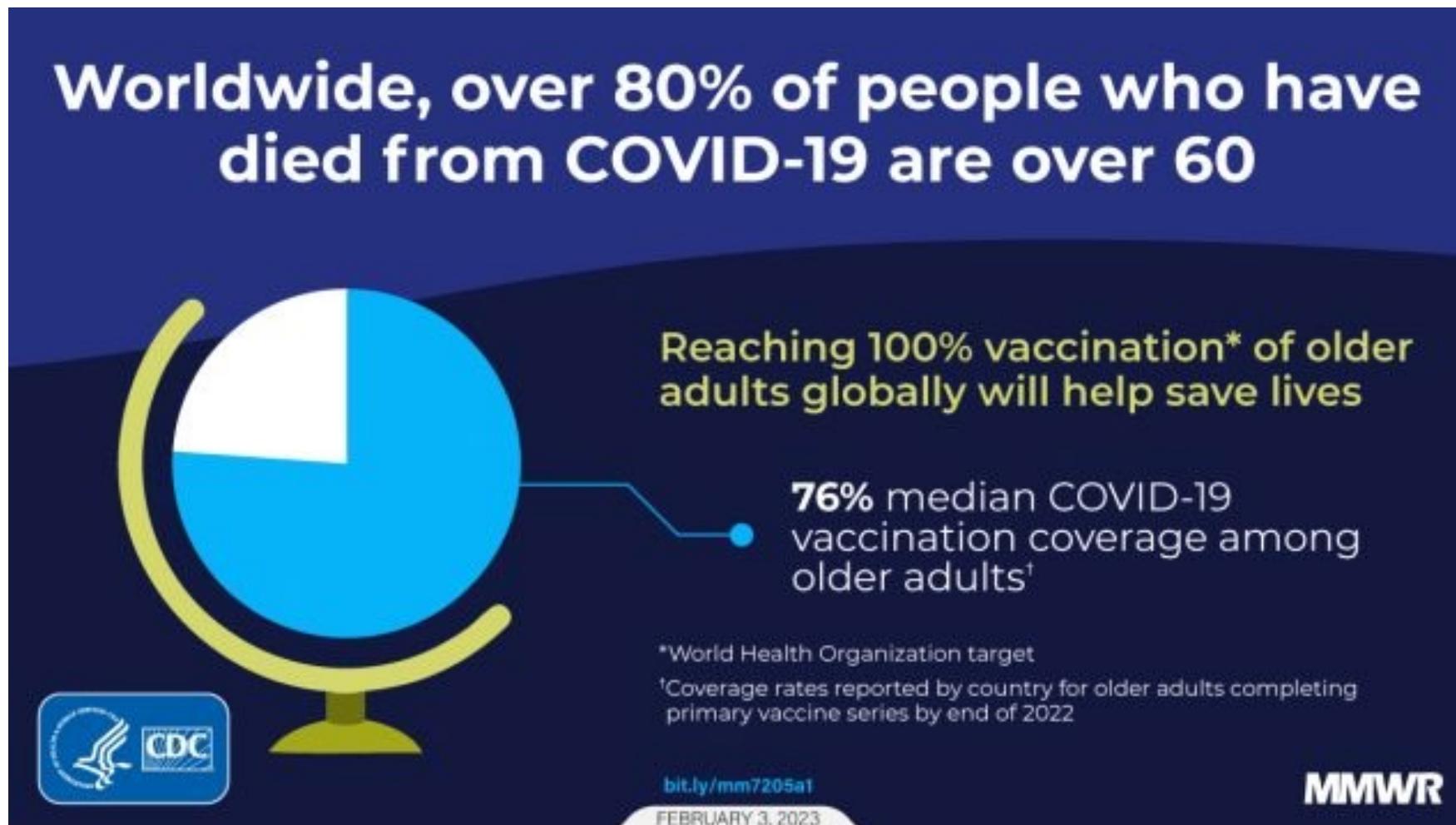
This shows the average percentage among facilities who have reported vaccination data in the current or prior week.



# CDC Morbidity & Mortality Weekly Report (MMWR)

- COVID-19 Mortality and Progress Toward Vaccinating Older Adults — World Health Organization, Worldwide, 2020–2022
- Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARS-CoV-2 Infection Attributable to Omicron BA.5– and XBB/XBB.1.5–Related Sublineages Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, December 2022–January 2023
- SARS-CoV-2 Antibody Responses to the Ancestral SARS-CoV-2 Strain and Omicron BA.1 and BA.4/BA.5 Variants in Nursing Home Residents After Receipt of Bivalent COVID-19 Vaccine — Ohio and Rhode Island, September–November 2022
- Laboratory-Confirmed COVID-19 Case Incidence Rates Among Residents in Nursing Homes by Up-to-Date Vaccination Status — United States, October 10, 2022–January 8, 2023

# COVID-19 Mortality and Progress Toward Vaccinating Older Adults — World Health Organization, Worldwide, 2020–2022



# Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARS-CoV-2 Infection Attributable to Omicron BA.5– and XBB/XBB.1.5–Related Sublineages Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, December 2022–January 2023

- Nationwide COVID-19 testing via pharmacies, immunocompetent adults
- Design: Test-negative, case-control analysis, testing done December 1, 2022 – January 13, 2023
- Bivalent mRNA booster dose provided additional protection against symptomatic XBB/XBB.1.5 infection for at least the first 3 months after vaccination in persons who had previously received 2–4 monovalent vaccine doses
- Across age groups, VE was generally similar against BA.5-related infections and XBB/XBB.1.5-related infections
- Limitations: some self-reported data may have recall bias, prior infection may be under-reported, behavioral differences

# SARS-CoV-2 Antibody Responses to the Ancestral SARS-CoV-2 Strain and Omicron BA.1 and BA.4/BA.5 Variants in Nursing Home Residents After Receipt of Bivalent COVID-19 Vaccine — Ohio and Rhode Island, September–November 2022

- Booster dose coverage has been lower than that initially seen with the primary series
- Analysis of serum from 233 nursing home residents
- Antibody titers and neutralizing antibodies against ancestral and BA.1 strain declined considerably prior to bivalent booster administration
- Bivalent booster increased antibody titers and restored immunity after prior vaccine or infection-induced immunity
- Immunologic evidence of additional protection offered by bivalent booster against SARS-CoV-2 infection among nursing home residents who have previously received only monovalent vaccine
- Limitations: immunologic findings may not directly translate, limited sample size

# Laboratory-Confirmed COVID-19 Case Incidence Rates Among Residents in Nursing Homes by Up-to-Date Vaccination Status — United States, October 10, 2022–January 8, 2023

- Analysis from CDC National Healthcare Safety Network (NHSN)
- Examination of weekly COVID-19 case incidence rates by up to date vaccination status
- Average of ~15,000 facilities reported both vaccination and case data weekly
- Weekly incidence rates of COVID-19 among nursing home residents who were not up to date with COVID-19 vaccines were 30%–50% higher than were those among residents who were up to date during October 10, 2022–January 8, 2023.
- Limitations: manually reported data, crude rates do not account for potential confounding factors, classification of up to date status

## AFL 21-34

- Reflect updates in the State Public Health Officer Order (September 2022)
- Rescinded routine COVID-19 screening test requirements for
  - Unvaccinated exempt HCP
  - Booster-eligible HCP who have not yet received their booster
- Under revision to match current CDC vaccine guidance
  - Authorization (EUA) for use of Novavax as booster dose (in limited situations)



# Upcoming: Communities of Practice Webinar

## Topic: Promoting COVID-19 Bivalent Vaccinations for Older Adults: Long-Term Care Provider Perspectives

Communities of Practice webinar focused on promoting COVID-19 bivalent vaccinations for older adults and residents/staff in long term care settings; speakers will present successful strategies in increasing bivalent booster uptake in their communities. Moderated by CDC's State, Tribal, Local, and Territorial (STLT) Task Force.

**Date:** Thursday, February 9, 2023

**Time:** 12PM – 1PM, PT

**Register Now:** [Communities of Practice Webinar](#)

Featuring presentations from:

- Patrick Cote, PharmD, Director, Pharmacy Services, Good Samaritan Society (Sanford Health), North Dakota
- Kaylea Watkins, RN, CIC, Infection Preventionist, Providence Mount St. Vincent, Seattle, WA
- Winter Viverette, MAIO, MATD, Infection Prevention Specialist, Healthcare Settings, Chicago Department of Public Health
- Karen McDonald, BSN, RN, Vice President, Chief Clinical Officer, Mission Health Communities