

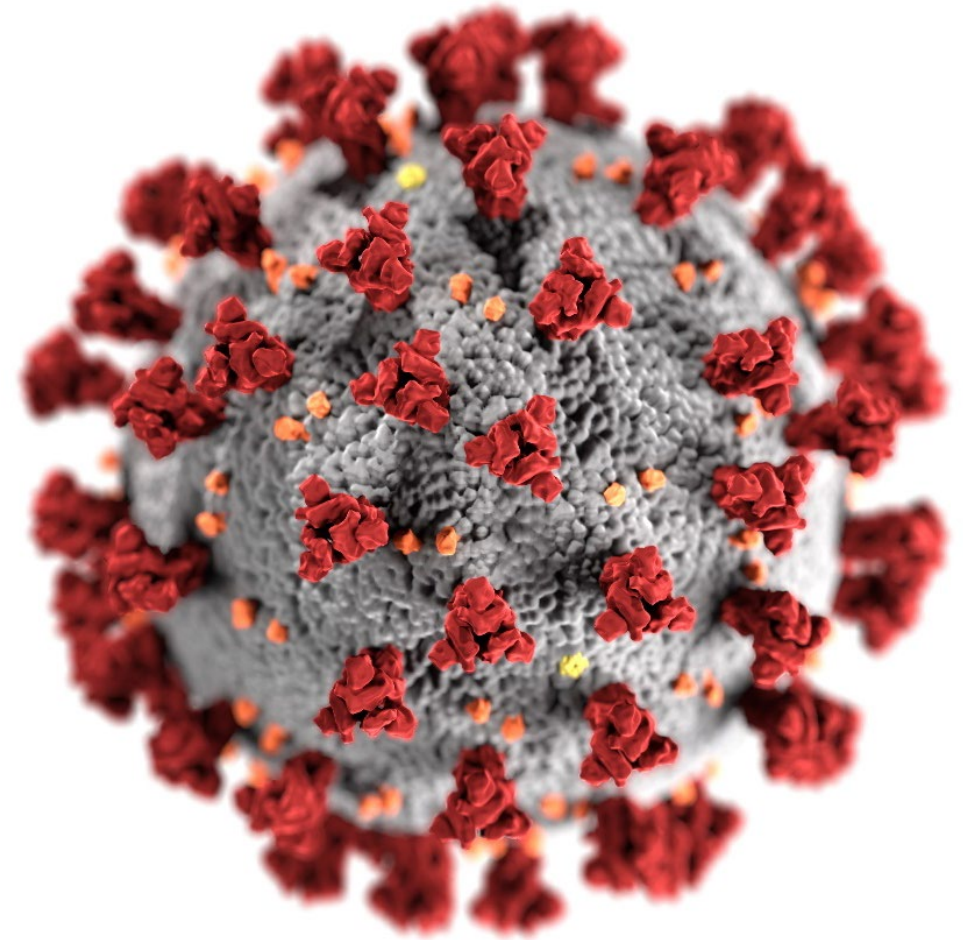
## **Vaccines and Related Biological Products Advisory Committee Meeting**

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.

# Update on the Epidemiology of SARS-CoV-2 Strains

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

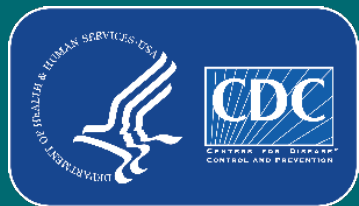
April 6, 2022



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



# SARS-CoV-2 Variants

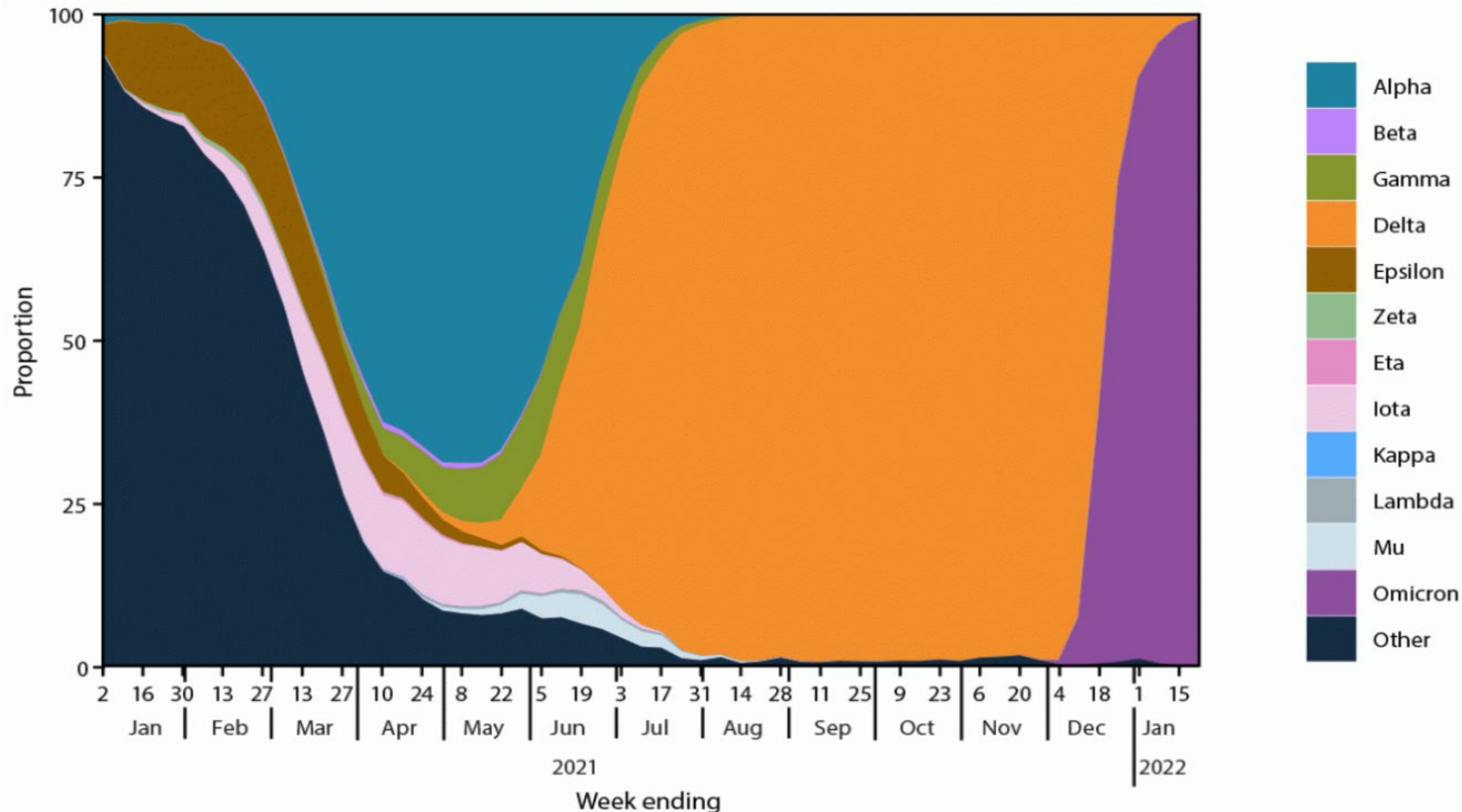


# Genomic Surveillance in the United States

- Multifaceted genomic surveillance system for analyzing SARS-CoV-2 variants circulating in the United States
  - National SARS-CoV-2 Strain Surveillance
  - CDC-supported contracts with several commercial diagnostic laboratories
  - Partners deposit and tag randomly sampled viral sequence in public repositories (GISAID and NCBI)
- CDC estimates that if a variant is circulating at 0.1% frequency, there is a >99% chance that it will be detected in national genomic surveillance
- During Omicron, temporarily enhanced genomic surveillance strategies:
  - Rapid screening of PCR-based diagnostic tests for S-gene Target Failure (SGTF) for confirmation
  - Expanded voluntary airport-based genomic surveillance programs in four U.S. cities

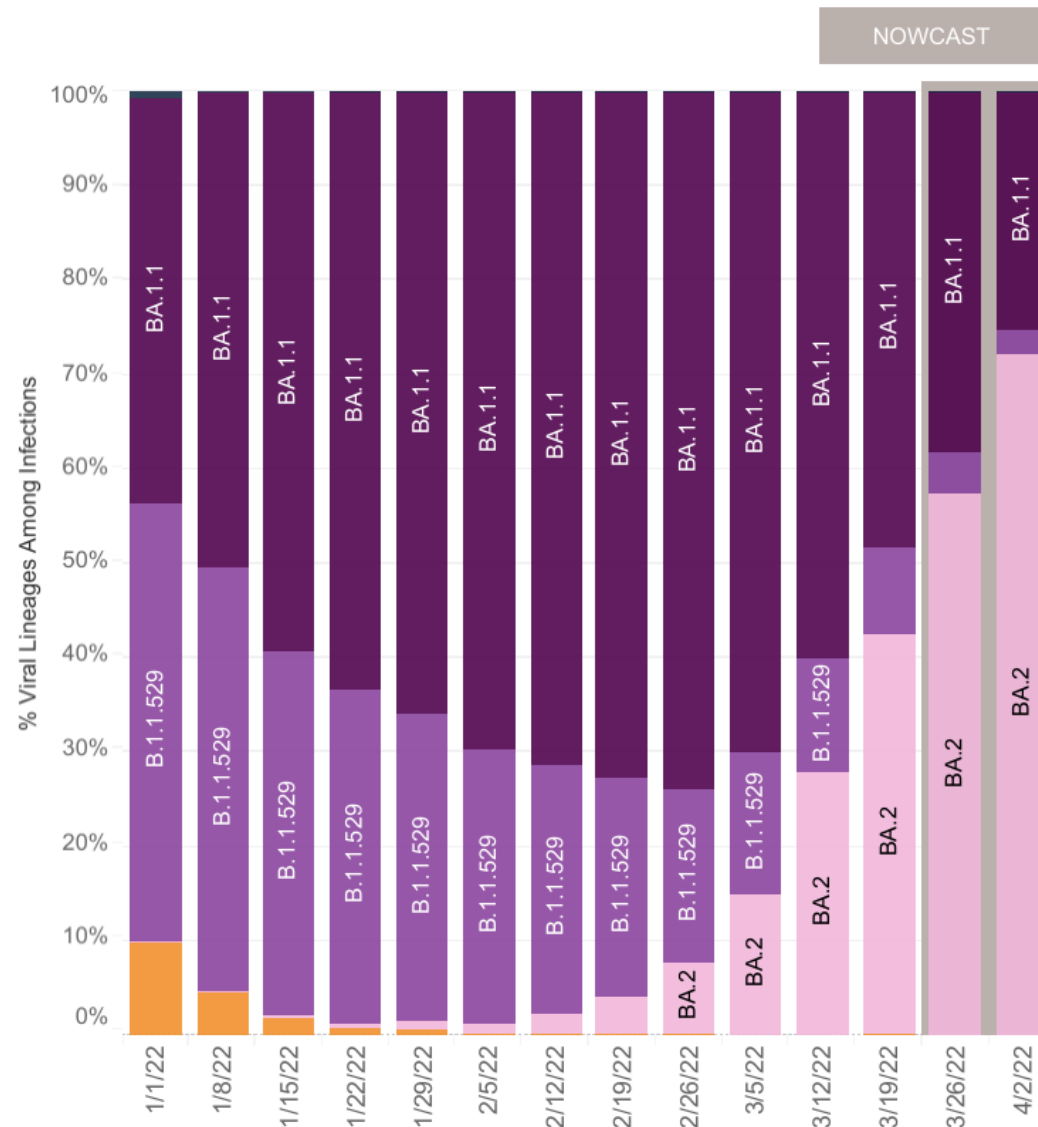
# Changing Landscape of Circulating Variants

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>

# Recent Trends in Weighted Variant Proportion Estimates & Nowcast



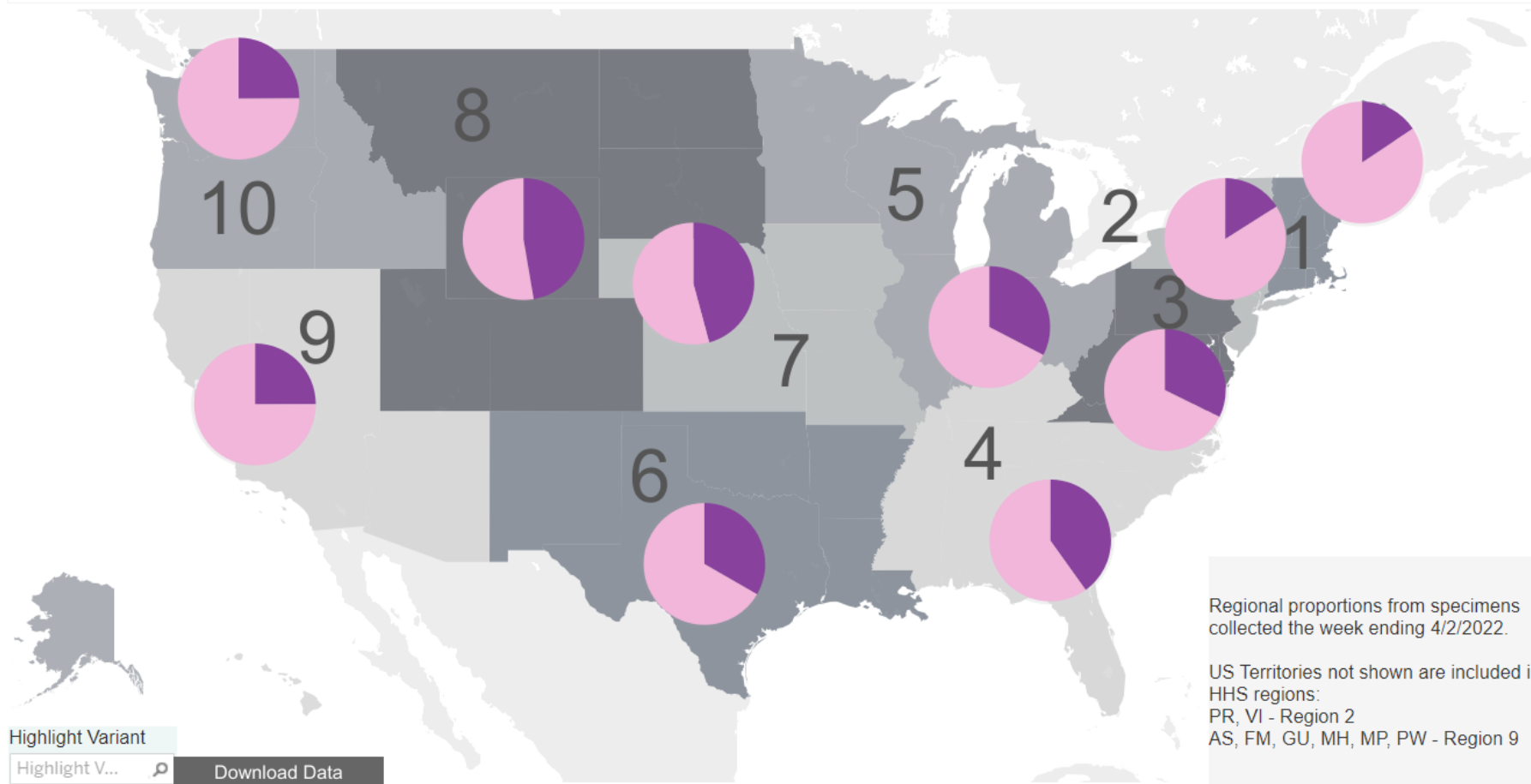
**USA**

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2	VOC	72.2%	68.1-75.9%
	BA.1.1	VOC	25.3%	21.9-29.1%
	B.1.1.529	VOC	2.5%	2.0-3.2%
Delta	B.1.617.2	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

\* 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 and BA.3 are aggregated with B.1.1.529. For regional data, BA.1.1 is also aggregated with B.1.1.529, as it currently cannot be reliably called in each region.

# Nowcast Estimates of Variant Proportions by HHS Region

March 27-April 2, 2022



Highlight Variant  
Highlight V...  Download Data

Lineages called using pangoln v1.2.127, pangolin v3.1.20, pangoleARN version 02/02/28 and Scorpio v0.3.16.  
Lineage BA.1.1 is aggregated with B.1.1.529 at the regional level as it currently cannot be reliably called in each region.

Updated March 31, 2022

HHS=Health and Human Services

<https://covid.cdc.gov/covid-data-tracker/#variant-proportions> Accessed April 4, 2022



# 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



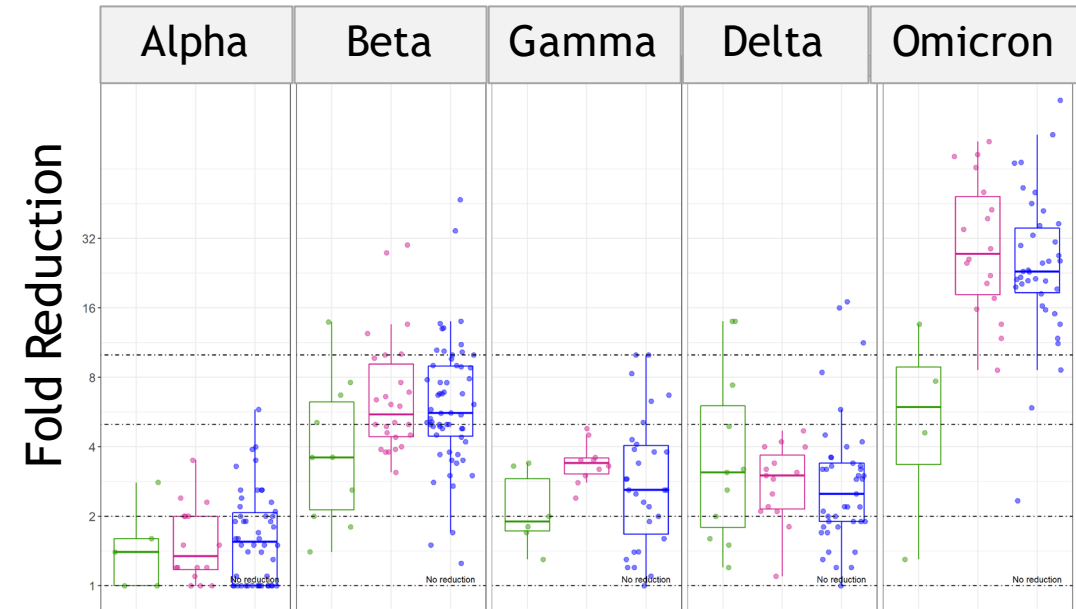
Key mutations (yellow) in the Omicron spike protein (top view)  
Source: New York Times



# 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



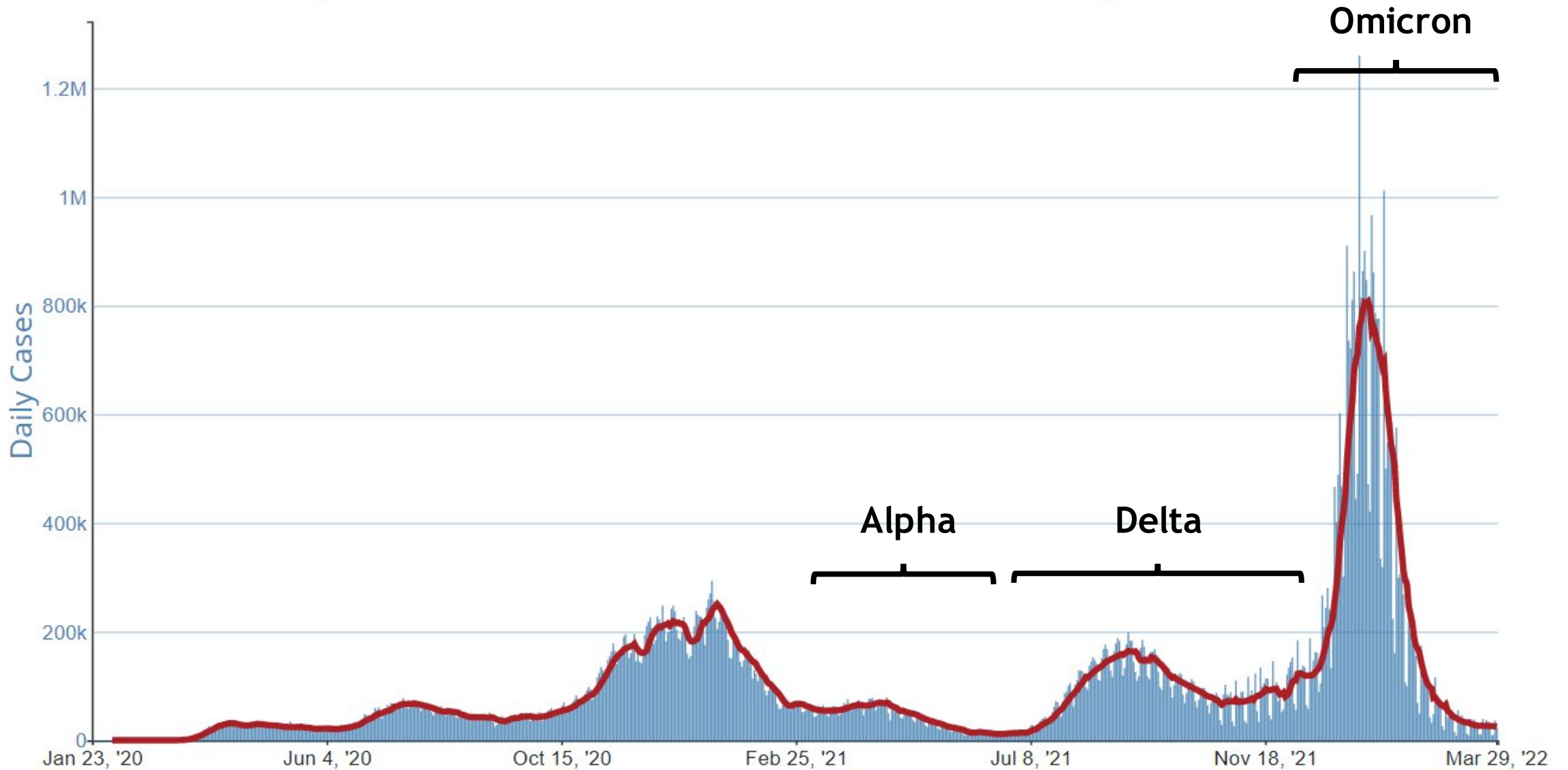
## Primary vaccine series

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

# COVID-19 Disease Trends

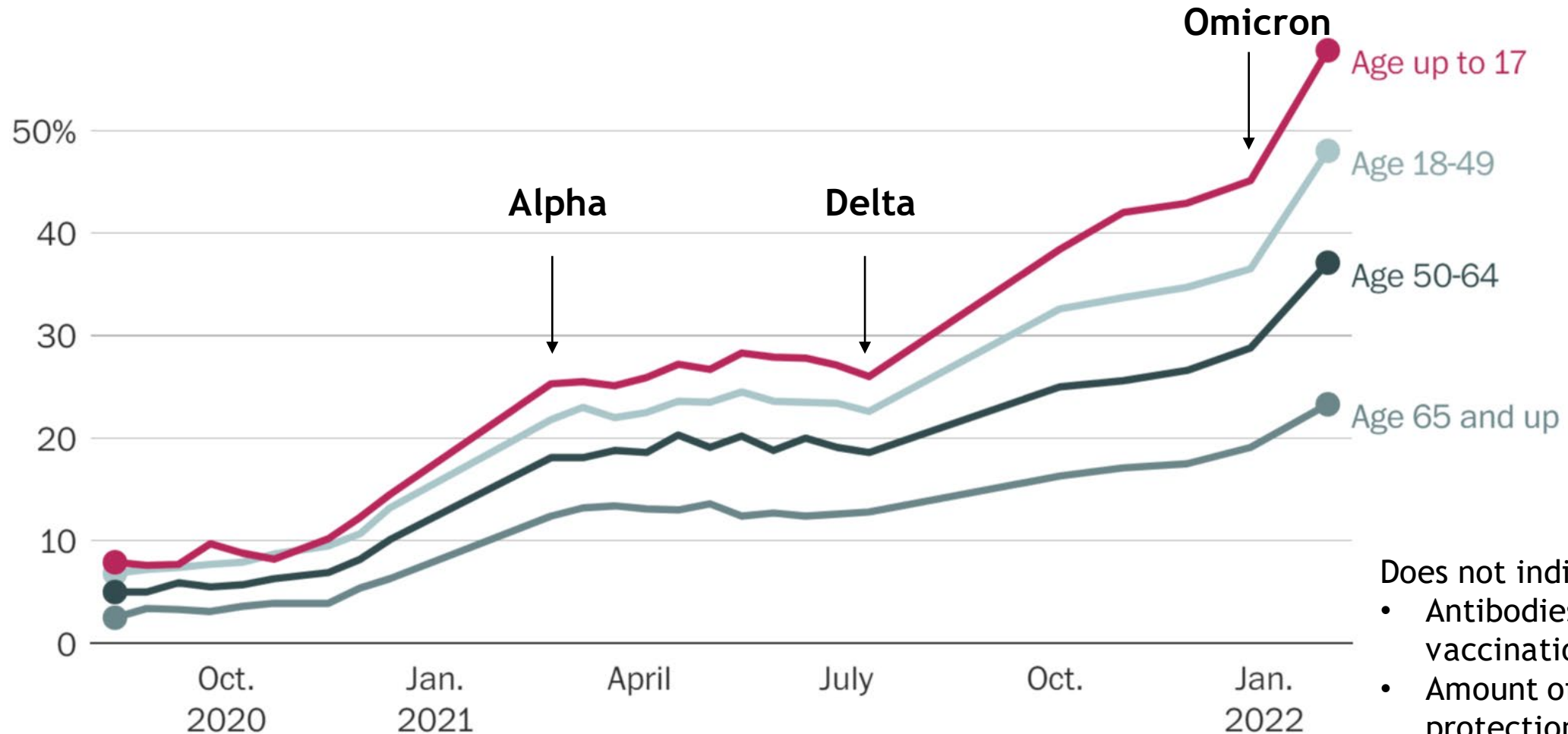


# Daily Trends in Number of COVID-19 Cases, United States



# Percentage of People with Antibodies (Anti-Nucleocapsid) Indicating Resolving or Past Infection with SARS-CoV-2, United States

August 30, 2020 - January 29, 2022



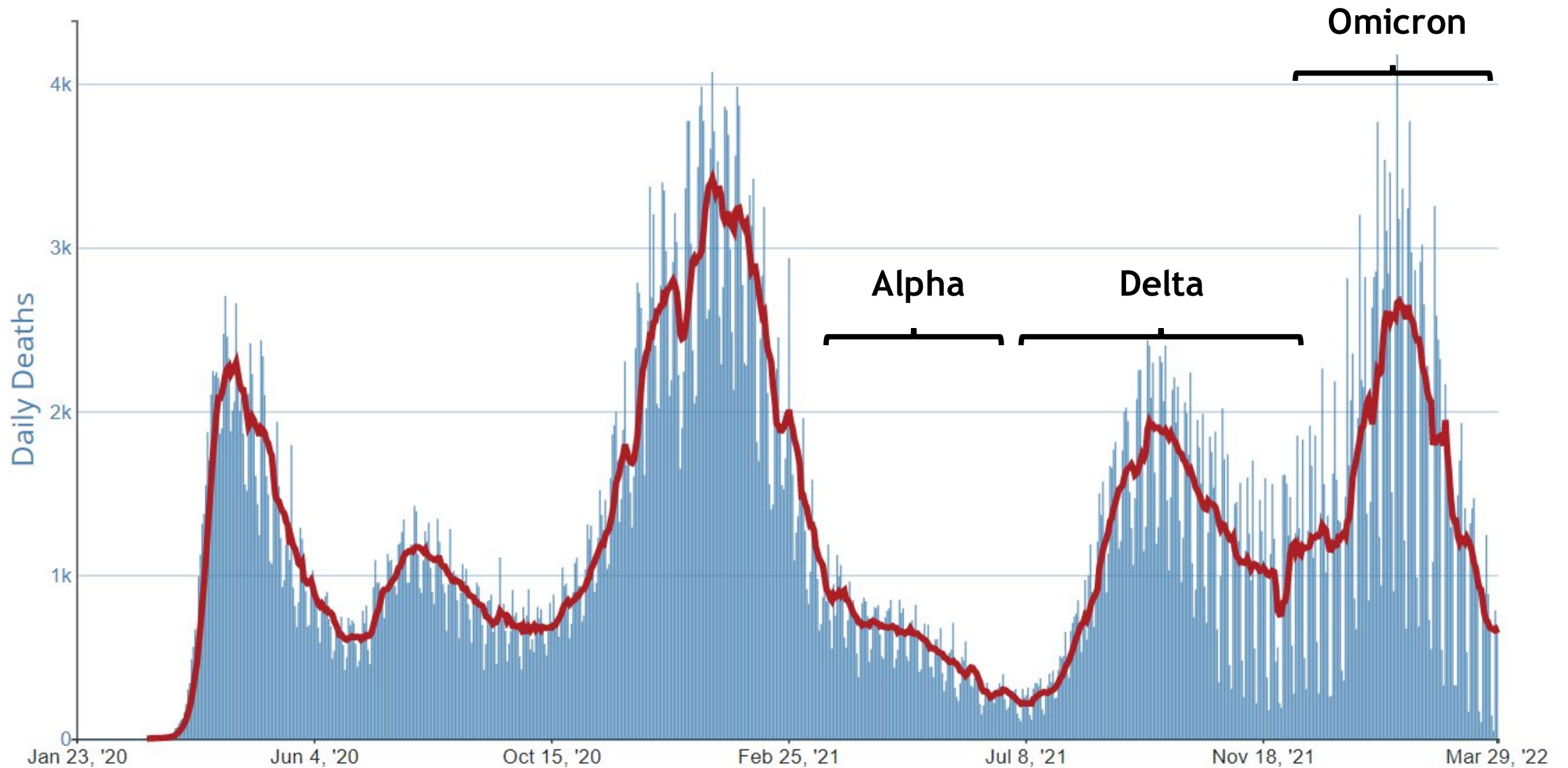
Does not indicate:

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

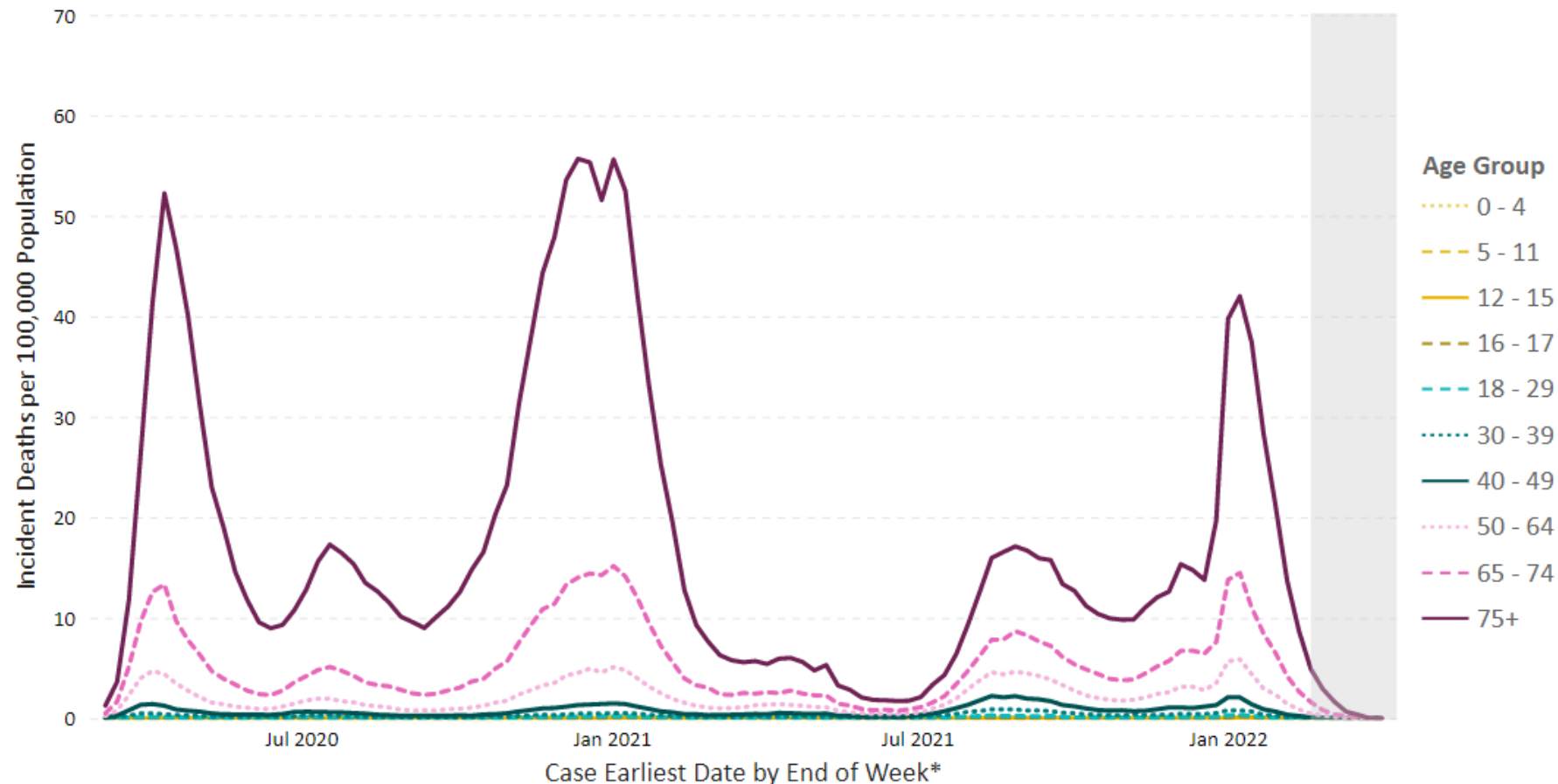
Data Source: CDC COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/#national-lab>

Data Visualization: Dan Keating, Washington Post: <https://www.washingtonpost.com/health/2022/02/28/covid-cases-nationwide/>

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



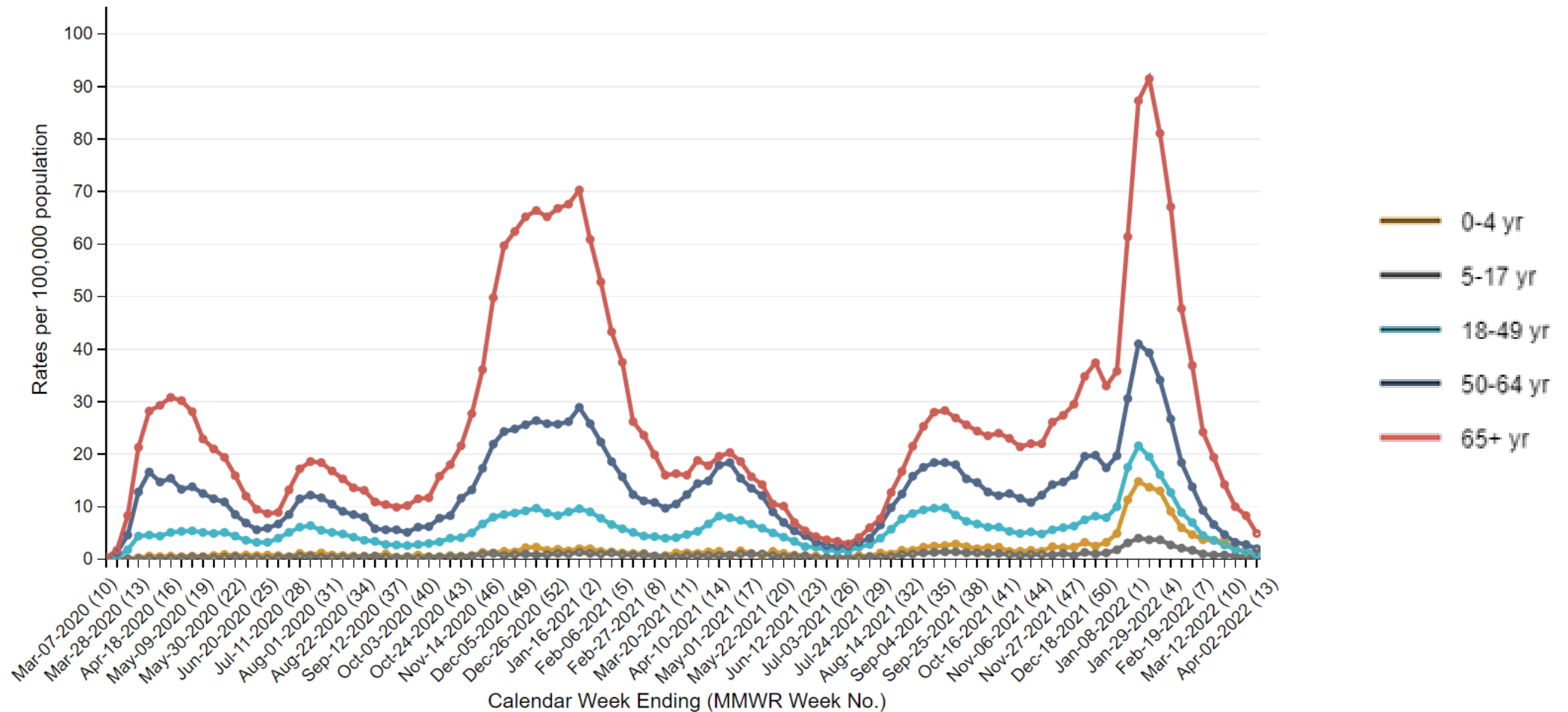
# Weekly Trends in COVID-19 Mortality Rates by Age Group, United States, March 1, 2020 - April 2, 2022



US: The most recent case record was reported during the week ending on Apr 02, 2022. Percentage of deaths among reported cases - 1.14%. Percentage of deaths reporting age by date - 99.90%.  
 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 COVID-19-Associated Hospitalization Rates by Age Group, United States, March 7, 2020 - March 26, 2022



A population-based surveillance system (COVID-NET) collected data on laboratory-confirmed COVID-19-associated hospitalizations among adults through a network of over 250 acute-care hospitals in 14 states.

CDC COVID-NET. [https://gis.cdc.gov/grasp/covidnet/covid19\\_3.html](https://gis.cdc.gov/grasp/covidnet/covid19_3.html) Accessed March 31, 2022

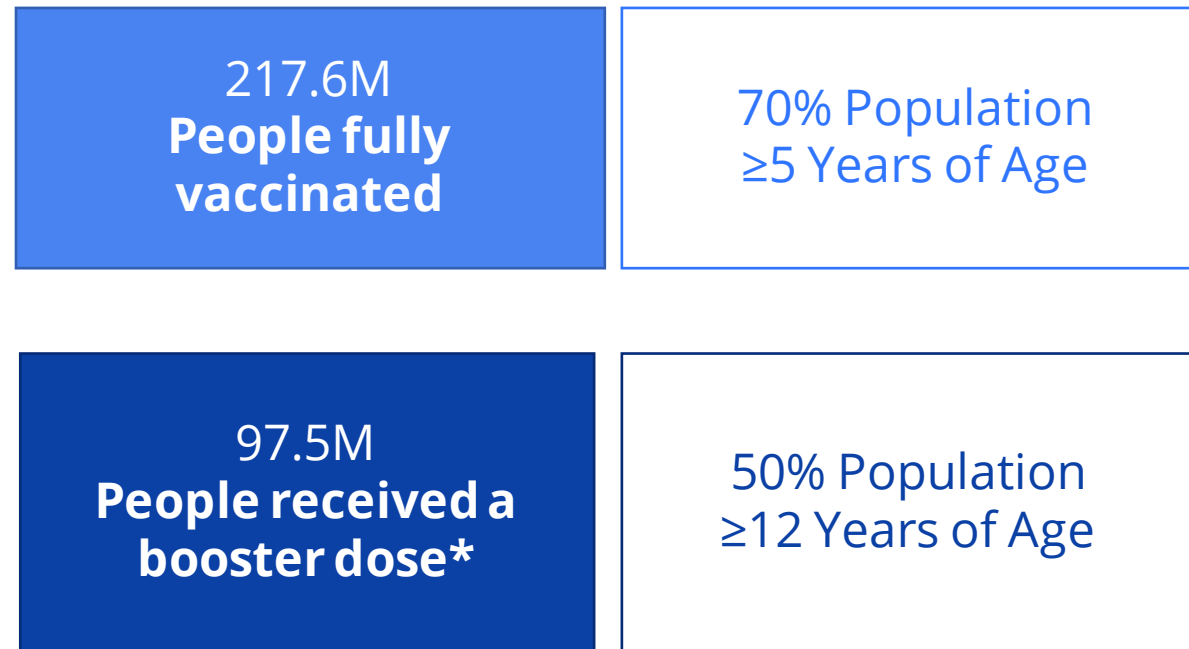


# COVID-19 Trends by Vaccination Status



# COVID-19 Vaccinations in the United States

As of March 30, 2022

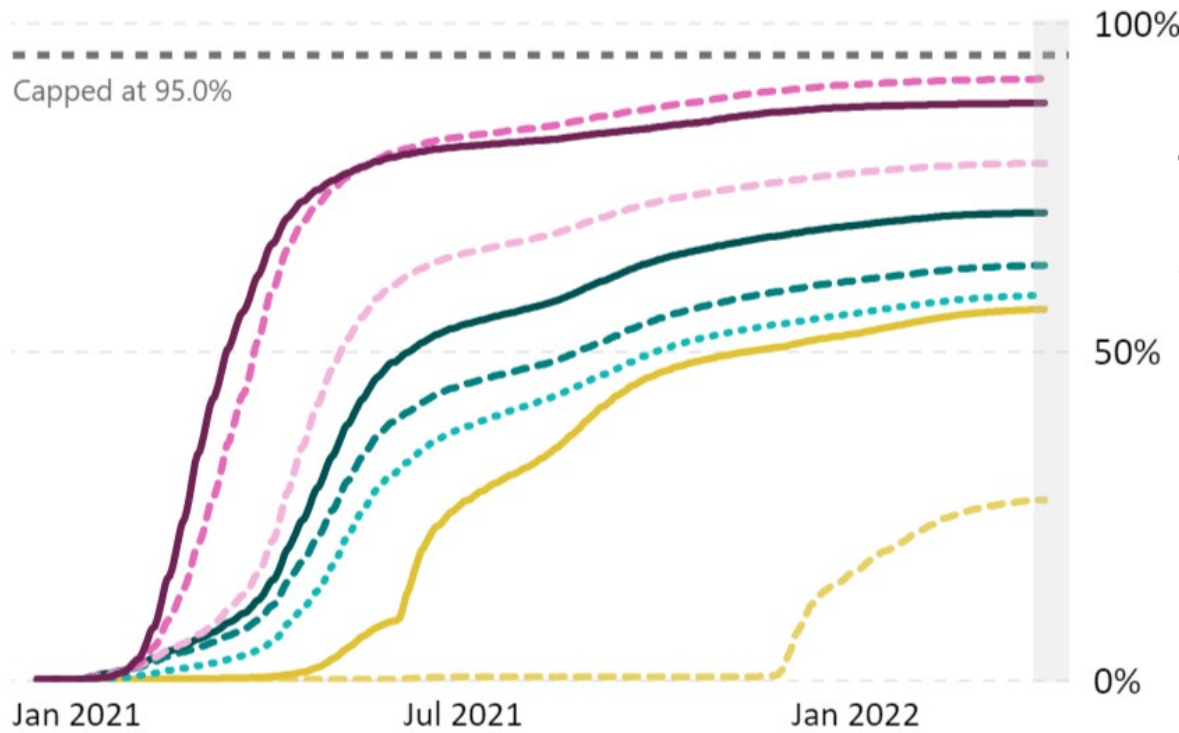


\*This includes people who received booster doses and people who received additional doses.

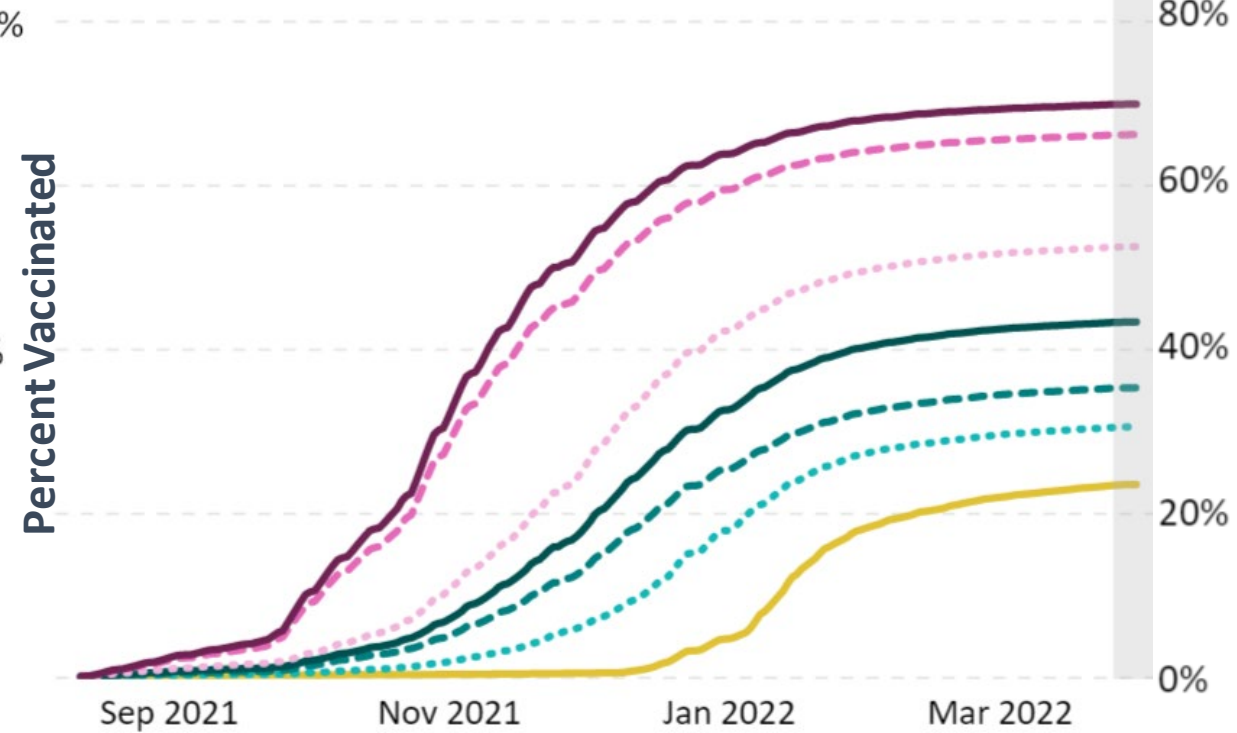
[https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total) Accessed March 31, 2022

# 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

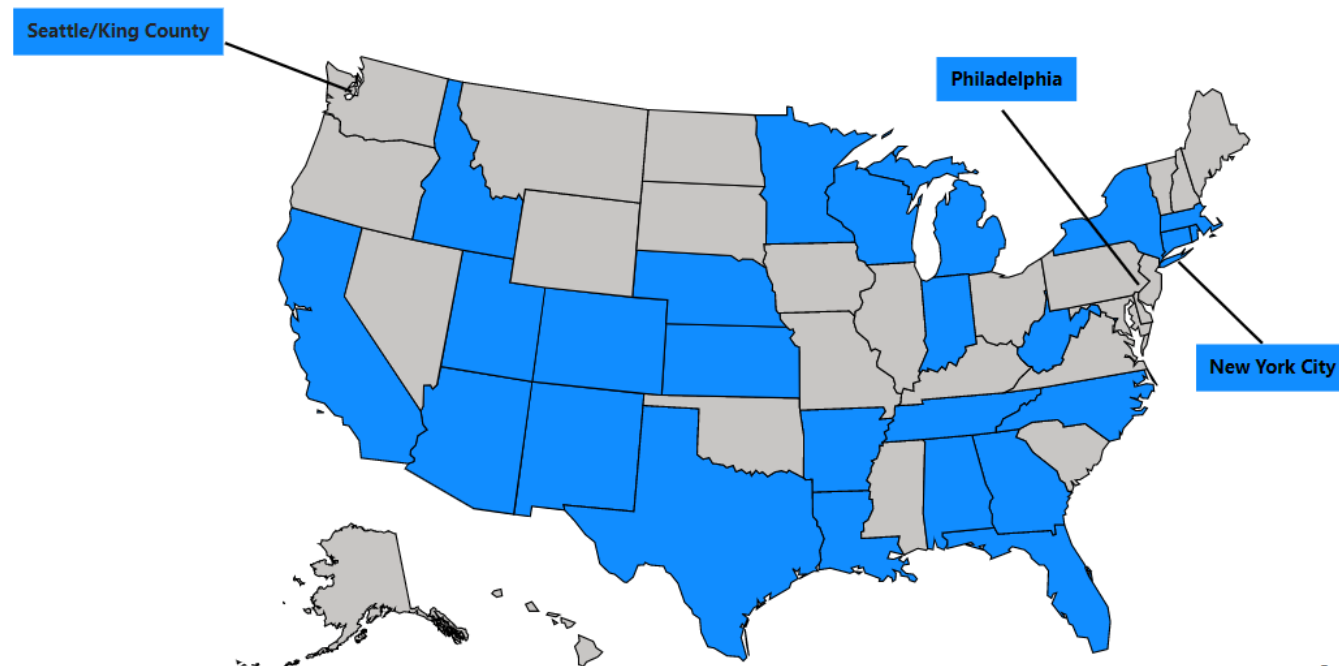


5-11 yrs 12-17 yrs 18-24 yrs 25-39 yrs 40-49 yrs 50-64 yrs 65-74 yrs 75+ yrs  
 27.3% 56.3% 58.5% 63.0% 71.0% 78.5% 91.4% 87.7%

12-17 yrs 18-24 yrs 25-39 yrs 40-49 yrs 50-64 yrs 65-74 yrs 75+ yrs  
 23.4% 30.4% 35.2% 43.2% 52.4% 66.1% 69.8%

# Monitoring Rates of Cases and Deaths by Vaccination Status

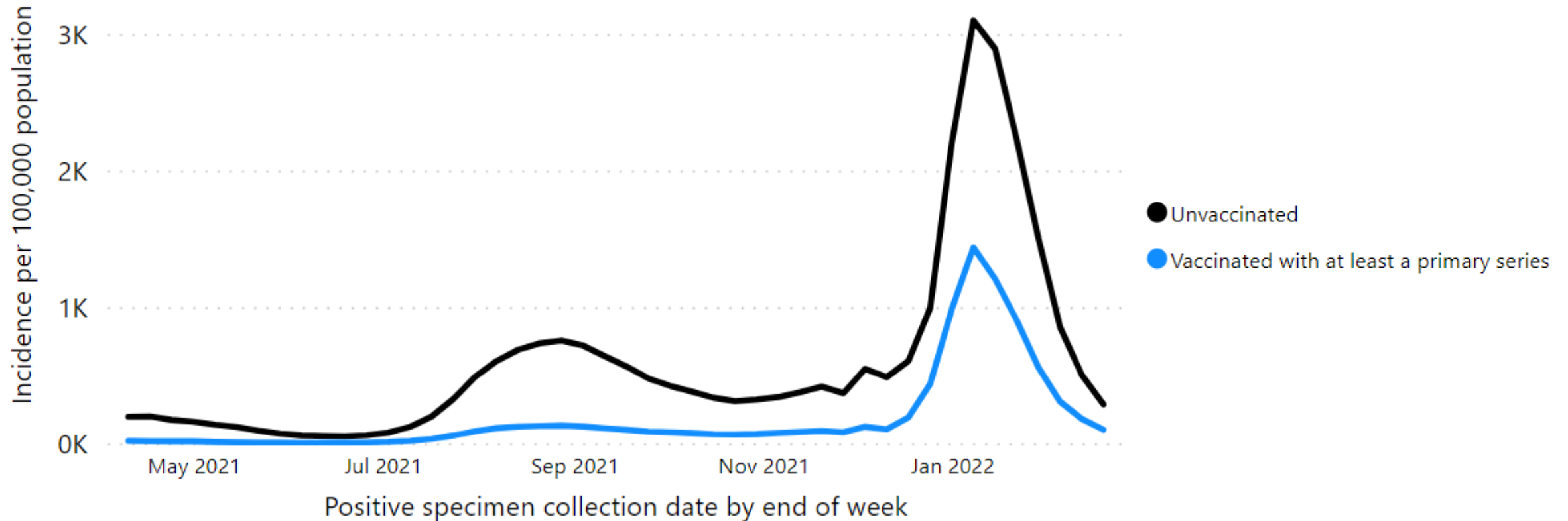
- 29 jurisdictions that routinely link surveillance and immunization data\*
  - 67% of total U.S. population
- Report COVID-19 cases and COVID-associated deaths by vaccination status
- Weekly rates and incidence rate ratios
  - Unvaccinated vs. fully vaccinated (overall, with or without a booster dose)



\* AL, AR, AZ, CA, CO, CT, DC, FL, GA, ID, IN, KS, LA, MA, MI, MN, NC, NE, NM, NY, NY City, RI, Seattle/King County, TN, TX, UT, WI, WV

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

April 04 - February 19, 2022 (29 U.S. Jurisdictions)



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

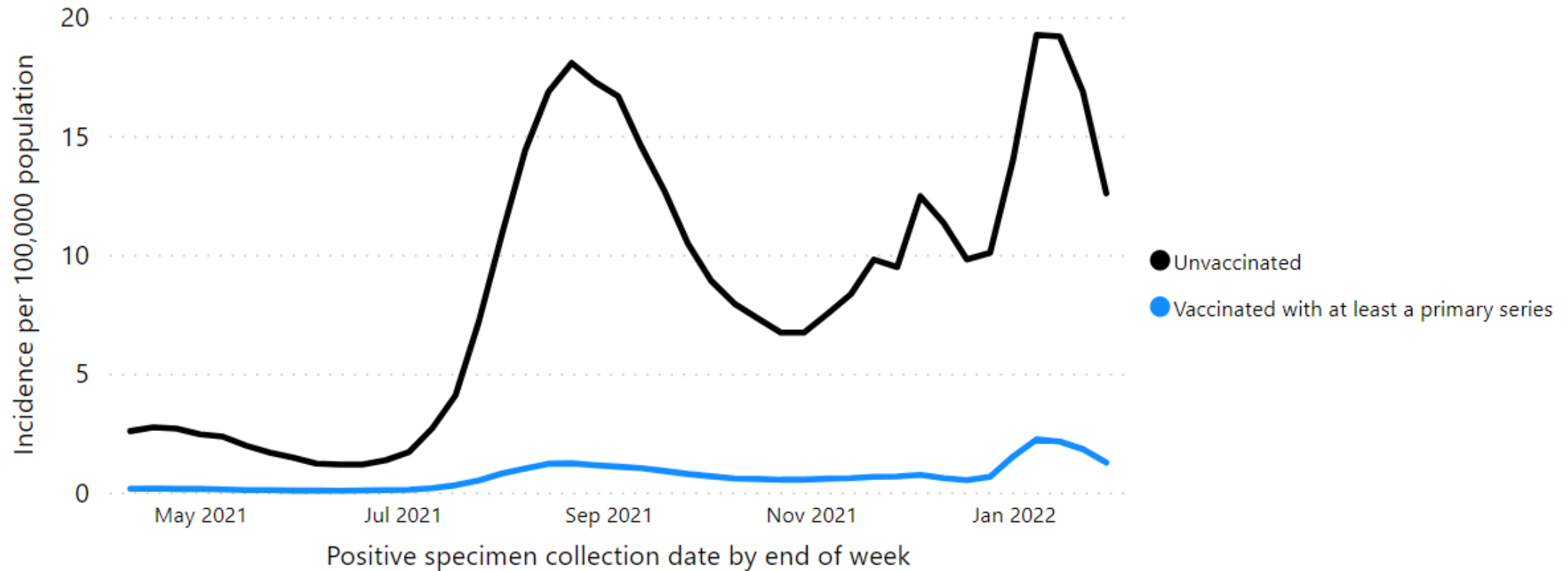
**2.8X**

*Risk of Testing Positive for COVID-19*

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

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

April 04 - February 19, 2022 (29 U.S. Jurisdictions)

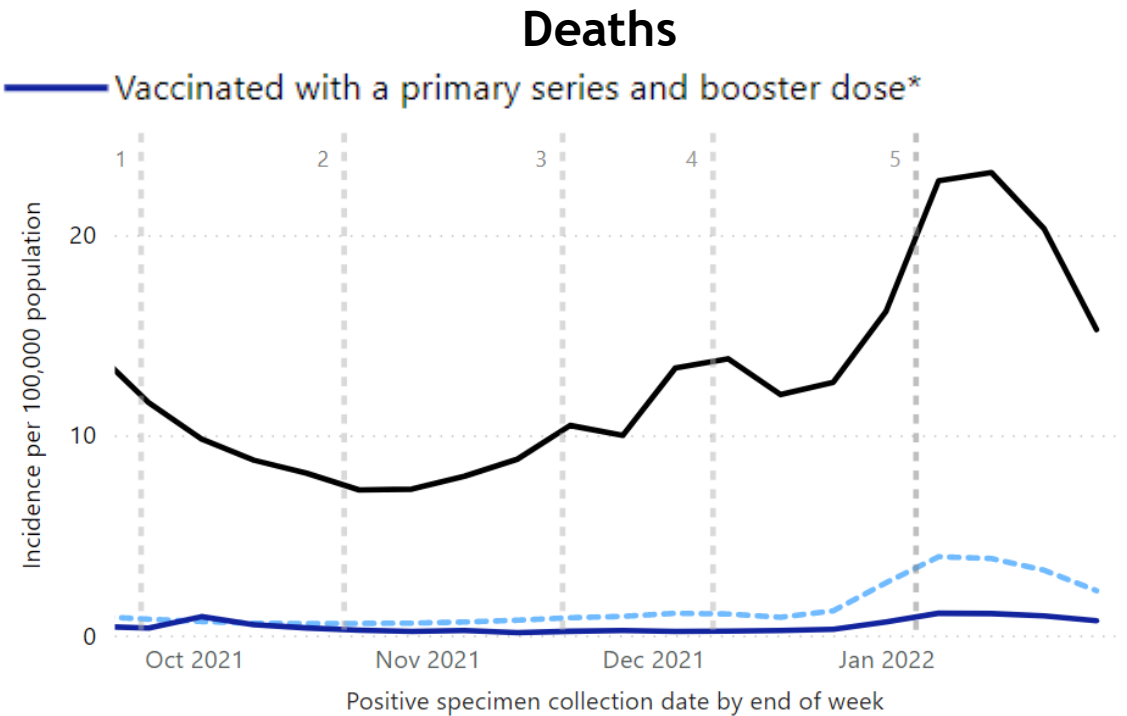
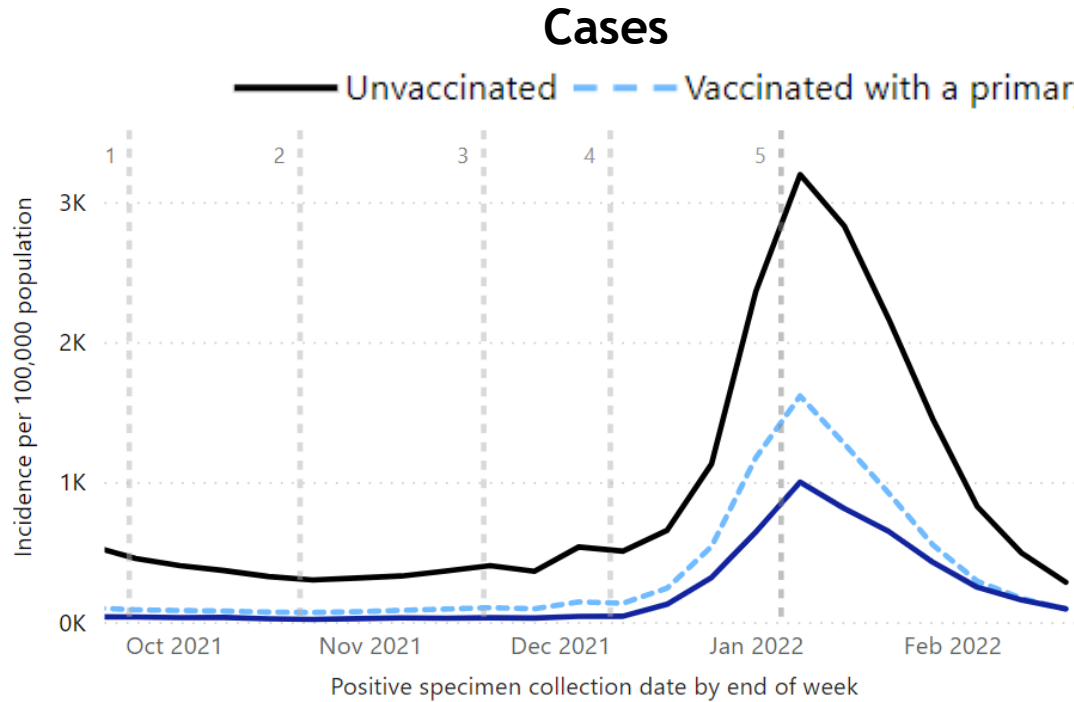


**Unvaccinated people aged 5 years and older had:**

**9X**  
*Risk of Dying from COVID-19*

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

# Age-Adjusted Rates of COVID-19 Cases & Deaths by Vaccination Status and Receipt of Booster Dose,\* September 19 - January 29, 2022 (26 U.S. Jurisdictions)



Unvaccinated people aged 12 years and older had:

**3.5X**  
Risk of Testing Positive for COVID-19

AND

**21X**  
Risk of Dying from COVID-19

in January, and

**3.2X**  
Risk of Testing Positive for COVID-19

in February, compared to people vaccinated with a primary series and a booster dose.\*

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



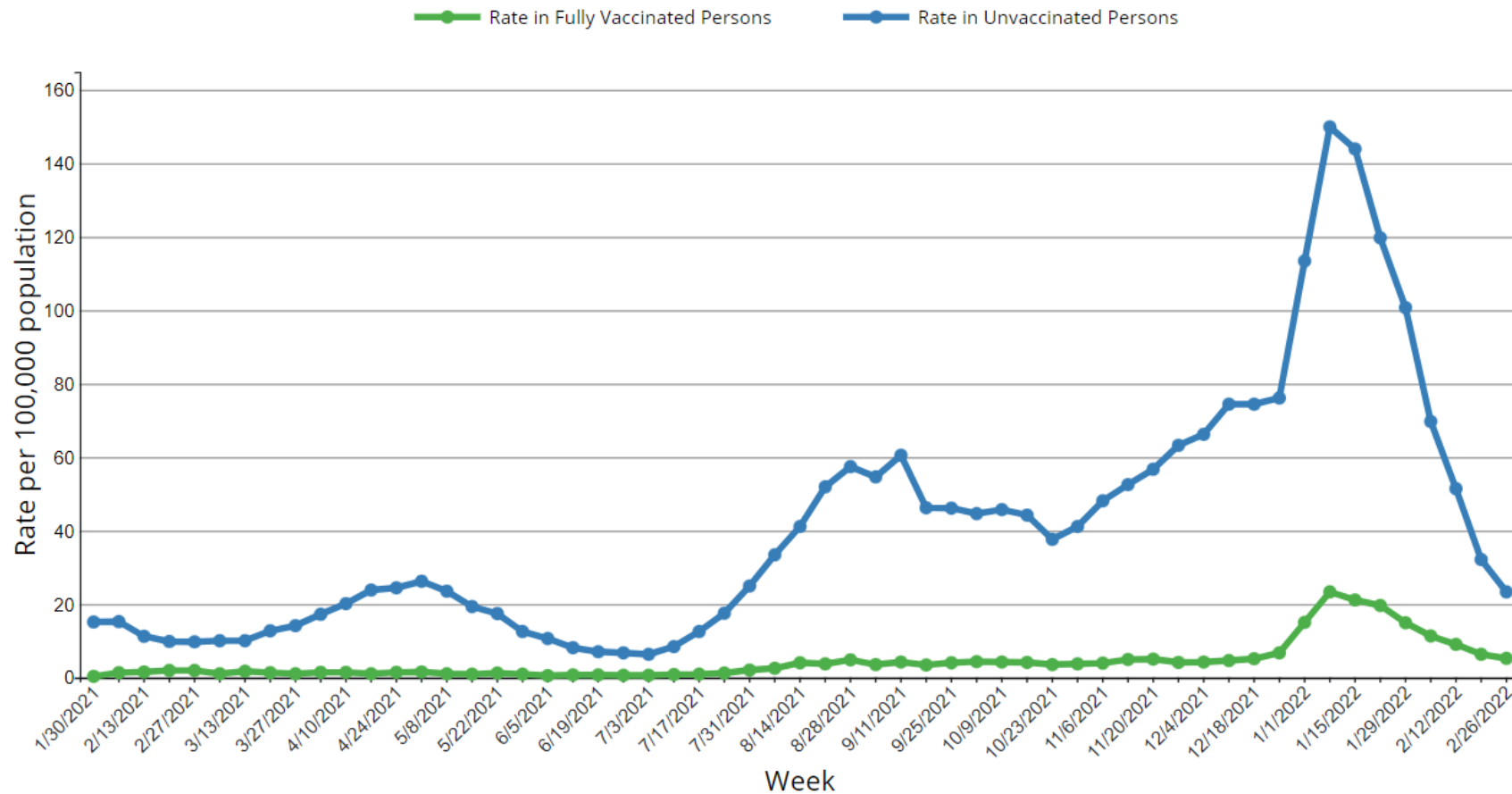
# COVID-19-Associated Hospitalization Surveillance Network (COVID-NET)

- Population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations
- Catchment area: >250 acute care hospitals in 99 counties in 14 states, representing 10% of U.S. population
- **Case definition:** Resident of the surveillance area and positive SARS-CoV-2 test within 14 days prior to or during hospitalization
- **Rates by vaccination status\***
  - Linkage to immunization information systems
  - Representative sample of hospitalized cases (>37,000 to date)



\*California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah are included in these analyses

# Age-adjusted rates of COVID-19-associated hospitalizations by vaccination status in adults ages $\geq 18$ years, January 2021 - February 2022

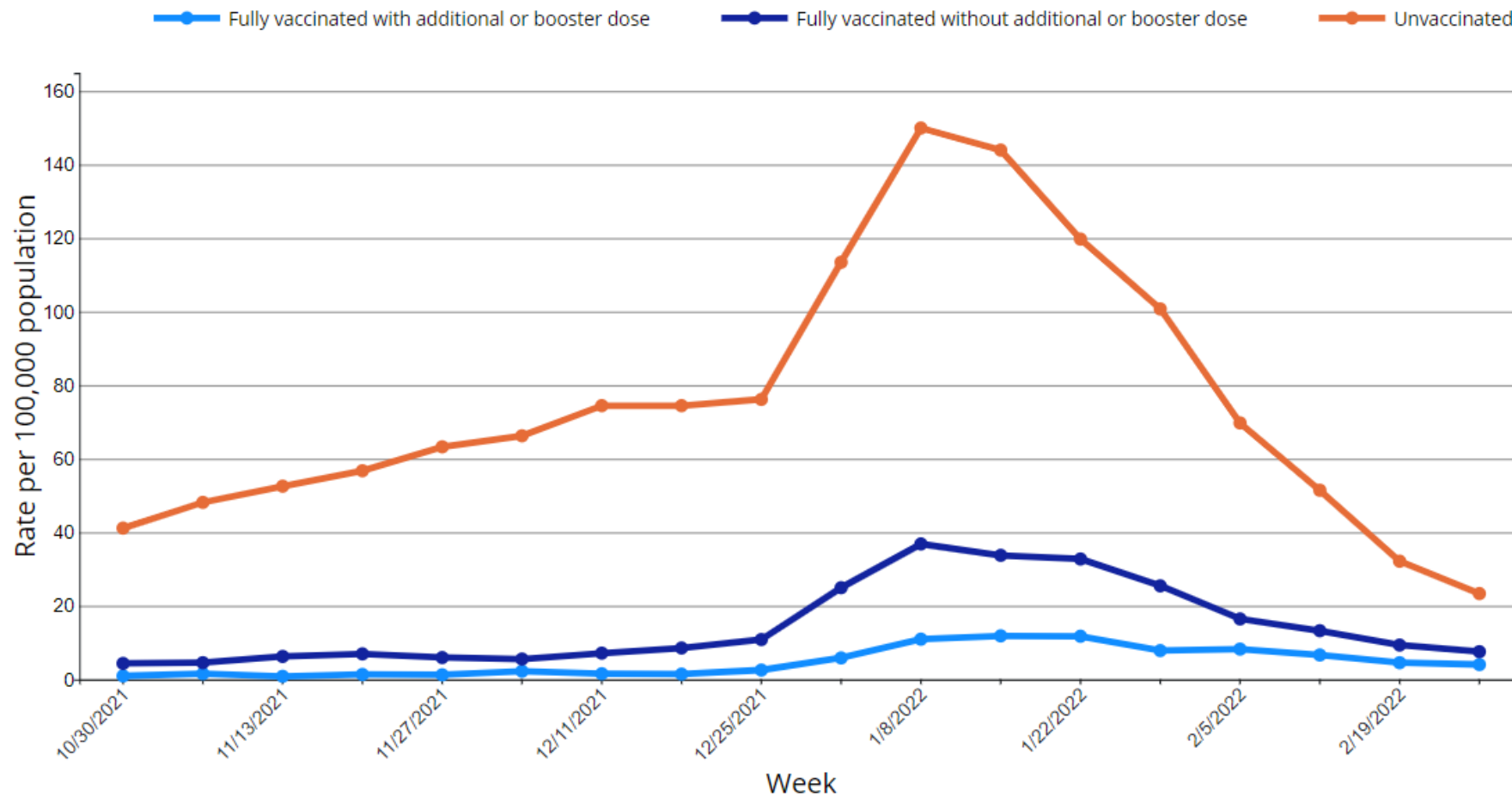


In February, compared to fully vaccinated adults ages  $\geq 18$  years, monthly rates of COVID-19-associated hospitalizations were **5X** higher in unvaccinated adults

A population-based surveillance system (COVID-NET) collected data on laboratory-confirmed COVID-19-associated hospitalizations among adults through a network of over 250 acute-care hospitals in 14 states.

CDC COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination> Accessed March 17, 2022

# Age-Adjusted Rates of COVID-19-Associated Hospitalizations by Vaccination Status in Adults Ages $\geq 18$ Years, October 2021-February 2022



In February, compared to fully vaccinated adults ages  $\geq 18$  years with additional or booster doses, monthly rates of COVID-19-associated hospitalizations were **7X** higher in unvaccinated adults

# COVID-19-associated Hospitalizations Among Vaccinated Adults ≥18 Years with COVID-19 as Primary Reason for Admission – COVID-NET

January 1, 2021-January 31, 2022

- Fully vaccinated cases more likely to be:
  - Older
  - Long-term care facility resident
  - DNR/DNI/CMO code
- More underlying medical conditions

Category	Unvaccinated weighted % N=8,013	Fully vaccinated weighted % N=1,768
<b>Age group (median, IQR)</b>	58 (46-70)	70 (59-80)
18-49 years	31	11
50-64 years	33	16
≥65 years	37	72
LTCF residence	4	12
DNR/DNI/CMO	6	14
<b>Underlying medical conditions*</b>		
Chronic lung disease	28	42
Cardiovascular disease	33	56
Neurologic disease	15	29
Renal disease	14	30
Immunosuppressive condition	11	24
<b>≥3 Underlying medical conditions</b>	50	76

\* Conditions significantly different in multivariable model of factors associated with hospitalization

DNI = do not intubate; DNR = do not resuscitate; CMO=comfort measure only

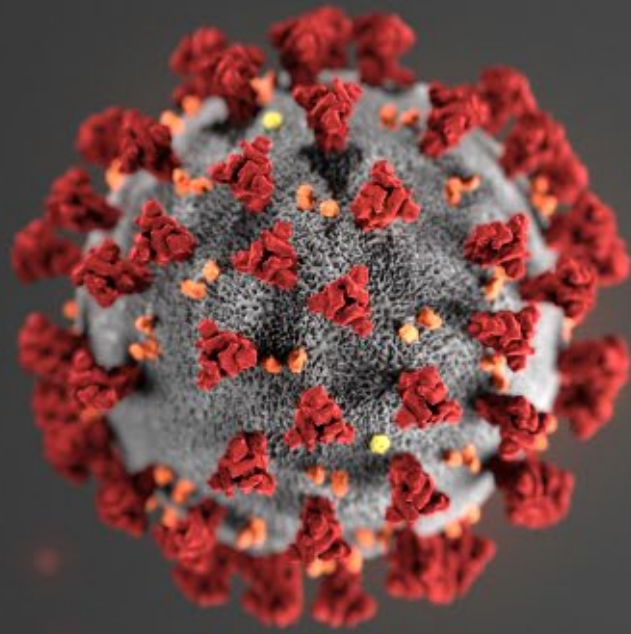
Unpublished data, as described at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html>

# Summary

- In 2021, the US experienced a dynamic landscape of SARS-CoV-2 variants, including Delta- and Omicron-driven resurgences of SARS-CoV-2 transmission
- 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 severe disease — important to stay up to date with vaccination, including boosters in eligible populations

# Acknowledgements

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- Ruth Link-Gelles
- Sara Oliver
- Aron Hall
- Adam MacNeil
- Rebecca Kondor
- Phillip Shirk
- Clint Paden
- Dave Wentworth
- Staff in 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, NM, NY, NY City, OH, RI, Seattle/King County, 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.





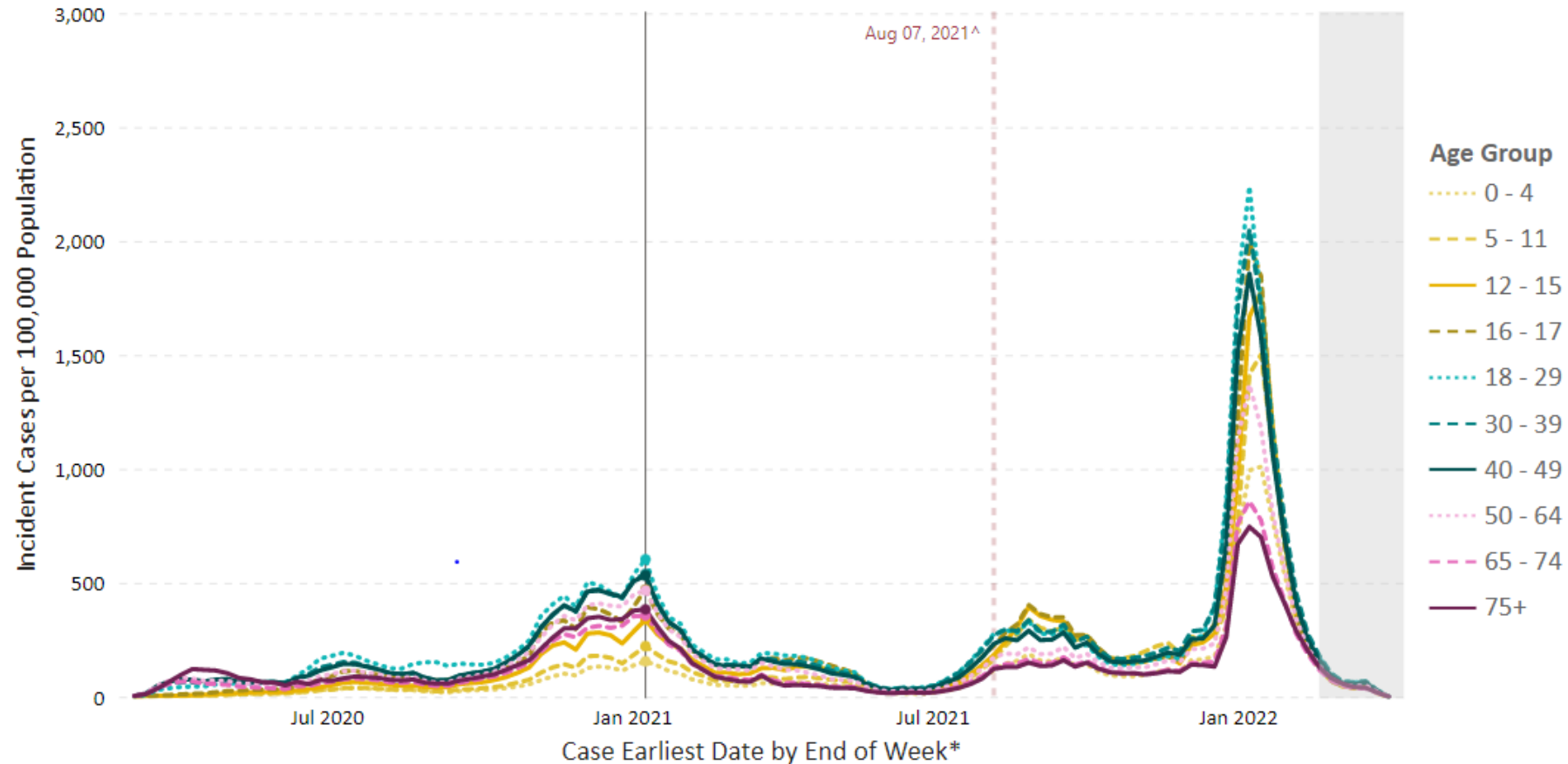
# Extra Slides



# 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>

# Weekly Trends in COVID-19 Case Rates by Age Group, United States, March 1, 2020 - April 2, 2022



US: The most recent case record was reported during the week ending on Apr 02, 2022. Percentage of cases reporting age by date - 99.90%.

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 cases have been suppressed.

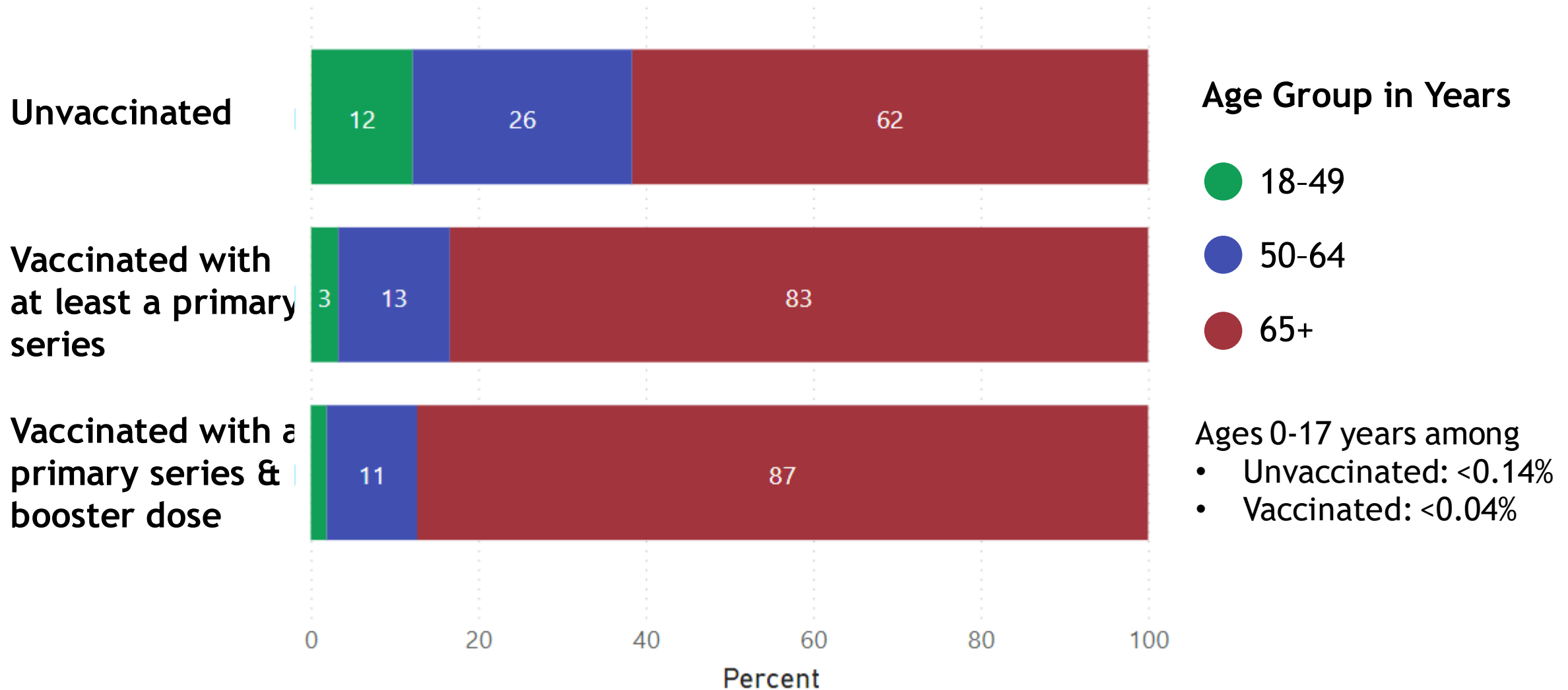
\*Case Earliest Date is the earliest of the clinical date (related to illness or specimen collection and chosen by a defined hierarchy) and the Date Received by CDC. The date for the current week extends through Saturday.

^Case rates during the week ending Aug 07, 2021 are reflective of a data reporting artifact from South Dakota. Surveillance data are provisional, and as additional clinical date data becomes available, the case rates over time are subject to change.

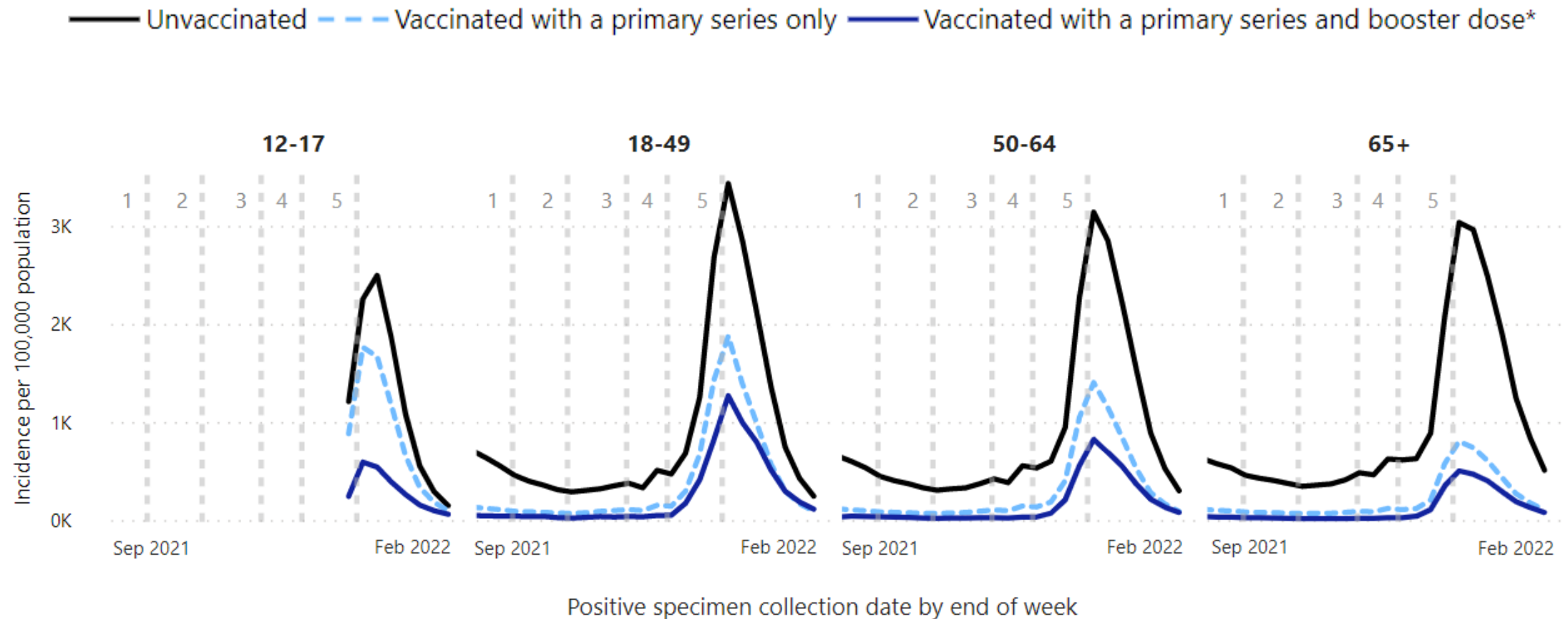
Source: CDC COVID-19 Case Line-Level Data, 2019 US Census, HHS Protect; Visualization: Data, Analytics & Visualization Task Force and CDC CPR DEO Situational Awareness Public Health Science Team

# Percentage of Deaths by Vaccination Status and Age Group

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



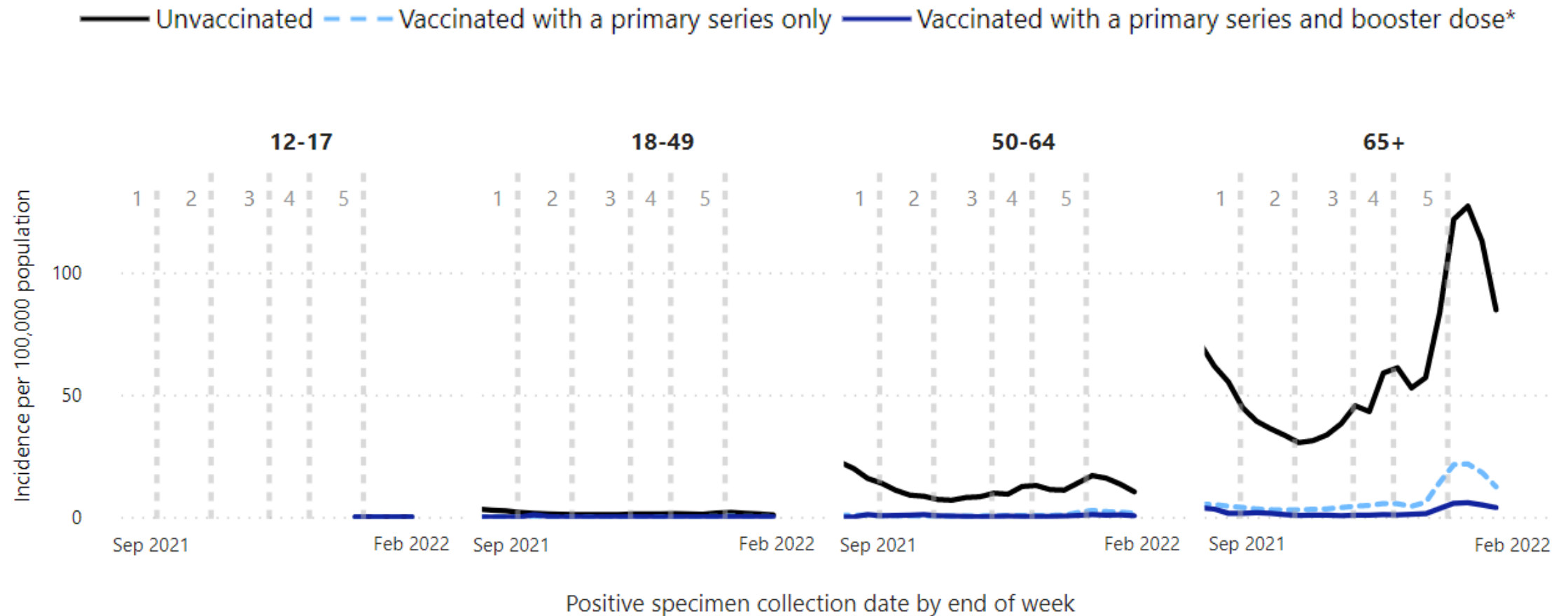
# Rates of COVID-19 Cases by Vaccination Status, Receipt of Booster Dose,\* and Age Group, September 19 - January 29, 2022 (26 U.S. Jurisdictions)



\*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 March 28, 2022

# Rates of COVID-19 Cases by Vaccination Status, Receipt of Booster Dose,\* and Age Group, September 19 - January 29, 2022 (26 U.S. Jurisdictions)



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