

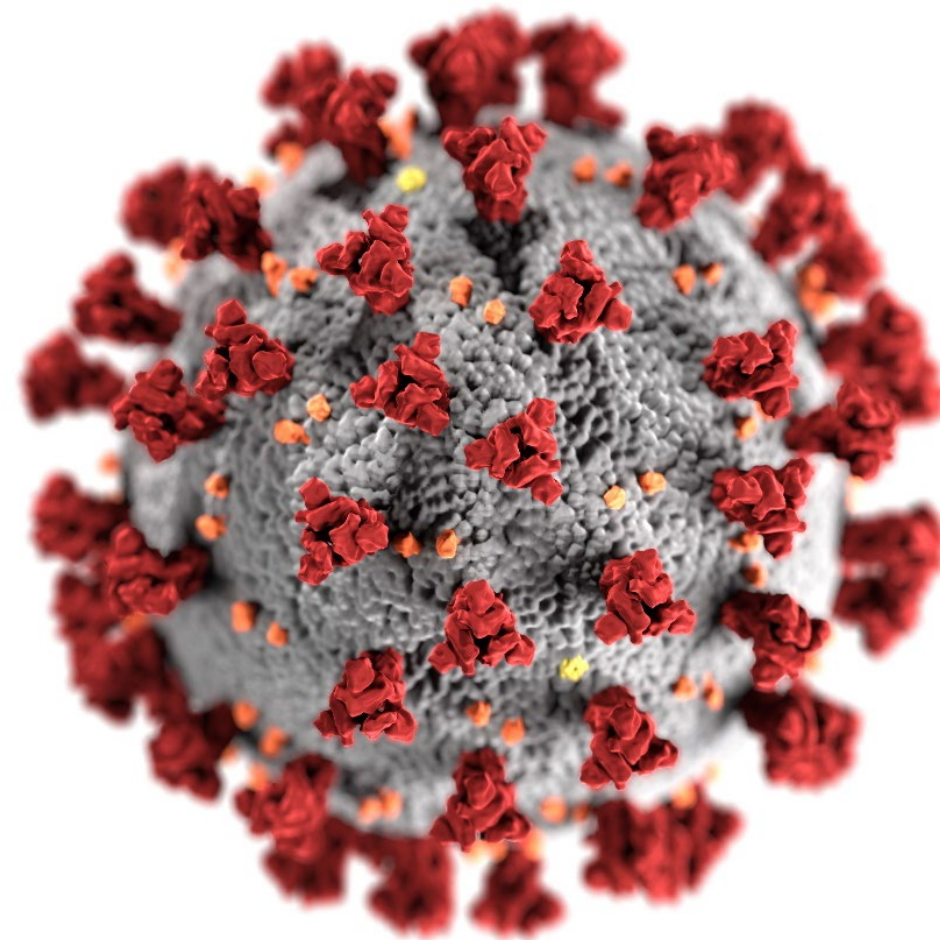
## **Vaccines and Related Biological Products Advisory Committee Meeting**

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov) and include 508 Accommodation and the title of the document in the subject line of your e-mail.

# COVID-19 Epidemiology and Vaccination Rates in the United States

CDR Heather Scobie, PhD, MPH  
COVID-19 Epidemiology Task Force  
Centers for Disease Control and Prevention

June 7, 2022



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)



# SARS-CoV-2 Variants



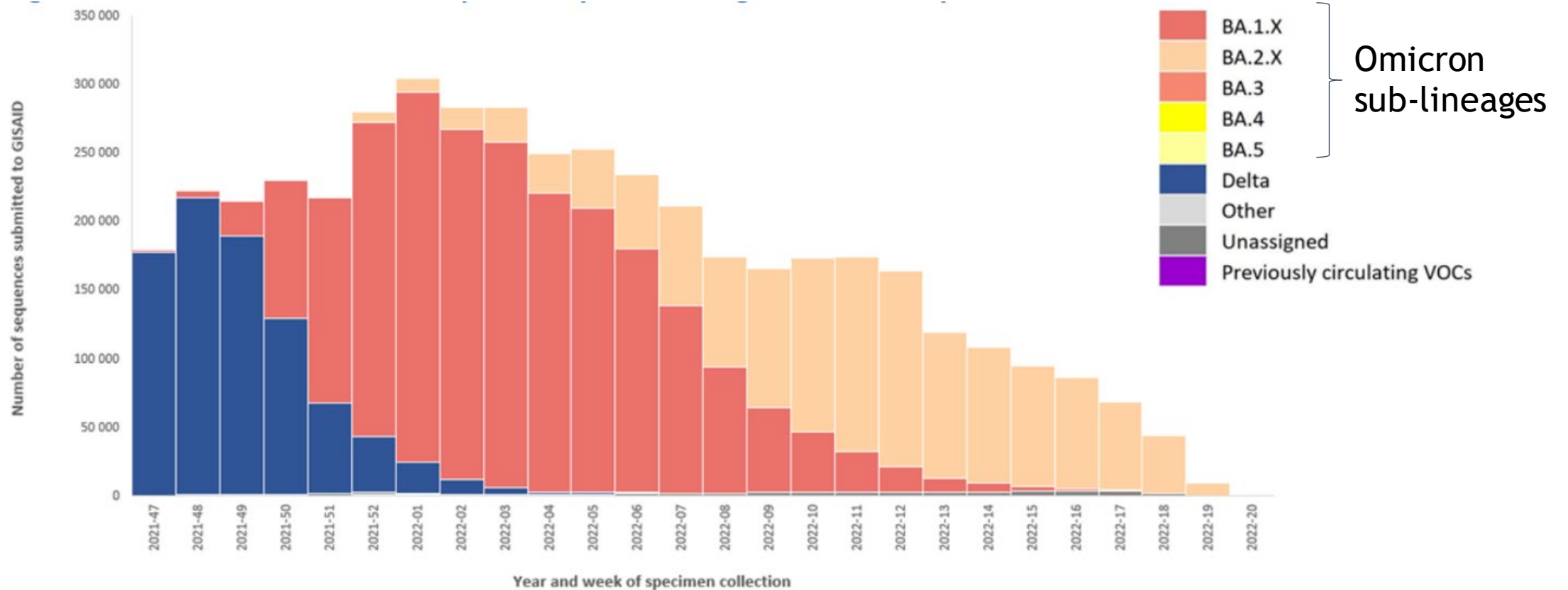
# Characteristics of SARS-CoV-2 Omicron variant

- Increased transmissibility
- Decreased disease severity
- 30 mutations in spike gene (S-gene)
  - 15 in receptor binding domain
- Reduction in efficacy of some monoclonal antibody treatments
- Reduction in neutralization by sera from vaccinated or convalescent individuals



Key mutations (yellow) in the Omicron spike protein (top view)  
Source: New York Times

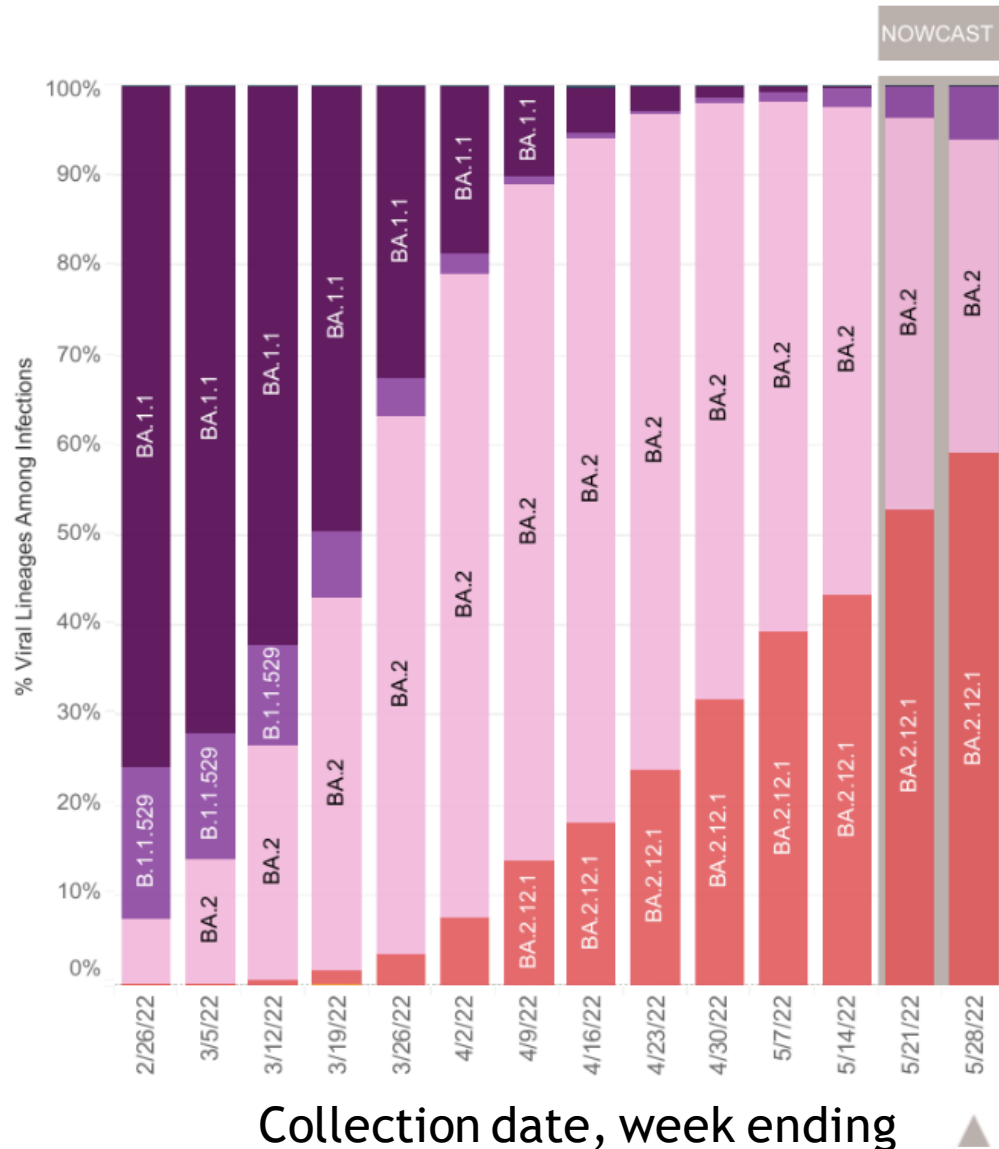
# Global SARS-CoV-2 Genomic Sequences Submitted to GISAID as of May 23, 2022



Omicron sub-lineages related to BA.1 and BA.2 are pooled under BA.1.X and BA.2.X, respectively  
World Health Organization. Weekly epidemiological update on COVID-19 - 25 May 2022  
<https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---25-may-2022>

# Trends in Weighted Variant Proportion Estimates & Nowcast

## February 20-May 28, 2022



NOWCAST

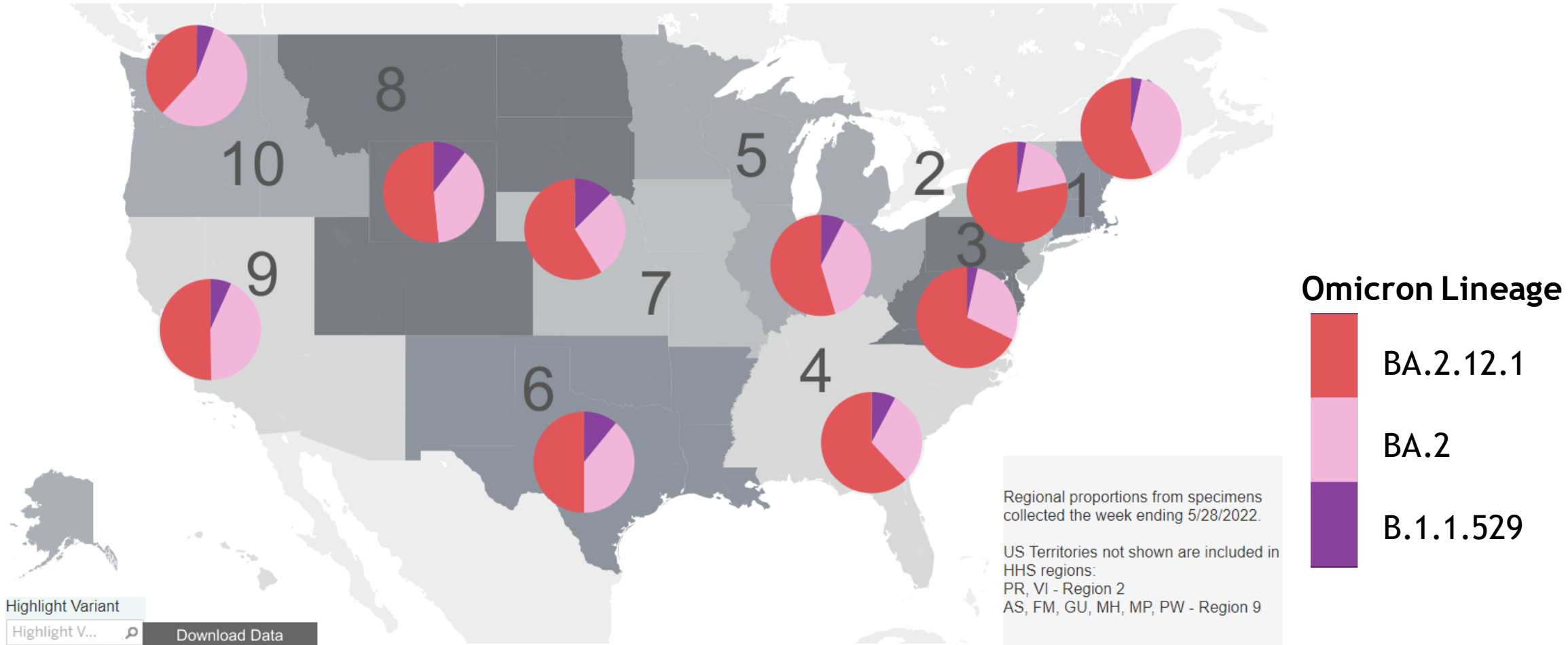
USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2.12.1	VOC	59.1%	54.7-63.3%
	BA.2	VOC	34.7%	30.8-38.8%
	B.1.1.529	VOC	6.1%	4.1-8.8%
	BA.1.1	VOC	0.1%	0.0-0.1%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.1%	0.0-0.1%

\* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.  
 \*\* These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates  
 # AY.1-AY.133 and their sublineages are aggregated with B.1.617.2.  
 BA.1, BA.3, BA.4, BA.5 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. For regional data, BA.1.1 and its sublineages are also aggregated with B.1.1.529, as they currently cannot be reliably called in each region. Except BA.2.12.1 and its sublineages, BA.2 sublineages are aggregated with BA.2.

# Nowcast Estimates of Variant Proportions by HHS Region

May 22-28, 2022



Lineages called using pangolin v4.0.6, pangolin-data v1.8, scorpio version 0.3.17 and constellations v0.1.9.  
Lineage BA.1.1 and its sublineages are aggregated with B.1.1.529 at the regional level as they currently cannot be reliably called in each region.

Updated May 31, 2022

HHS=Health and Human Services

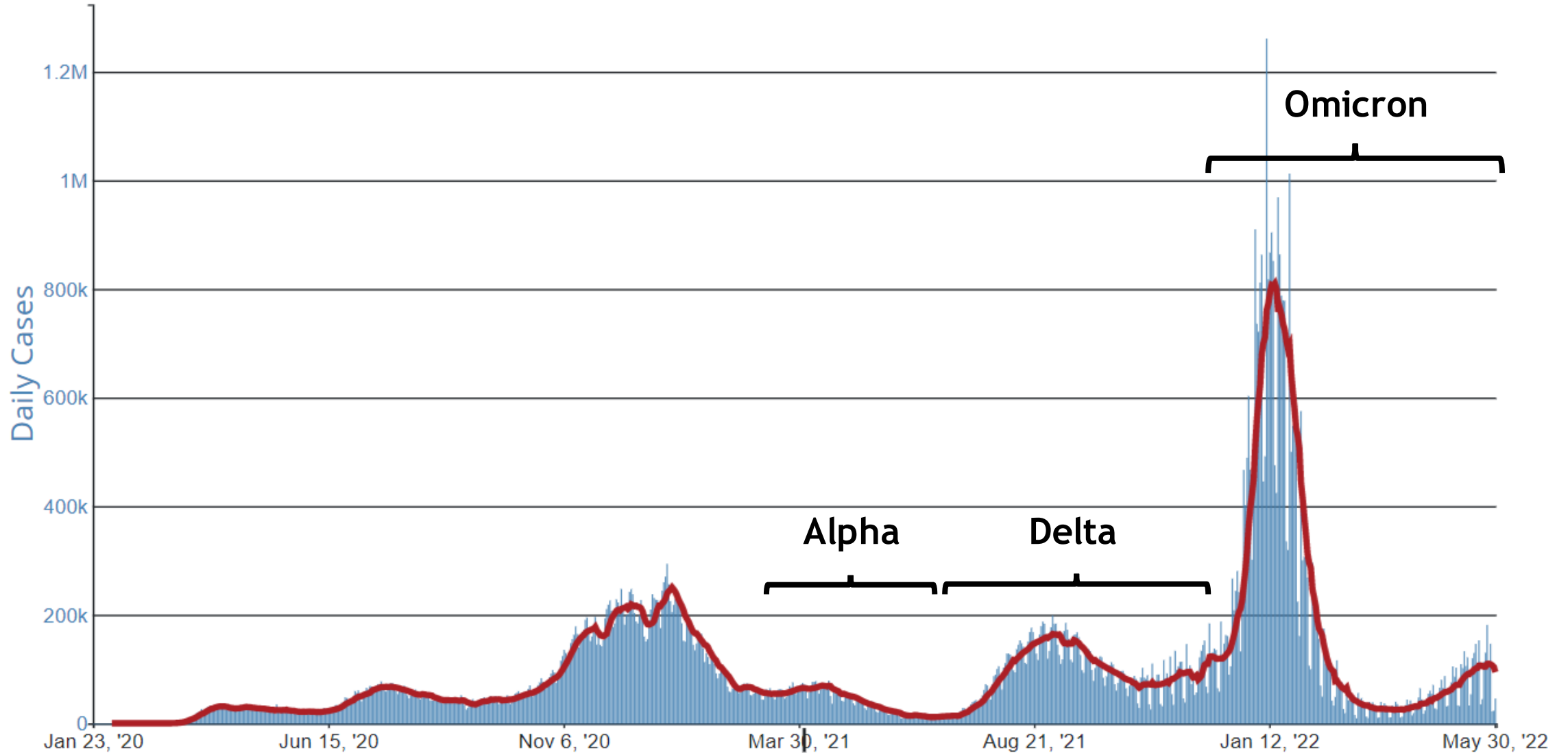
<https://covid.cdc.gov/covid-data-tracker/#variant-proportions> Accessed June 1, 2022

# COVID-19 Disease Trends

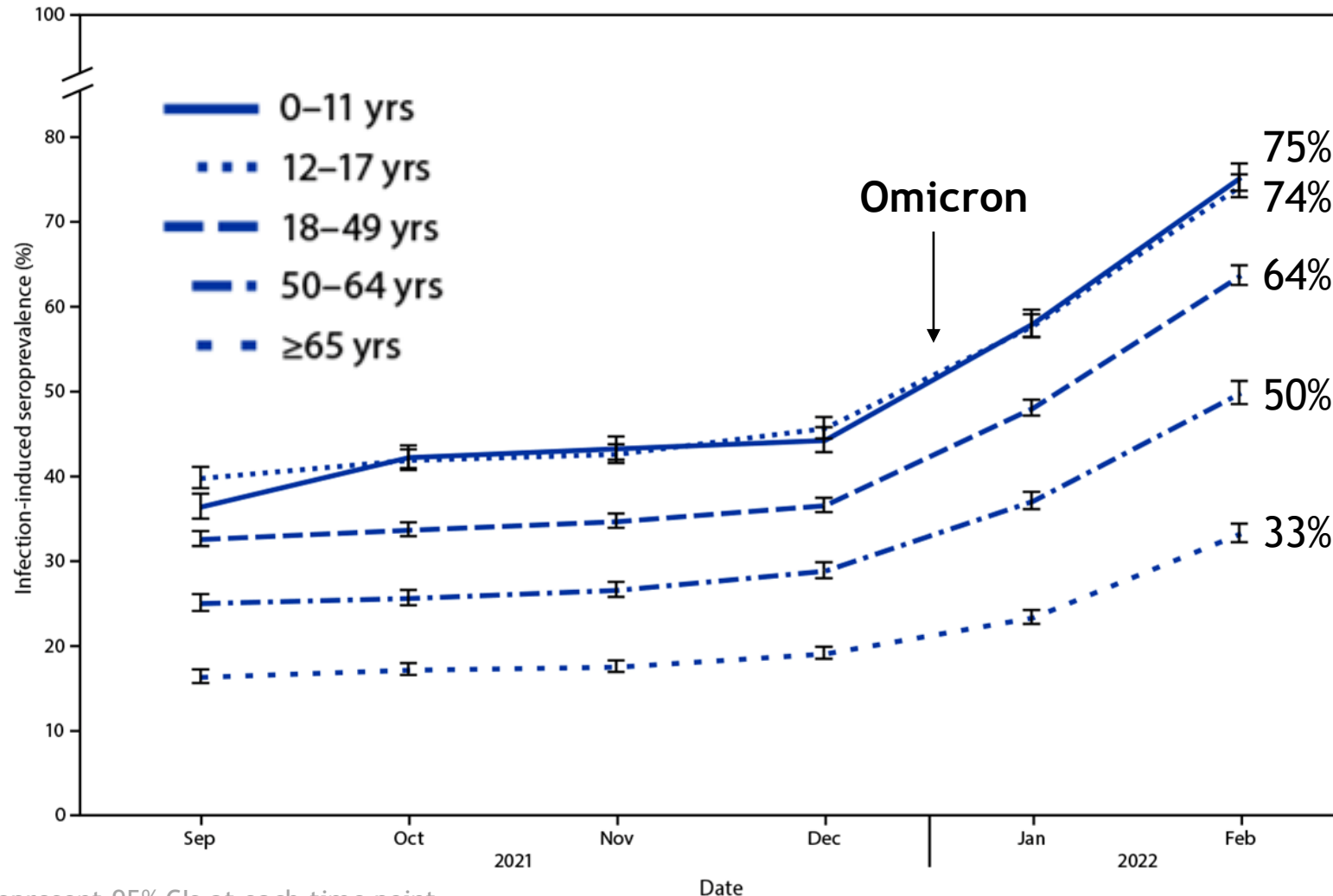




# Daily Trends in Number of COVID-19 Cases, United States



# Seroprevalence of infection-induced SARS-CoV-2 antibodies,\* by age group – United States, September 2021-February 2022



58% national seroprevalence in February 2022

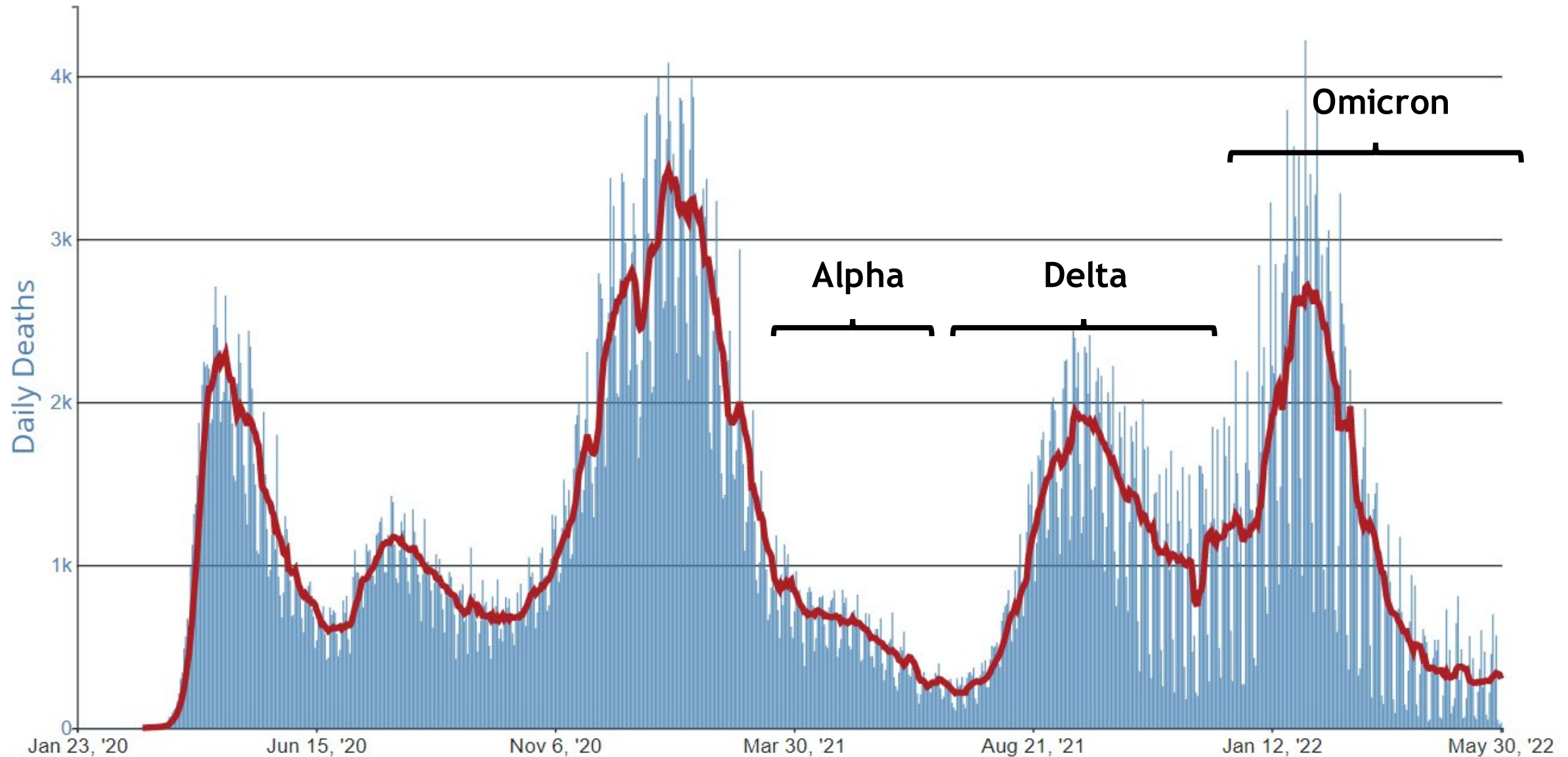
Does not indicate:

- Antibodies from vaccination (anti-spike)
- Amount of antibodies or protection from reinfection

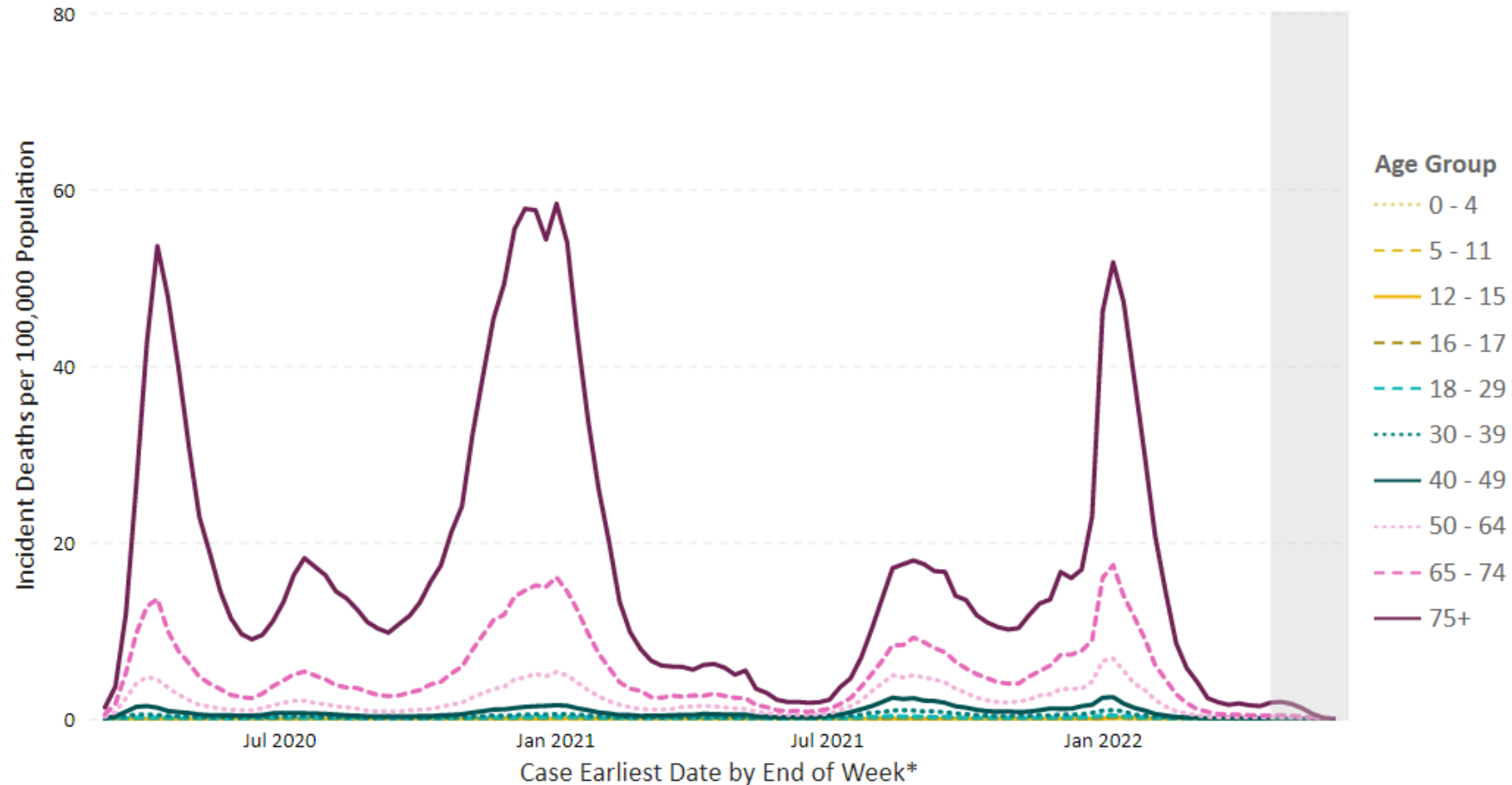
\*Error bars represent 95% CIs at each time point

Clarke et al. MMWR 2022;71:606-608. DOI: <http://dx.doi.org/10.15585/mmwr.mm7117e3>. CDC COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/#national-lab>

# Daily Trends in Number of COVID-19 Deaths, United States



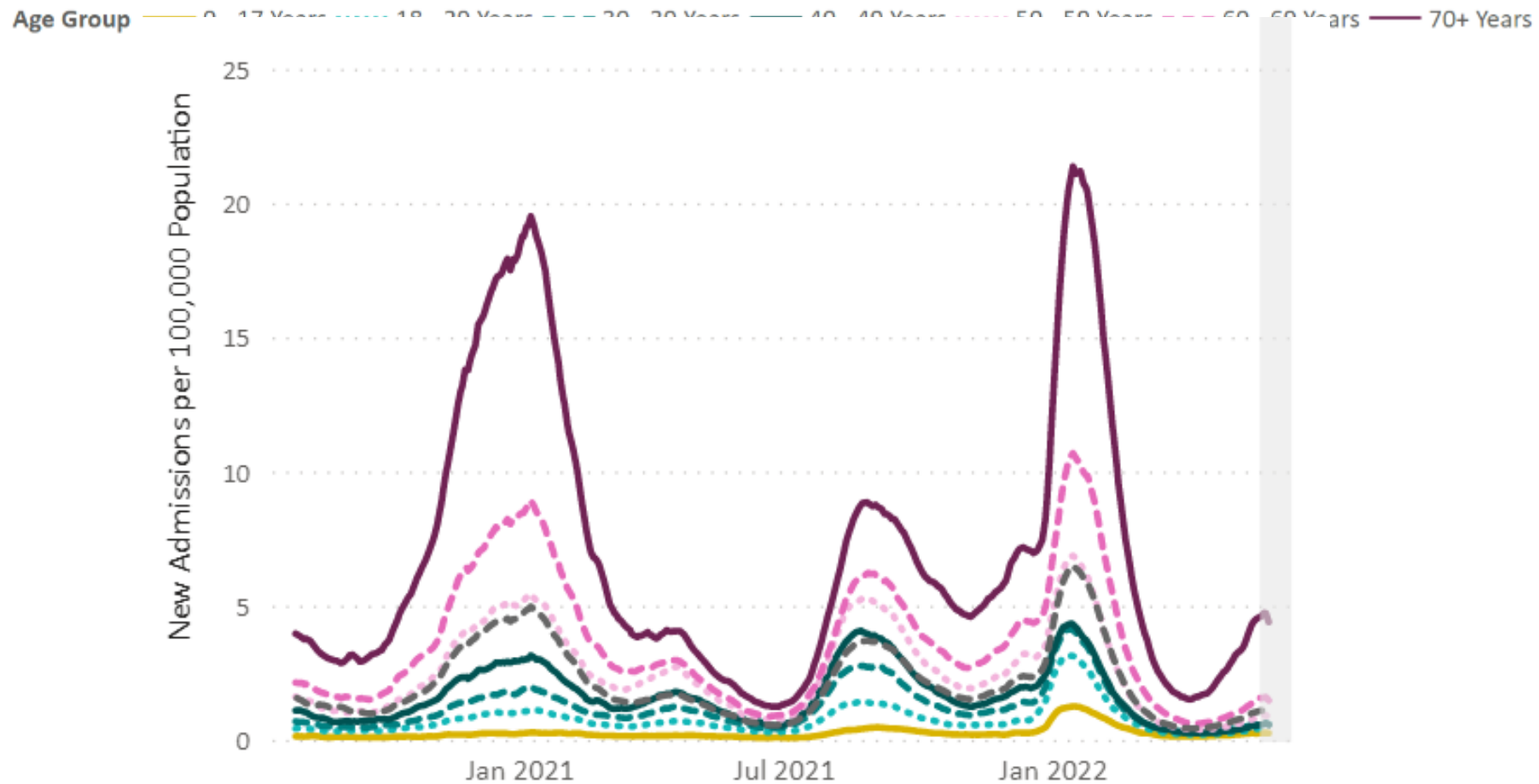
# Weekly Trends in COVID-19 Mortality Rates by Age Group, United States. March 1, 2020 - June 4, 2022



US: The most recent case record was reported during the week ending on Jun 04, 2022. Percentage of deaths among reported cases - 1.14%. Percentage of deaths reporting age by date - 99.91%. US territories are included in case and death counts but not in population counts. Potential six-week delay in case reporting to CDC denoted by gray bars. Weekly data with five or less deaths have been suppressed. \*Case Earliest Date is the earliest of the clinical date (related to illness or specimen collection and chosen by a defined hierarchy) and the Date Received by CDC. The date for the current week extends through Saturday.

Source: CDC COVID-19 Case Line-Level Data, 2019 US Census, HHS Protect; Visualization: Data, Analytics & Visualization Task Force and CDC CPR DEO Situational Awareness Public Health Science Team

# Weekly Trends in Rates of New Inpatient Admissions by Age Group, United States, August 1, 2020 - May 29, 2022



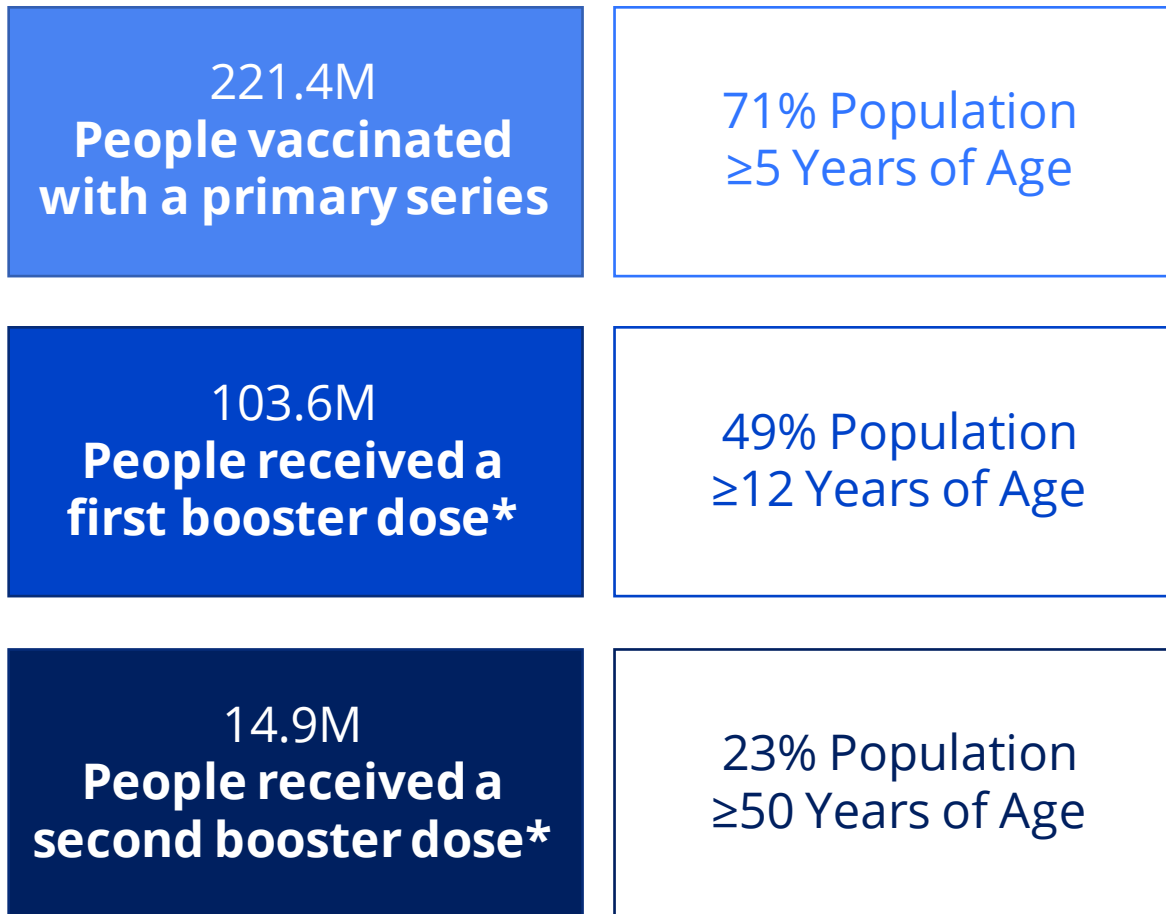
Based on reporting from all hospitals (N=5,295). Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution. Small shifts in historic data may occur due to changes in the CMS Provider of Services file, which is used to identify the cohort of included hospitals. Data since December 1, 2020 have had error correction methodology applied. Data prior to this date may have anomalies that are still being resolved. Note that the above graphs are often shown on different scales. Data prior to August 1, 2020 are unavailable.

# Trends in COVID-19 Vaccination



# COVID-19 Vaccinations in the United States

As of June 2, 2022



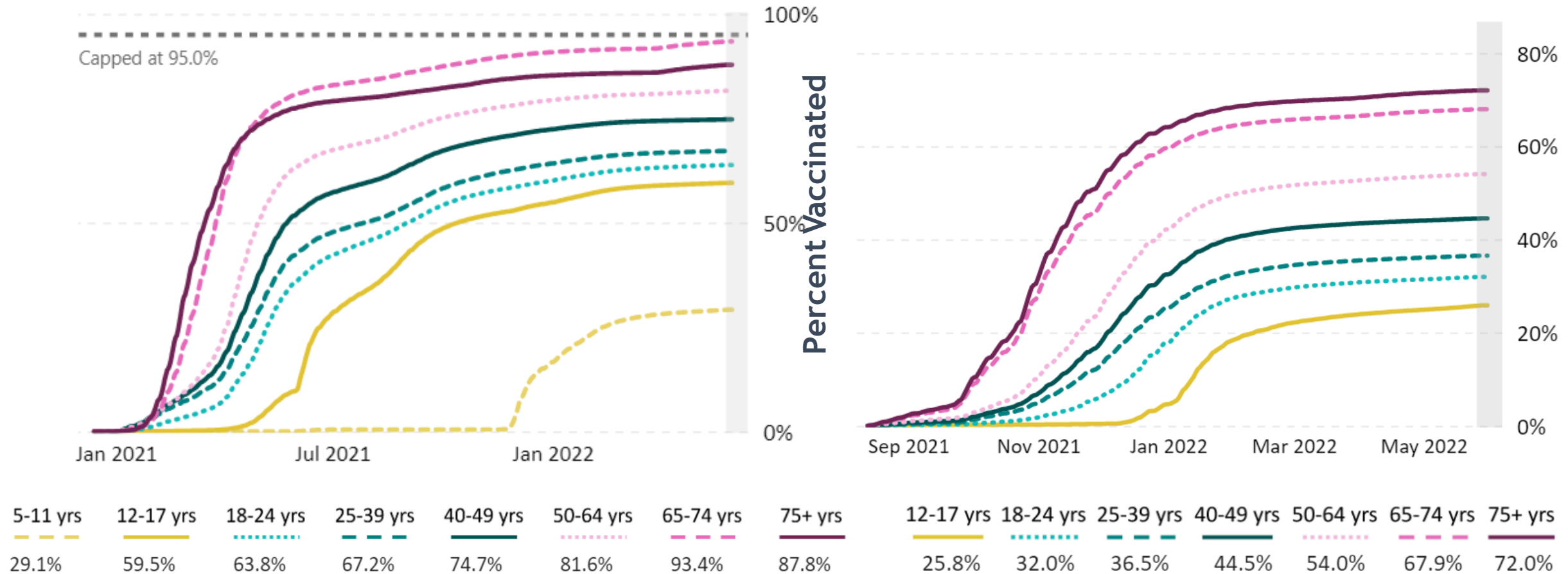
\*This includes people who received booster doses and people who received additional doses.

[https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total) Accessed June 2, 2022

# Percentage of People Vaccinated with at Least a Primary Series or Booster Dose by Age Group and Date Administered, United States

## Primary Series

## Booster Dose



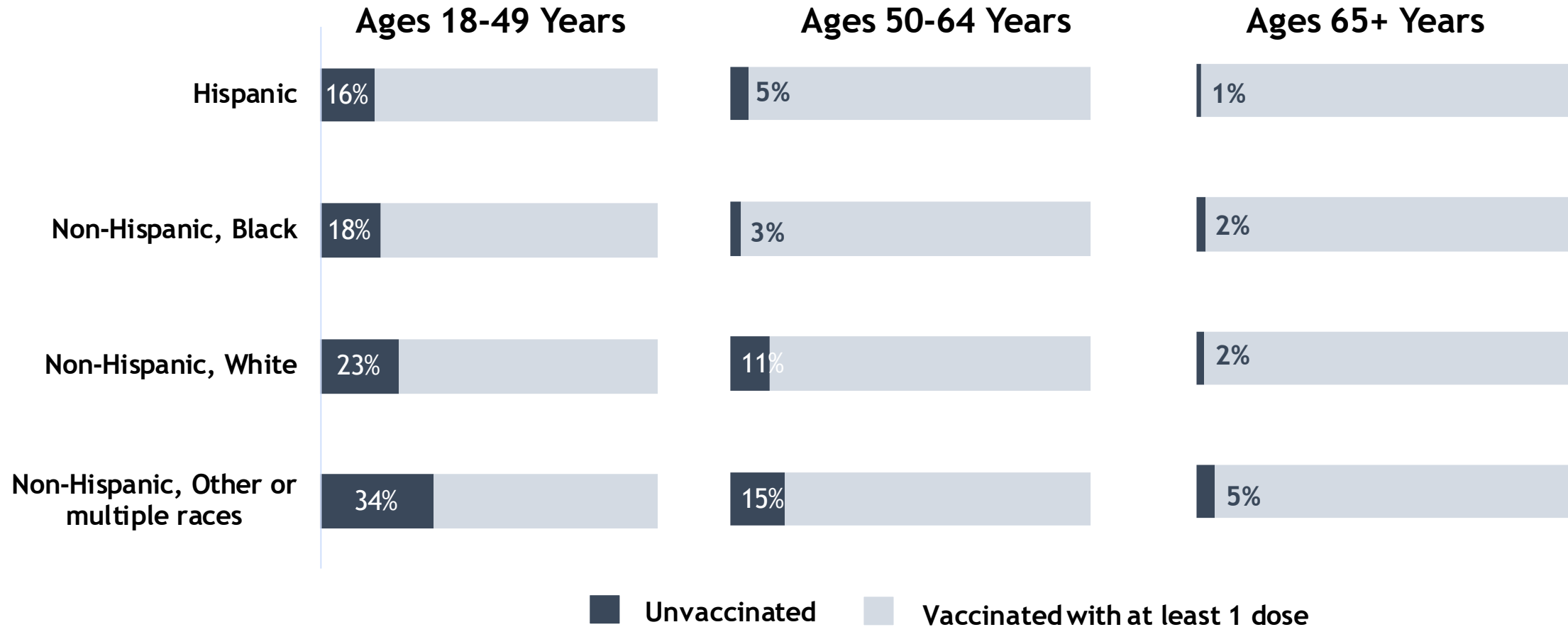


# COVID-19 Vaccination Among U.S. Adults

	Count of people with at least one COVID-19 vaccine dose	Percent of U.S. population	Estimated number remaining unvaccinated
Adults $\geq 18$ years	230.7M	89%	~27 million

- More than 95% of U.S. adults aged  $\geq 65$  years have received at least one dose of COVID-19 vaccine – not substantially contributing to the estimated number remaining unvaccinated

# Percent of U.S. Adults Not Yet Receiving a COVID-19 Vaccine by Age Group and Race and Ethnicity, May 2022



Source: COVIDVaxView. Estimates produced by NORC at the University of Chicago using CDC's National Immunization Survey-Adult COVID-19 Module (NIS-ACM). <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html>. Data as of May 8-14, 2022. Accessed June 1, 2022

# COVID-19 Disease Trends by Vaccination Status

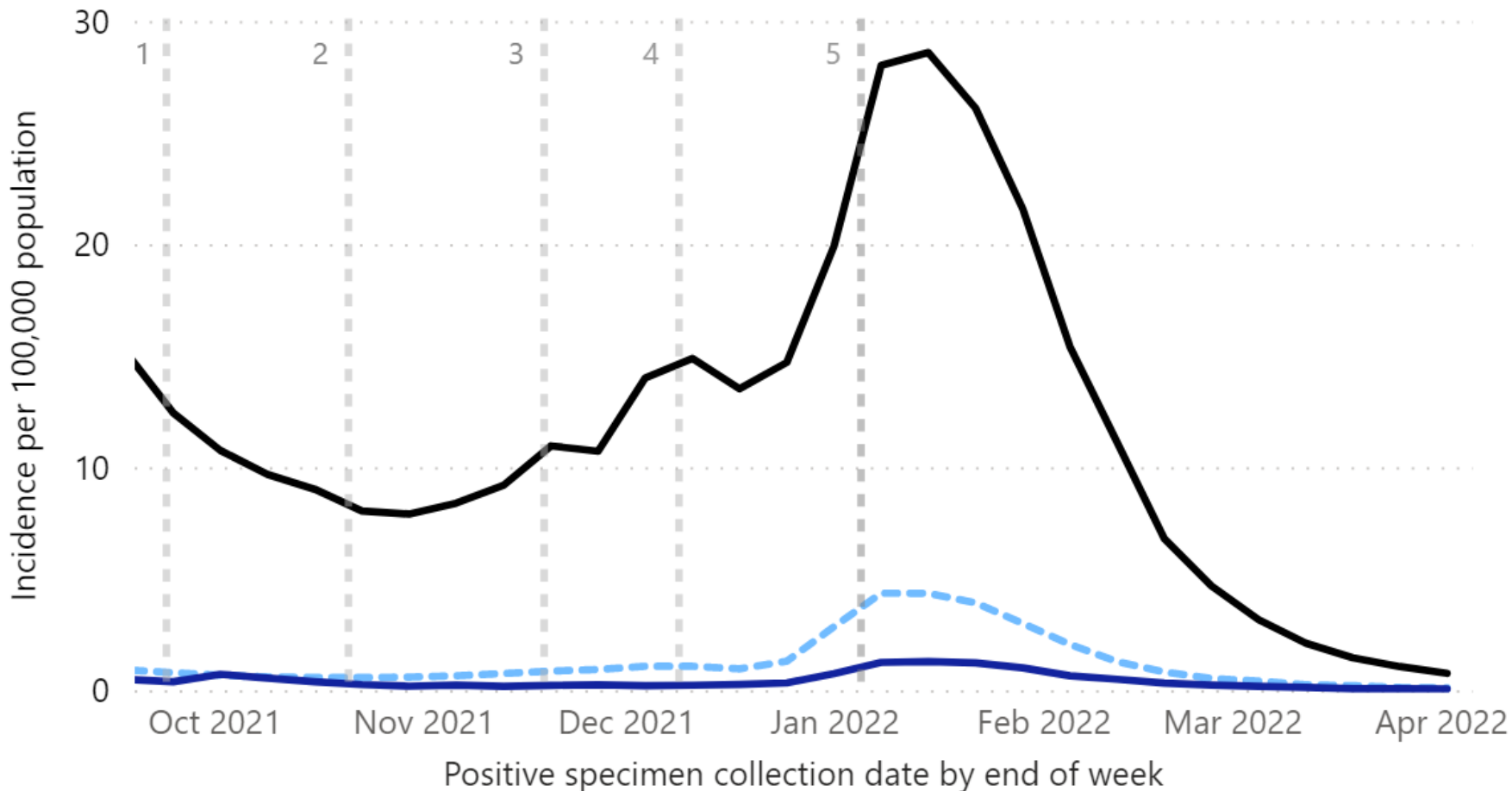


# Monitoring Rates of Cases, Hospitalizations, and Deaths by Vaccination Status

- CDC collaborates with 31 public health jurisdictions (70% population) that actively link case surveillance, immunization registry, and vital registration data to monitor [rates of COVID-19 cases and deaths by vaccination status](#)
- CDC tracks rates of [COVID-19 hospitalizations by vaccination status](#) using COVID-NET, a population-based, sentinel surveillance system in 99 counties in 14 states (10% population)
- Vaccine effectiveness (VE) studies allow for more robust analyses (i.e., based on extra information collected in defined settings) and a better understanding of how well vaccines are working
- Detailed data on serious illnesses in vaccinated persons available through COVID-NET, electronic health record, and VE platforms

# Age-Adjusted Rates of COVID-19 Deaths by Vaccination Status and Receipt of Booster Dose,\* September 19, 2021 - April 2, 2022 (28 U.S. Jurisdictions)

— Unvaccinated — Vaccinated with a primary series only — Vaccinated with a primary series and booster dose\*

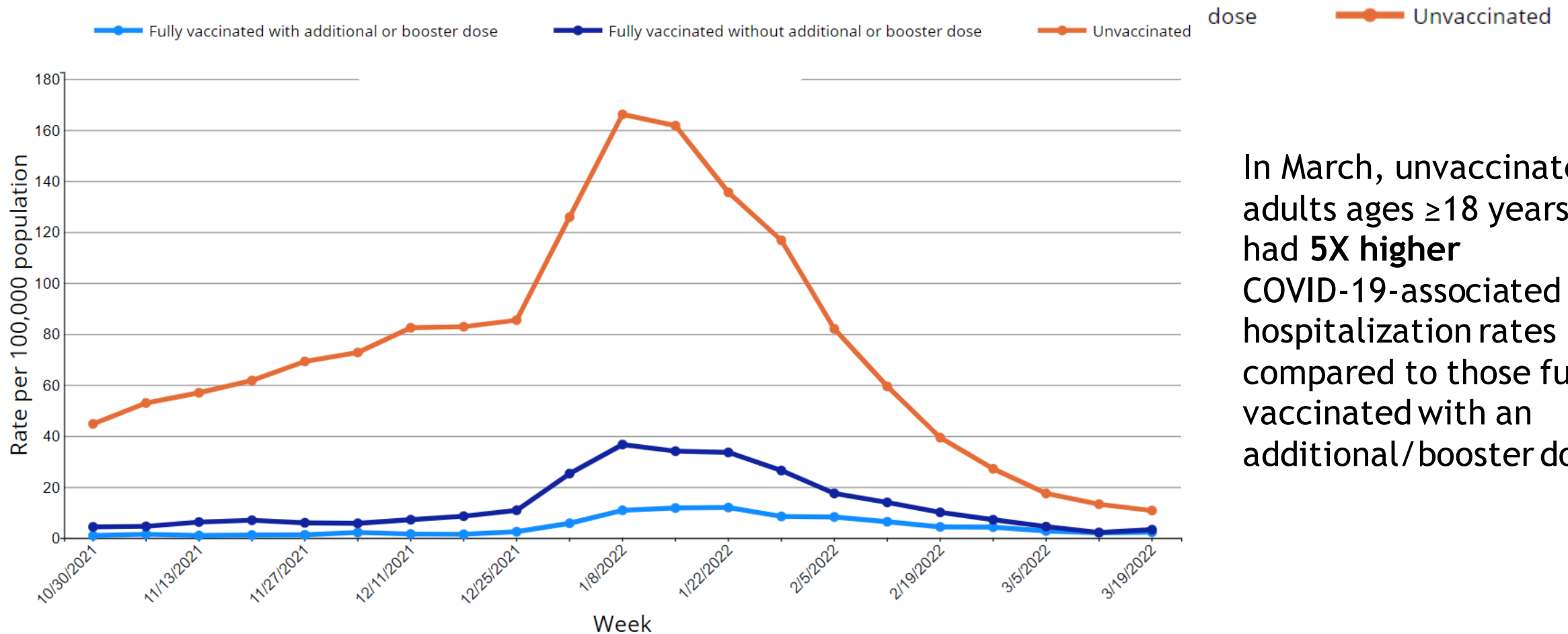


In March, unvaccinated people ages  $\geq 12$  years had **17X higher** COVID-19-associated death rates compared to those with a primary series and booster dose

\*This includes people who received booster doses and people who received additional doses.

CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status> Accessed June 1, 2022

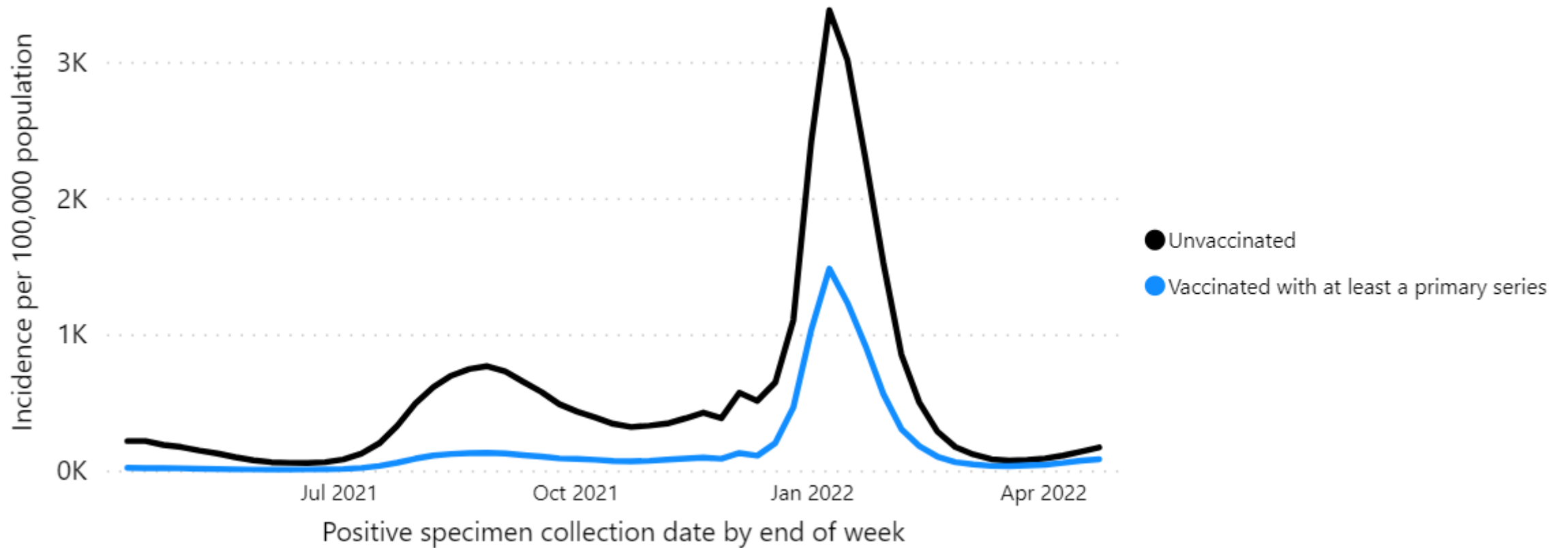
# Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages $\geq 18$ Years, October 2021-March 2022



In March, unvaccinated adults ages  $\geq 18$  years had **5X higher** COVID-19-associated hospitalization rates compared to those fully vaccinated with an additional/booster dose

# Age-Adjusted Rates of COVID-19 Cases by Vaccination Status

April 4, 2021 - April 23, 2022 (31 U.S. Jurisdictions)



**Unvaccinated people aged 5 years and older had:**

**2.0X**

*Risk of Testing Positive for COVID-19*

**in April, compared to people vaccinated with at least a primary series.**

# Risk of Severe COVID-19 Illness Among Vaccinated Persons

- Severe illness relatively rare in vaccinated persons compared with unvaccinated persons
- Fully vaccinated persons with severe COVID-19 illness more likely to be:
  - Older
  - Long-term care facility resident
  - Have underlying medical conditions
    - › Immunosuppression
    - › Diabetes mellitus
    - › Chronic kidney disease
    - › Chronic lung disease
    - › Chronic cardiovascular disease
    - › Chronic neurologic disease
  - Most (>75%) have multiple risk factors

Yek et al. MMWR 2022;71:19–25. <http://dx.doi.org/10.15585/mmwr.mm7101a4>

Taylor et al. MMWR 2022;71:466–473. <http://dx.doi.org/10.15585/mmwr.mm7112e2> and unpublished COVID-NET data, as described at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html>

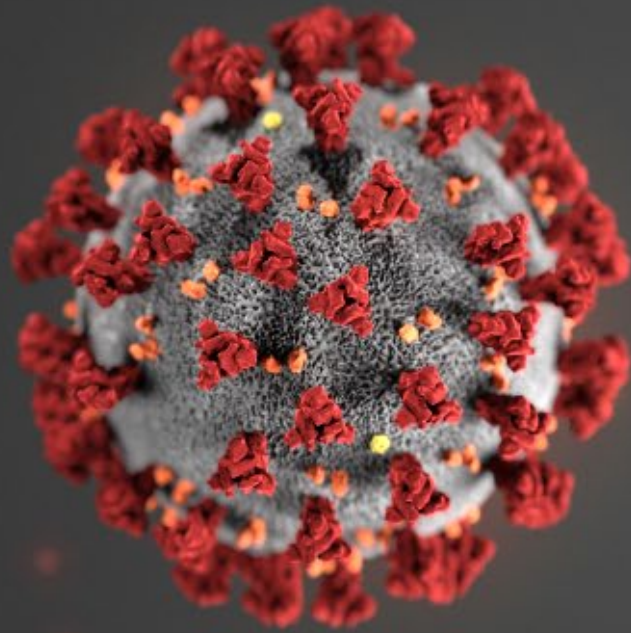


# Summary

- CDC continues to monitor emerging variants, including BA.2 sublineage of Omicron, including prevalence and impact on disease incidence and severity over time
- Monitoring trends in rates of cases, hospitalizations, and deaths by vaccination status has been helpful for monitoring the impact of variants
- Currently authorized vaccines offer protection against infection, severe illness, and death – important to stay up to date with vaccination, including first and second boosters in eligible populations

# Acknowledgements

- Amelia Johnson
- Akilah Ali
- Meagan Stephenson
- Steve Evener
- Justice King
- Betsy Gunnels
- Ben Silk
- Chris Taylor
- Fiona Havers
- Ruth Link-Gelles
- Sara Oliver
- Evelyn Twentyman
- Dani Moulia
- Katherine Fleming-Dutra
- Aron Hall
- Adam MacNeil
- Rebecca Kondor
- Phillip Shirk
- Clint Paden
- Dave Wentworth
- State and local health departments: AL, AR, AZ, CA, CO, CT, DC, FL, GA, ID, IN, IO, KS, LA, MA, MD, MI, MN, NC, NE, NJ, NM, NY, NY City, OH, Philadelphia, RI, Seattle/King County, SD, TN, TX, UT, WA, WI, WV



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



# Extra Slides

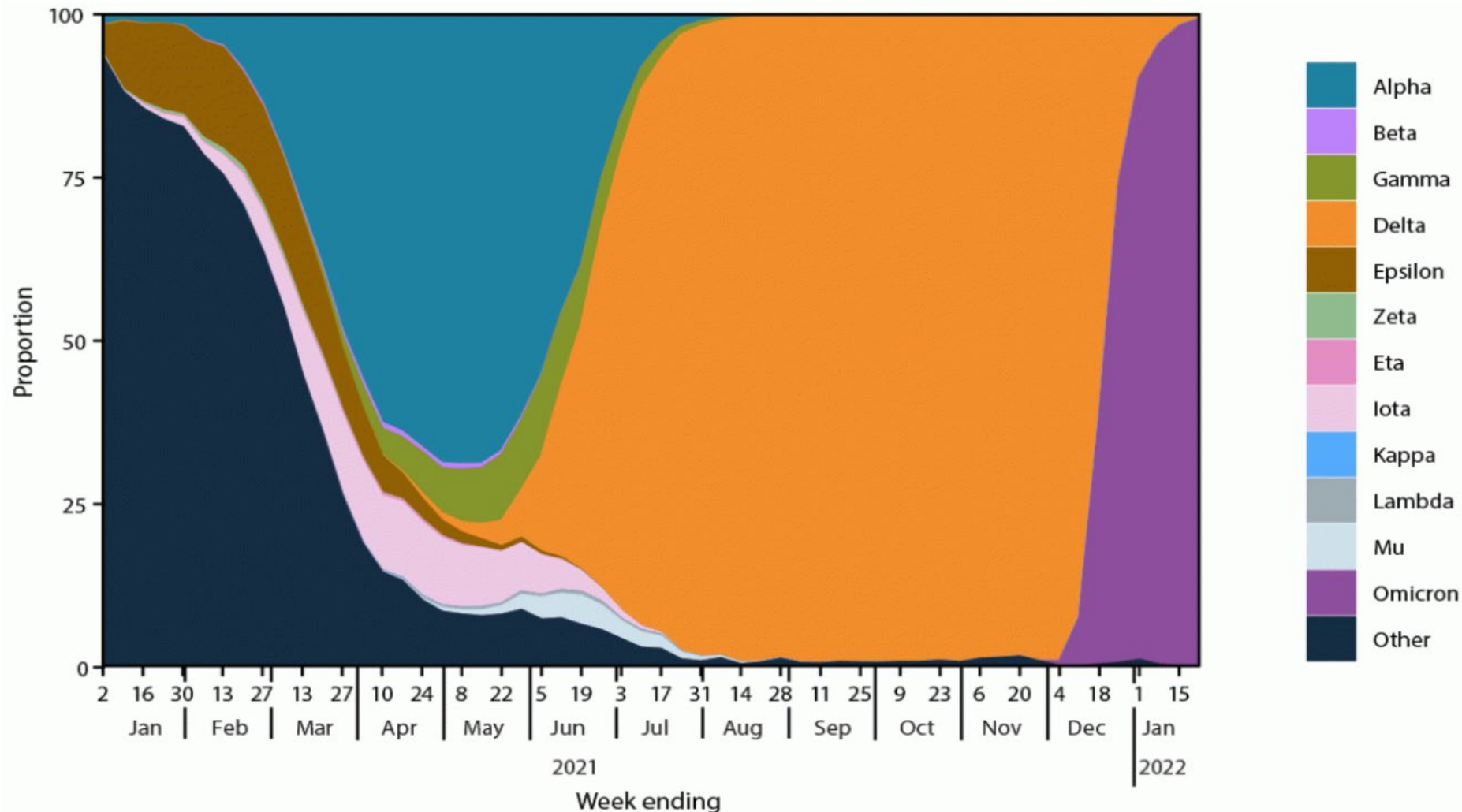


# Limitations of Surveillance Data in Describing Recent Case Trends by Vaccination Status

- Recent surveillance data displayed on COVID Data Tracker has shown higher case rates in people with a booster dose than those with primary series alone; both groups had lower rates than unvaccinated people
  - Similar trends observed for hospitalizations among younger people (<65 years) with a booster dose
  - Death rates remain lower in people with a booster dose
- Unexpected trends are likely related to relatively low incidence and several epidemiologic biases, including differences in people by vaccination status:
  - Testing and healthcare-seeking (e.g., increased use of at-home testing especially for mild cases)
  - Previous infections, which increased following Omicron surge
  - Underlying medical conditions (i.e., more likely to be boosted and have severe COVID-19 illness)
  - Exposure risk and prevention behaviors such as use of masks and social distancing
- Difficulty accounting for time since vaccination and waning protection using surveillance data
- In well-controlled vaccine effectiveness studies, booster doses shown to offer higher protection against infection, hospitalization, and death than a primary series alone, including during the Omicron period

# Changing Landscape of Circulating Variants

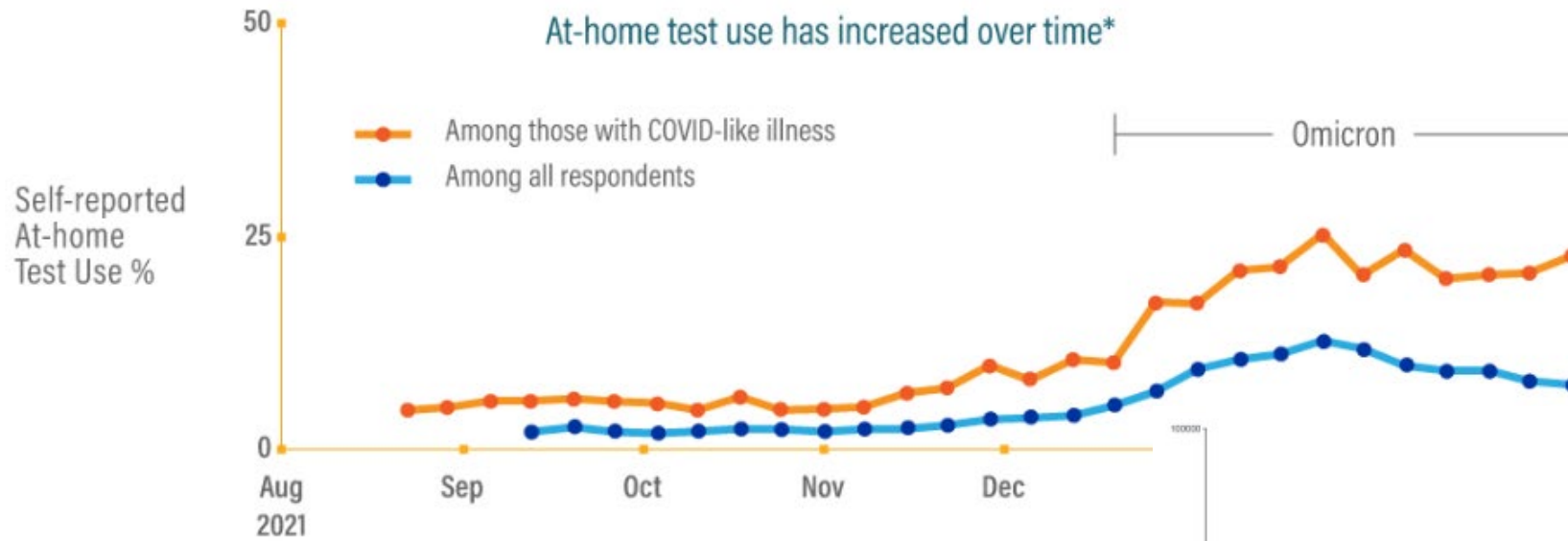
FIGURE 1. National weekly proportion estimates\* of SARS-CoV-2 variants† — United States, January 2, 2021–January 22, 2022



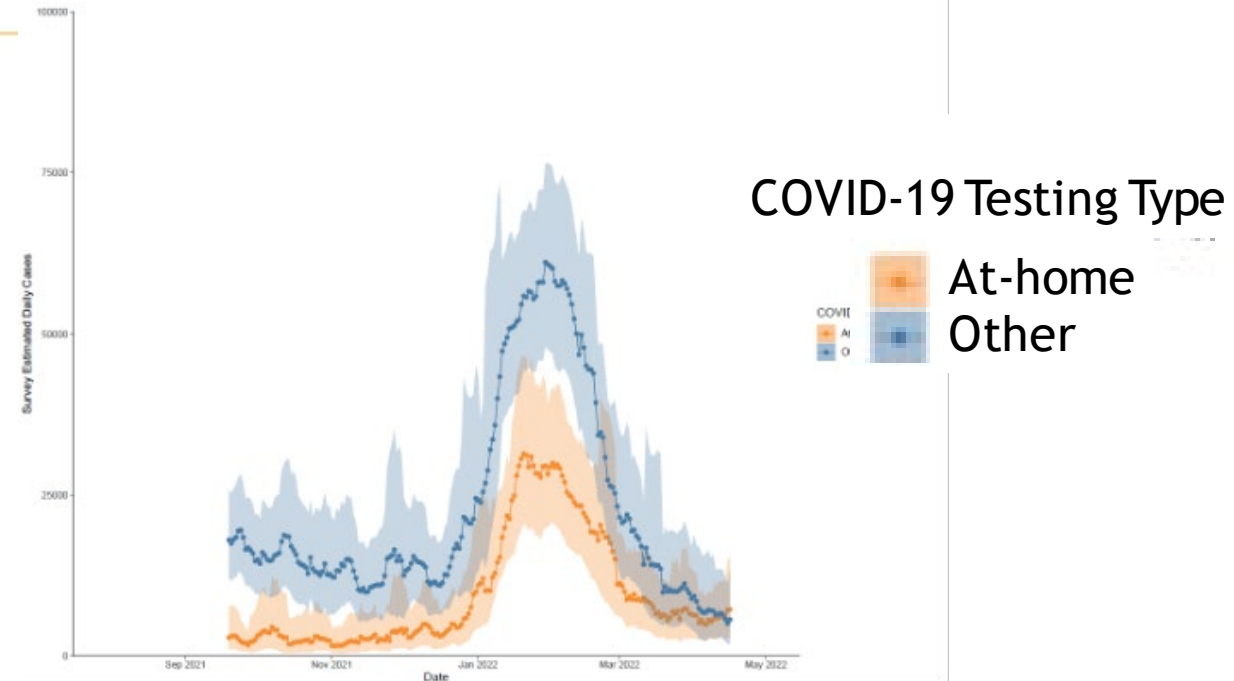
Lambrou et al. Genomic Surveillance for SARS-CoV-2 Variants: Predominance of the Delta (B.1.617.2) and Omicron (B.1.1.529) Variants — United States, June 2021-January 2022 <https://www.cdc.gov/mmwr/volumes/71/wr/mm7106a4.htm>

# At-home test use has increased over time

At-home test use among respondents with COVID-19-like illness more than tripled from 6% to 20% from the Delta to Omicron period



Update: Positive test results from at-home testing now exceed other types



MMWR: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7113e1.htm>;  
Twitter: <https://twitter.com/johnbrownstein/status/1517218593422950400>

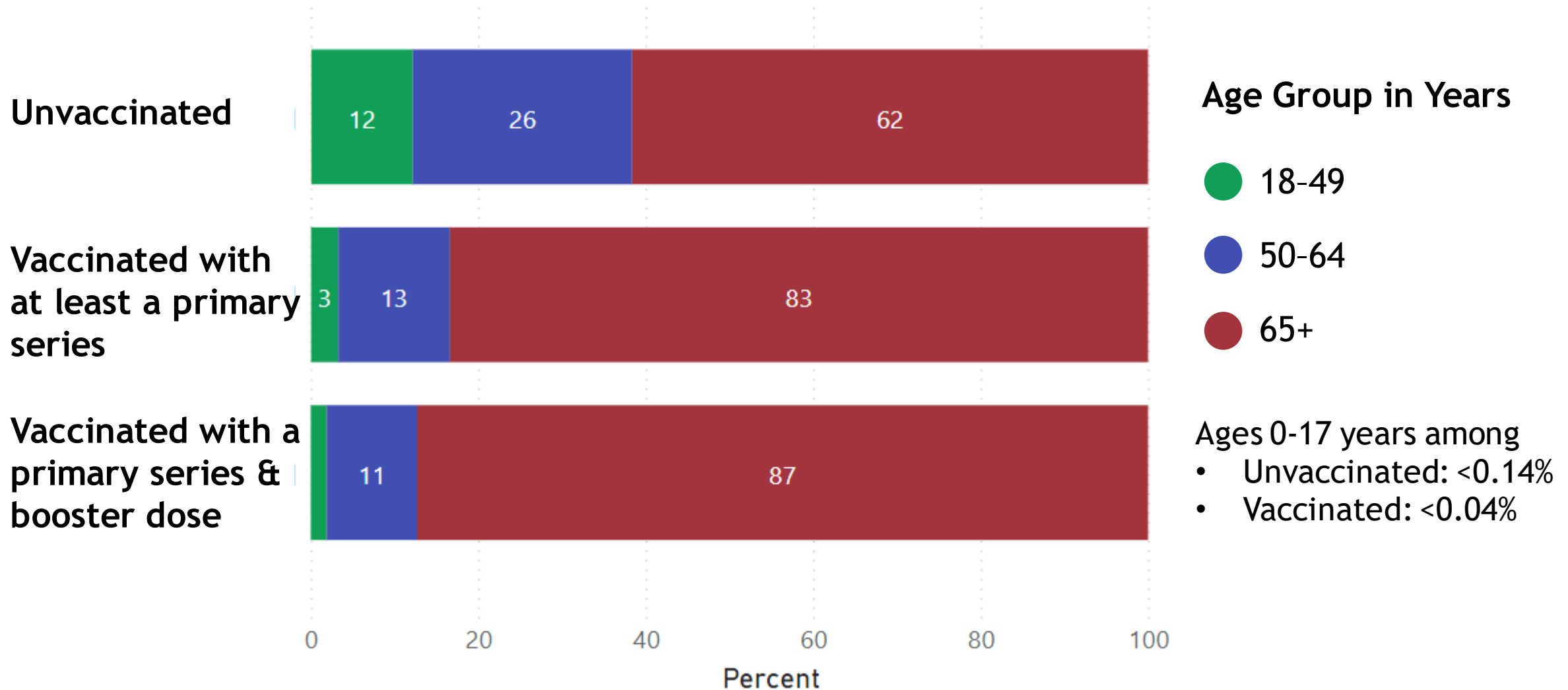
# SARS-CoV-2 variant classifications and definitions

Classification	Definition	Variants
<b>Variant of Concern (VOC)</b>	A variant for which there is evidence of: <ul style="list-style-type: none"><li>• increase in transmissibility</li><li>• more severe disease</li><li>• significant reduction in antibody neutralization</li><li>• reduced effectiveness of treatments or vaccines</li><li>• diagnostic detection failures</li></ul>	<ul style="list-style-type: none"><li>• <b>Delta</b> (B.1.617.2 &amp; AY lineages)</li><li>• <b>Omicron</b> (B.1.1.529 &amp; BA lineages)</li></ul>
<b>Variants Being Monitored (VBM)</b>	Variants with data indicating a potential or clear: <ul style="list-style-type: none"><li>• impact on approved or authorized medical countermeasures, or association with more severe disease or increased transmission, but</li><li>• no longer detected or circulating at very low levels</li><li>• not posing imminent risk to public health in U.S.</li></ul>	<ul style="list-style-type: none"><li>• Alpha (B.1.1.7 &amp; Q lineages)</li><li>• Beta (B.1.351, sub-lineages)</li><li>• Gamma (P.1, sub-lineages)</li><li>• Epsilon (B.1.427/B.1.429)</li><li>• Eta (B.1.525)</li><li>• Iota (B.1.526)</li><li>• Kappa (B.1.617.1)</li><li>• B.1.617.3</li><li>• Zeta (P.2)</li><li>• Mu (B.1.621, B.1.621.1)</li></ul>



# Percentage of Deaths by Vaccination Status and Age Group

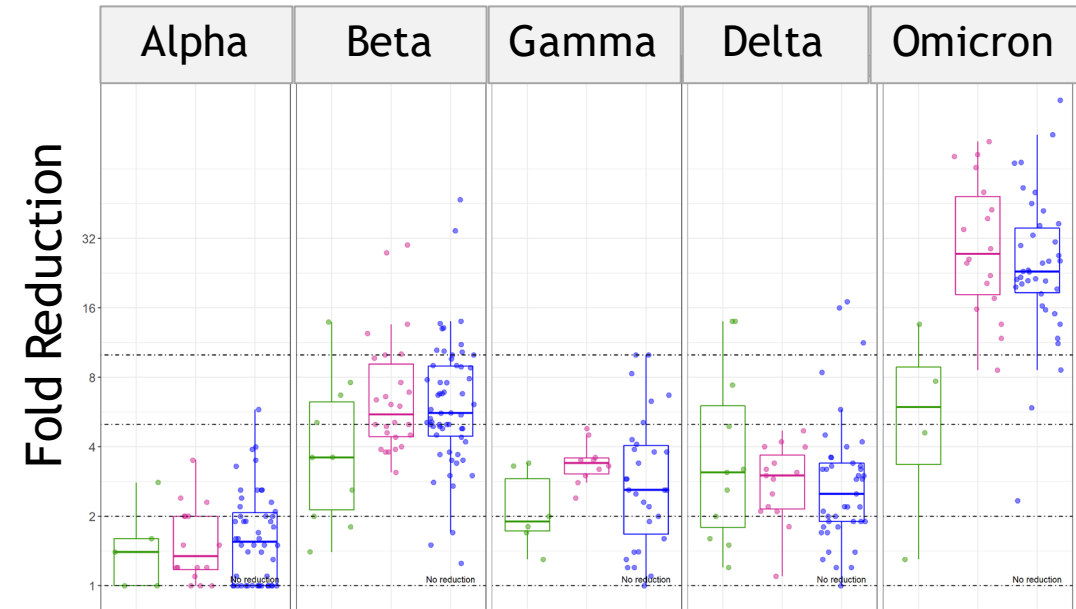
September 26, 2021 - January 29, 2022 (26 Jurisdictions)



# Neutralization of Omicron Variant by Sera from Vaccinees

Studies (n=42) of U.S. vaccinees using both pseudoviruses & live viruses

- Reduction compared with wild-type:
  - 25-fold for mRNA vaccine without booster dose
  - 6-fold for mRNA vaccine with booster dose
- Neutralization of Omicron below limit of detection for many individuals receiving two mRNA doses or one Janssen dose
  - Above limit of detection in many vaccinated people receiving booster or who were also previously infected
- Given detection limits of assays, difficult to evaluate whether people have levels of antibodies needed to protect against severe disease



## Primary vaccine series

- Janssen - Ad26.COV2.S
- Moderna - mRNA-1273
- Pfizer BioNTech - Comirnaty