Vaccines and Related Biological Products Advisory Committee Meeting

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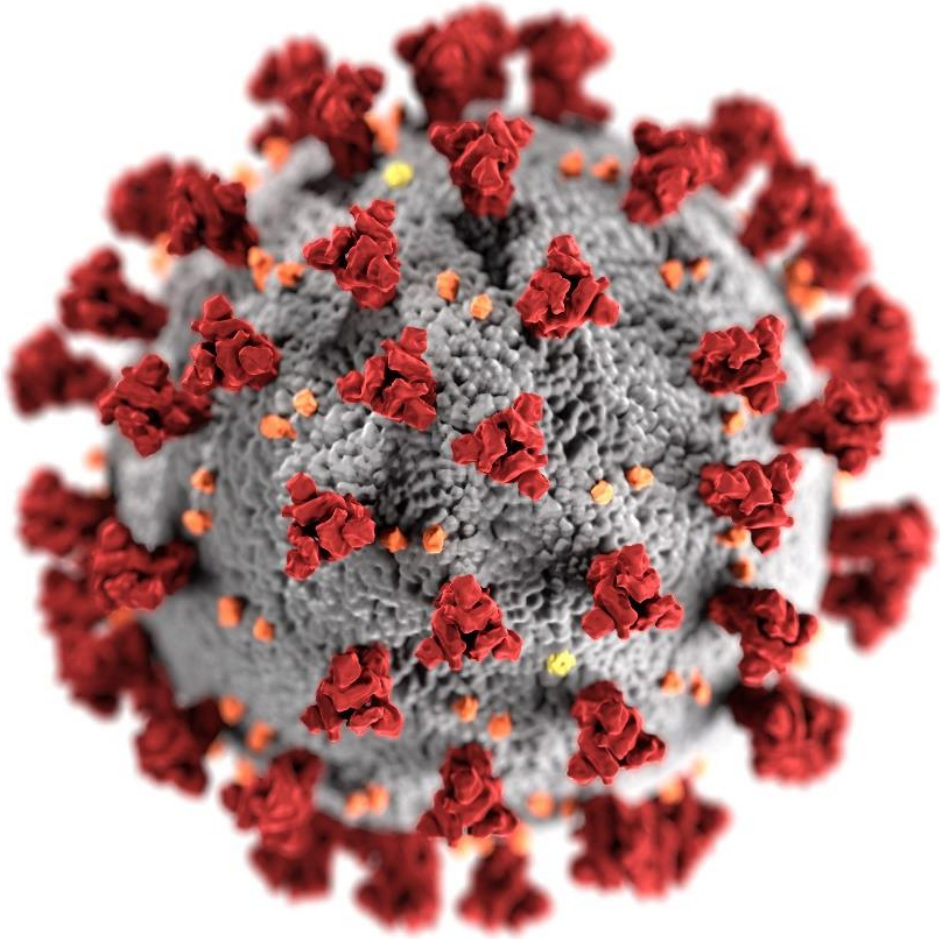
Update on Current Epidemiology of COVID-19 Pandemic and SARS-CoV-2 Variants

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

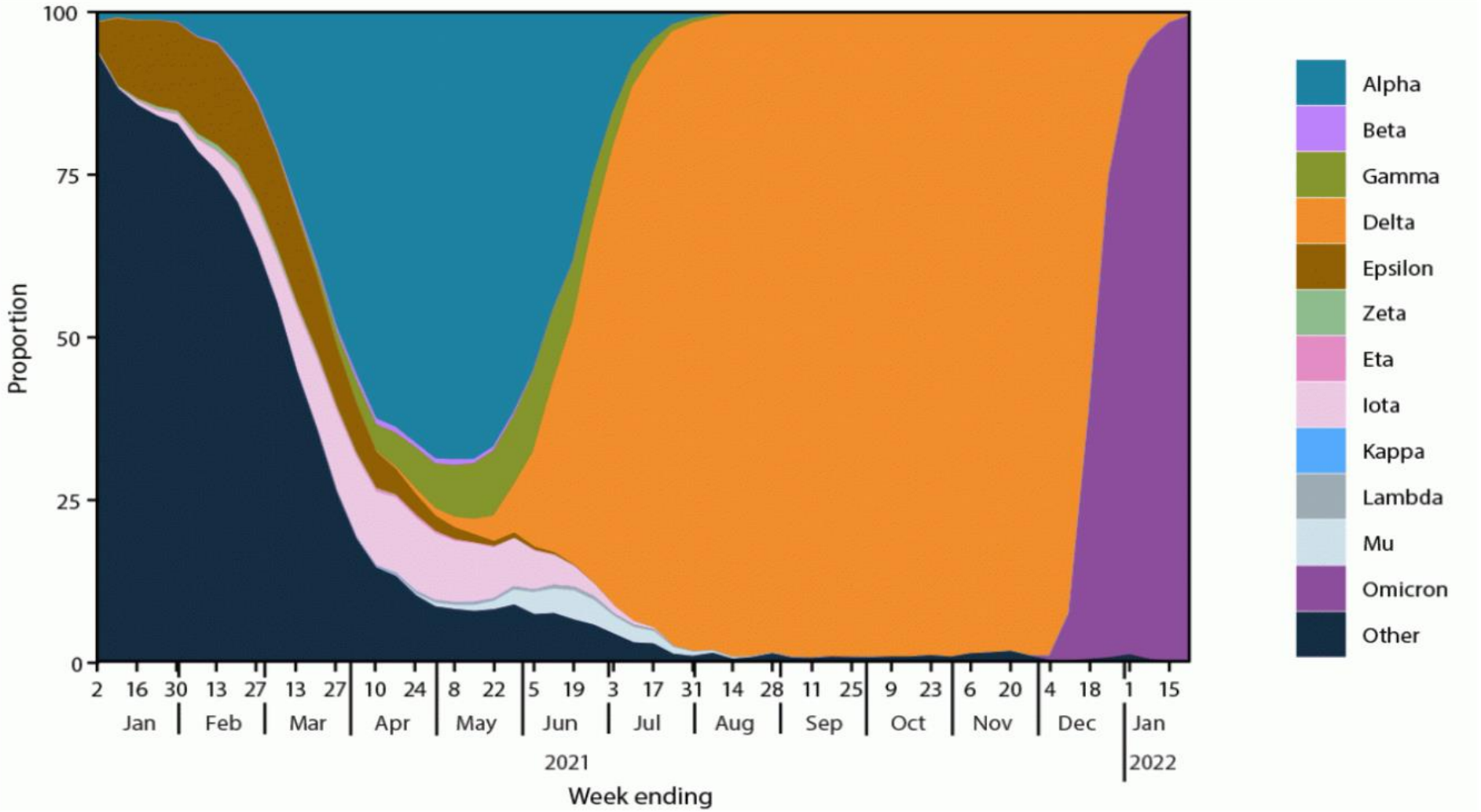


cdc.gov/coronavirus

SARS-CoV-2 Variants

Changing Landscape of Circulating Variants

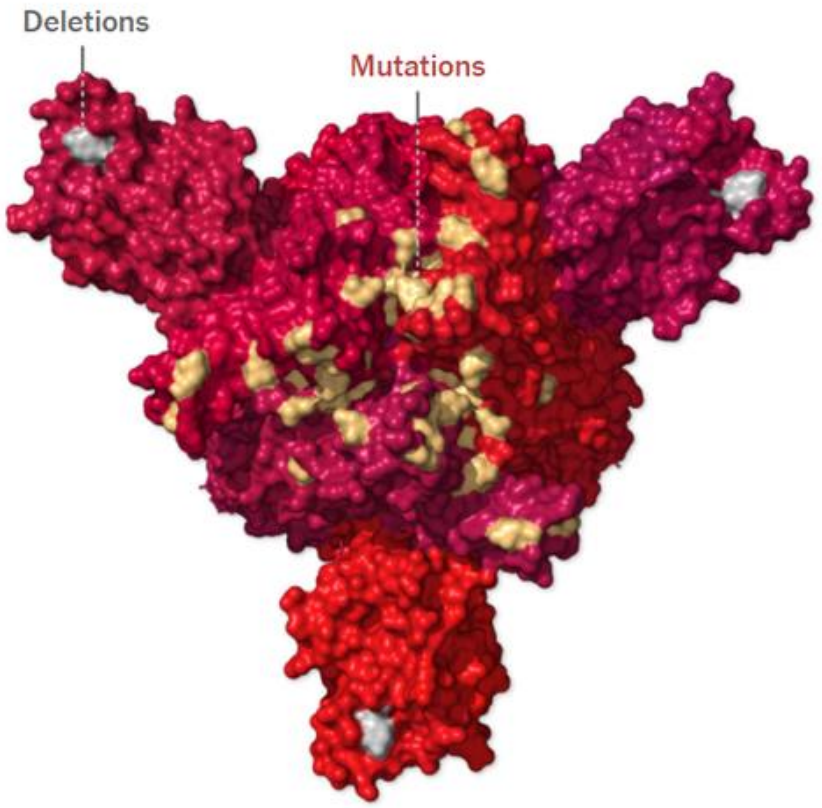
FIGURE 1. National weekly proportion estimates* of SARS-CoV-2 variants† — United States, January 2, 2021–January 22, 2022



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

SARS-CoV-2 Omicron (B.1.1.529) variant

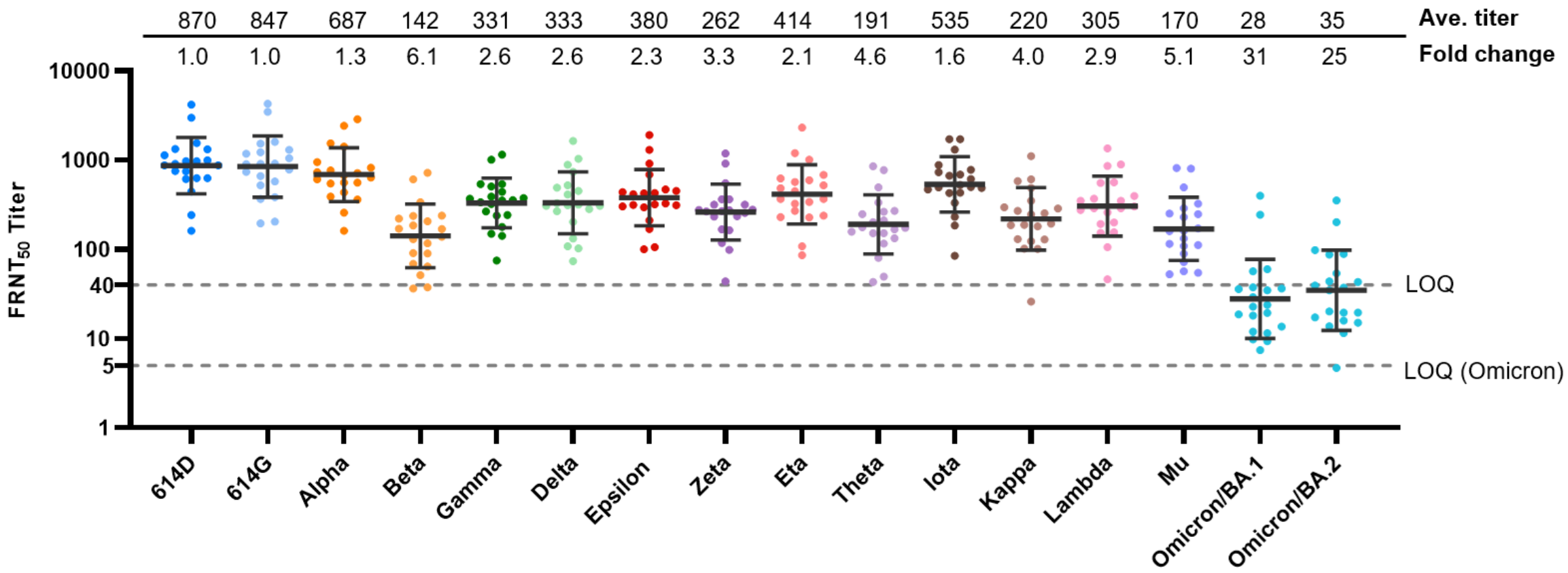
- Six sub-lineages: BA.1, BA.1.1, BA.2, BA.3, BA.4, and BA.5
- Increased transmissibility and immune evasion, but decreased disease severity
- 30+ mutations in spike gene (S-gene)
  - 15 in receptor binding domain
- Lower vaccine effectiveness
  - Reduced neutralization by sera from vaccinated or convalescent individuals
- Reduction in efficacy of some monoclonal antibody treatments



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

https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html
https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html

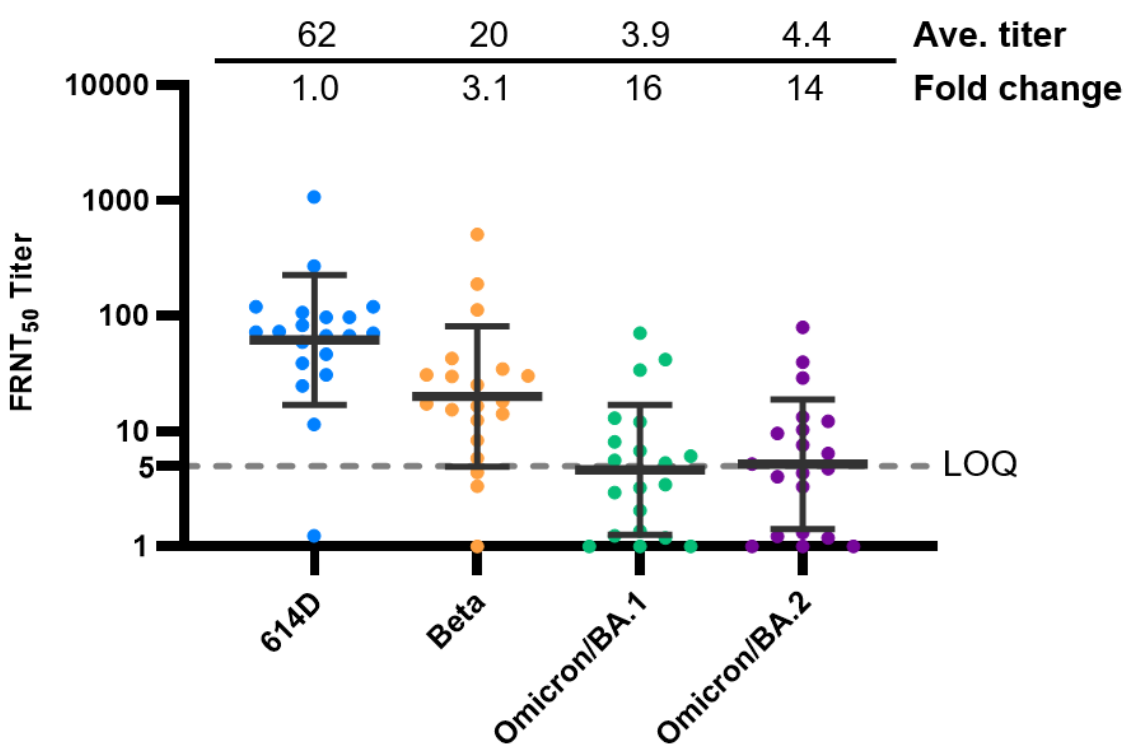
Neutralizing Activity of mRNA Vaccine Sera Against SARS-CoV-2 Variants from Alpha to Omicron



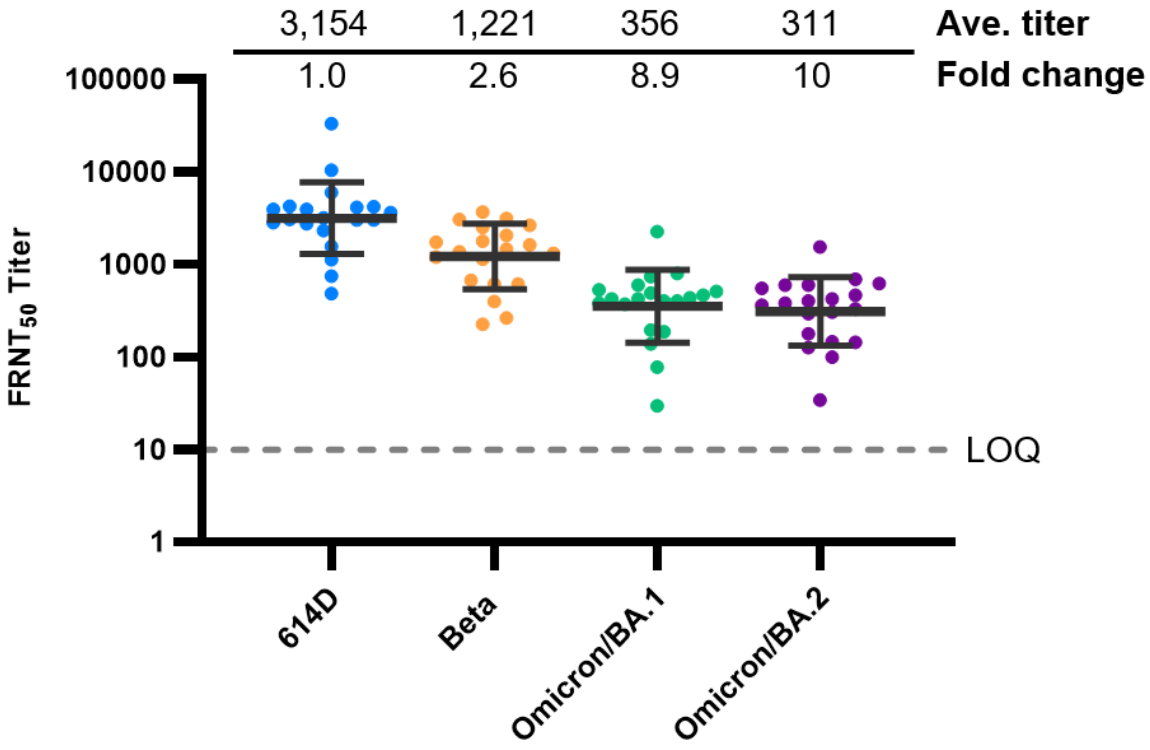
Sera from 2-6 weeks after completing second dose of Moderna (10 sera) and Pfizer-BioNTech (10 sera) vaccines, tested with recombinant SARS-CoV-2 reporter viruses

LOQ=Limit of quantitation. Zhou B, Davis T, Thornburg N, Wentworth D (CDC), *in publication*

Booster Vaccination Enhances Neutralizing Antibodies Against SARS-CoV-2 Viruses Including Omicron



Sera from 6-7 months after completing second dose (pre-booster)



Sera from 2-6 weeks after completing third dose (post-booster)

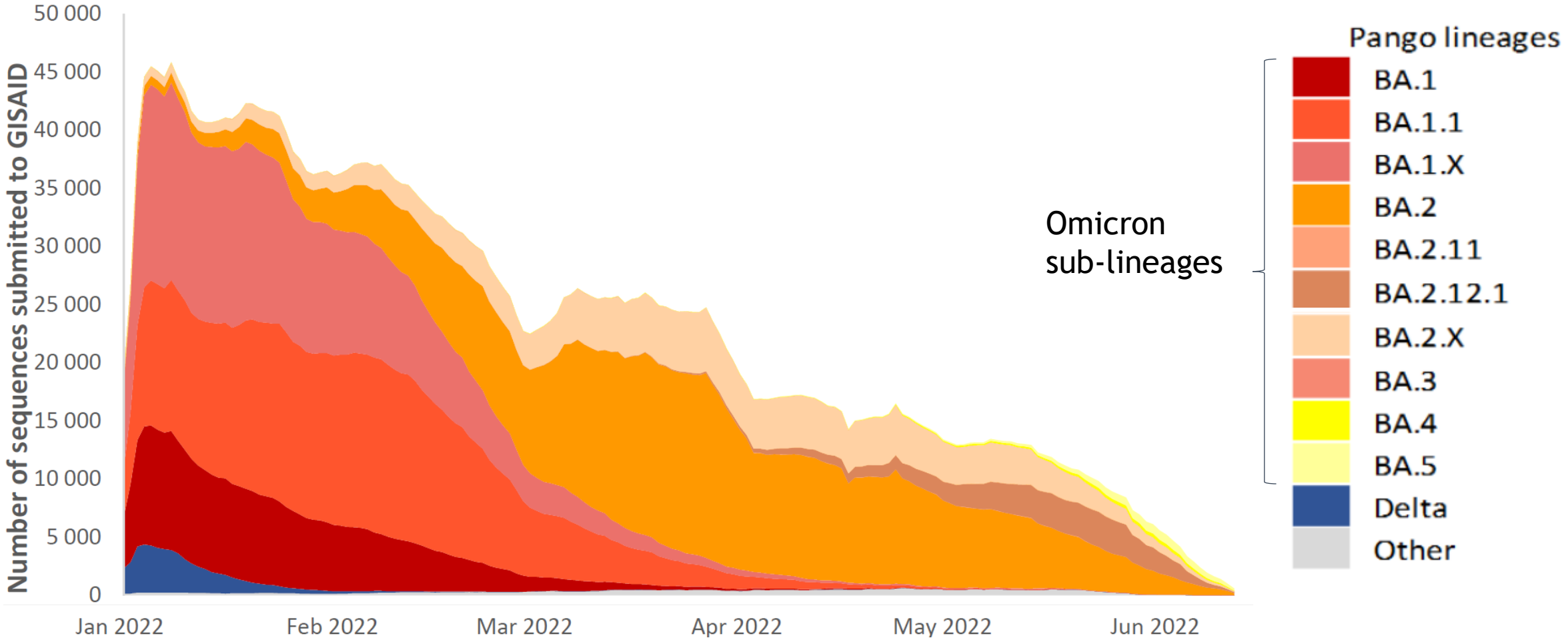
LOQ=Limit of quantitation. Tested with Recombinant SARS-CoV-2 reporter viruses. Zhou B, Davis T, Thornburg N, Wentworth D (CDC), *in publication*

Impact of Omicron on COVID-19 Pre-Exposure Prophylaxis and Treatment Options

- Since Omicron became predominant, several monoclonal antibodies no longer recommended as COVID-19 treatments due to reduced efficacy
  - Bamlanivimab plus etesevimab
  - Casirivimab plus imdevimab (REGEN-COV)
  - Sotrovimab — effective against BA.1 and BA.1.1, but substantially decreased against BA.2
- Bebtelovimab retains activity against circulating Omicron subvariants and can be used for non-hospitalized patients
- EVUSHELD (tixagevimab plus cilgavimab) still recommended for pre-exposure prophylaxis, but given at a higher dosage
- Oral antiviral therapeutics (small molecule inhibitors) retain efficacy against the Omicron variant

https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron
https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-evusheld-dosing

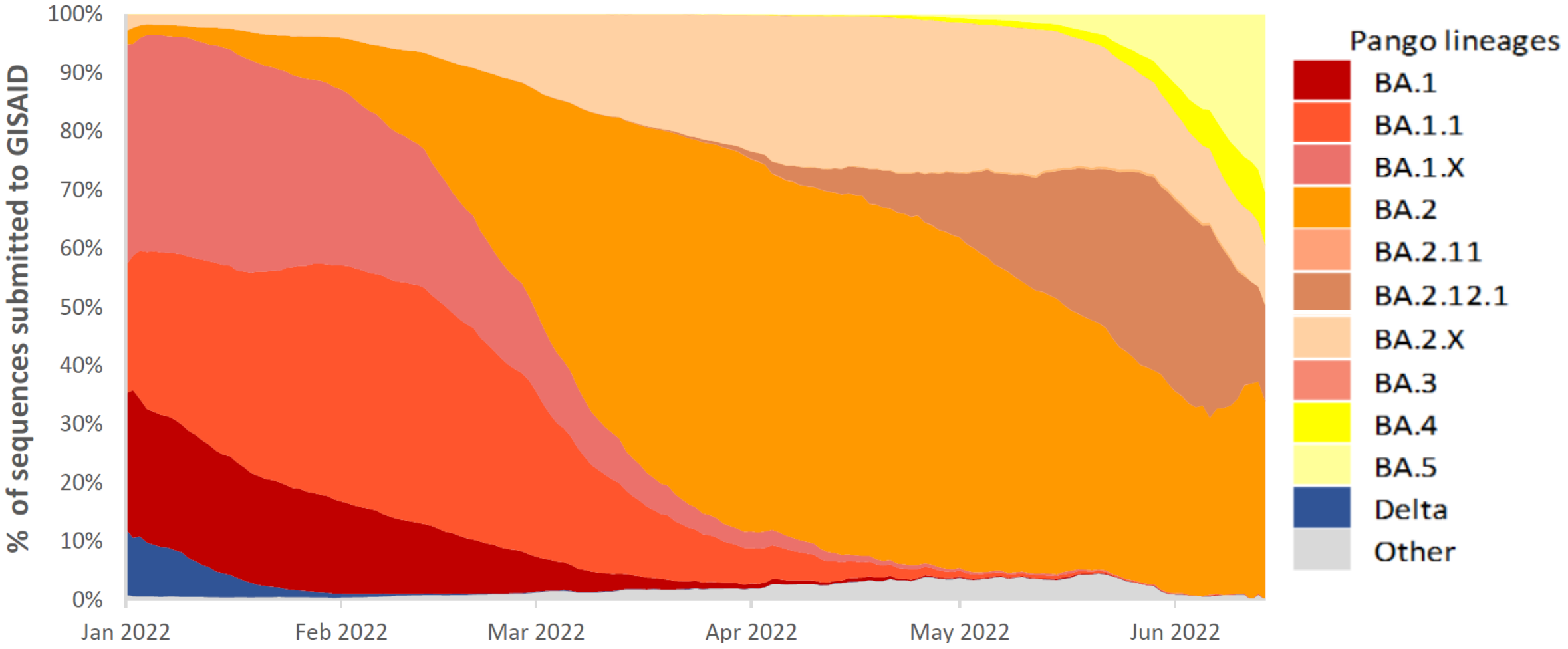
Number of SARS-CoV-2 Genomic Sequences by Lineage Submitted Globally to GISAID as of June 20, 2022



Omicron sub-lineages related to BA.1 and BA.2 are pooled under BA.1.X and BA.2.X, respectively

World Health Organization. https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---22-june-2022

Percentage of SARS-CoV-2 Genomic Sequences by Lineage Submitted Globally to GISAID as of June 20, 2022

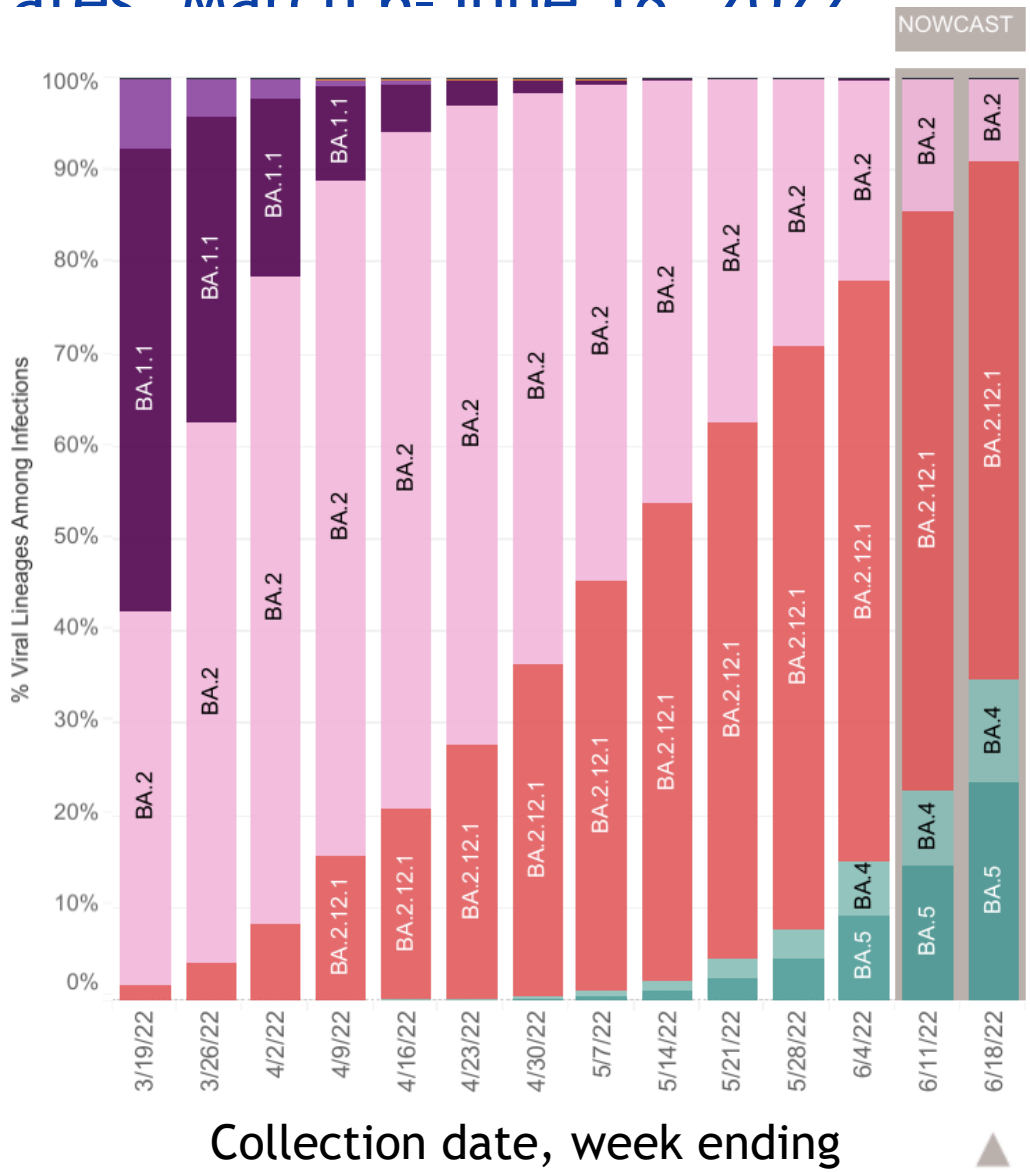


Omicron sub-lineages related to BA.1 and BA.2 are pooled under BA.1.X and BA.2.X, respectively

World Health Organization. https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---22-june-2022

Trends in Weighted Variant Proportion Estimates & Nowcast

United States, March 6- June 18, 2022



USA

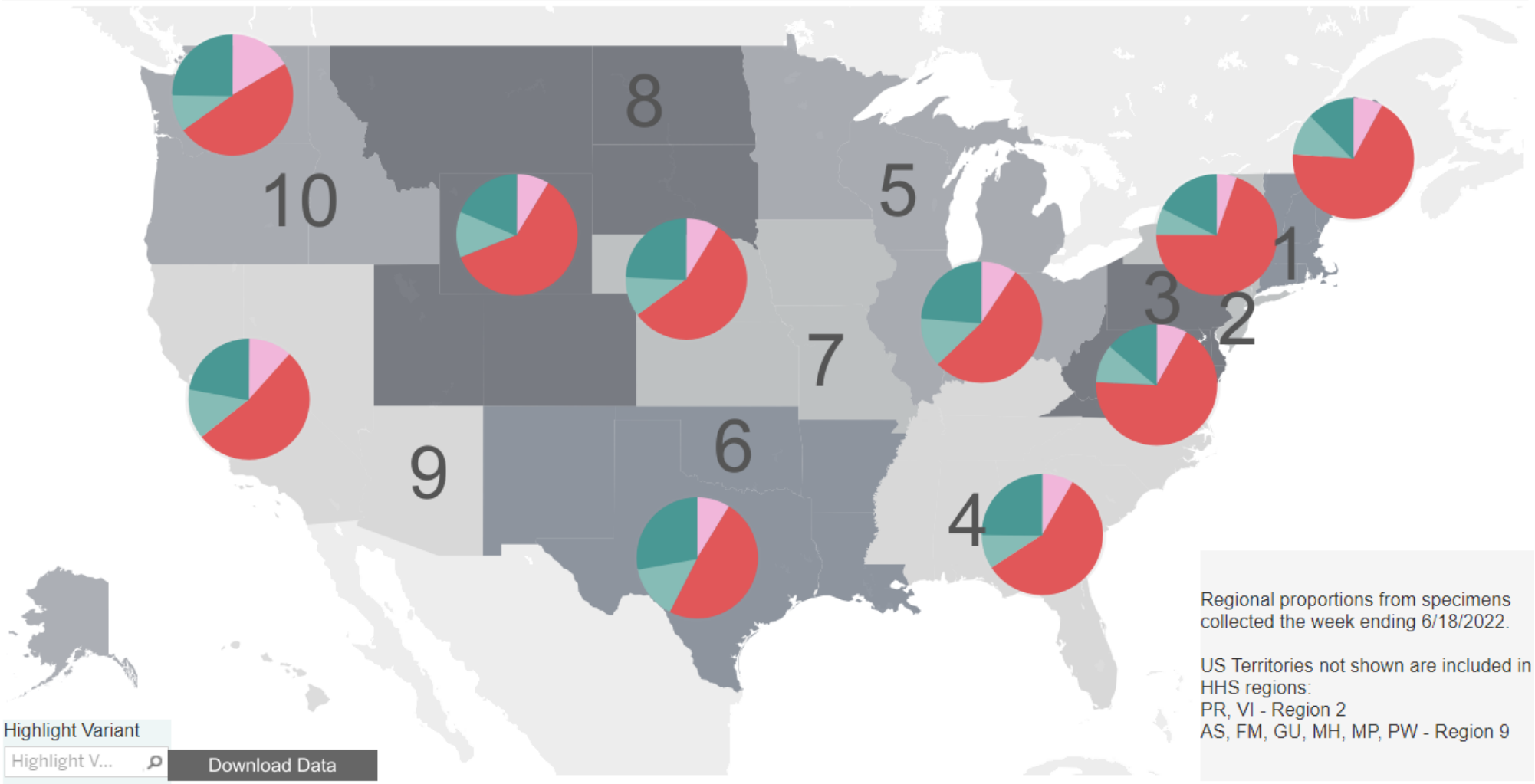
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2.12.1	VOC	56.0%	51.4-60.5%
	BA.5	VOC	23.5%	20.3-27.0%
	BA.4	VOC	11.4%	8.8-14.5%
	BA.2	VOC	9.1%	7.9-10.5%
	BA.1.1	VOC	0.0%	0.0-0.0%
	B.1.1.529	VOC	0.0%	0.0-0.0%
Delta	B.1.617.2	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

* 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, BA.3 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, BA.2 sublineages are aggregated with BA.2. BA.5.1 is aggregated with BA.5.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed June 24, 2022

Nowcast Estimates of Variant Proportions by HHS Region

United States, June 12-18, 2022

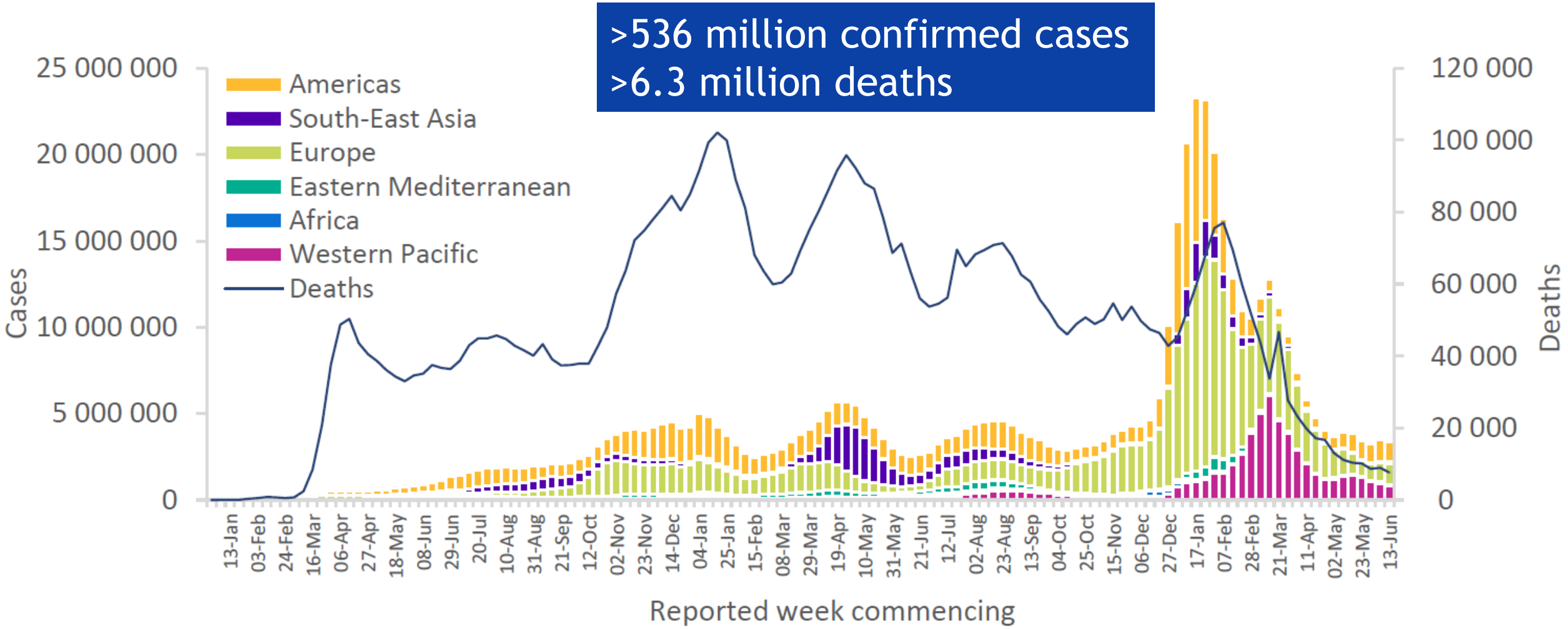


HHS=Health and Human Services

https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed June 24, 2022

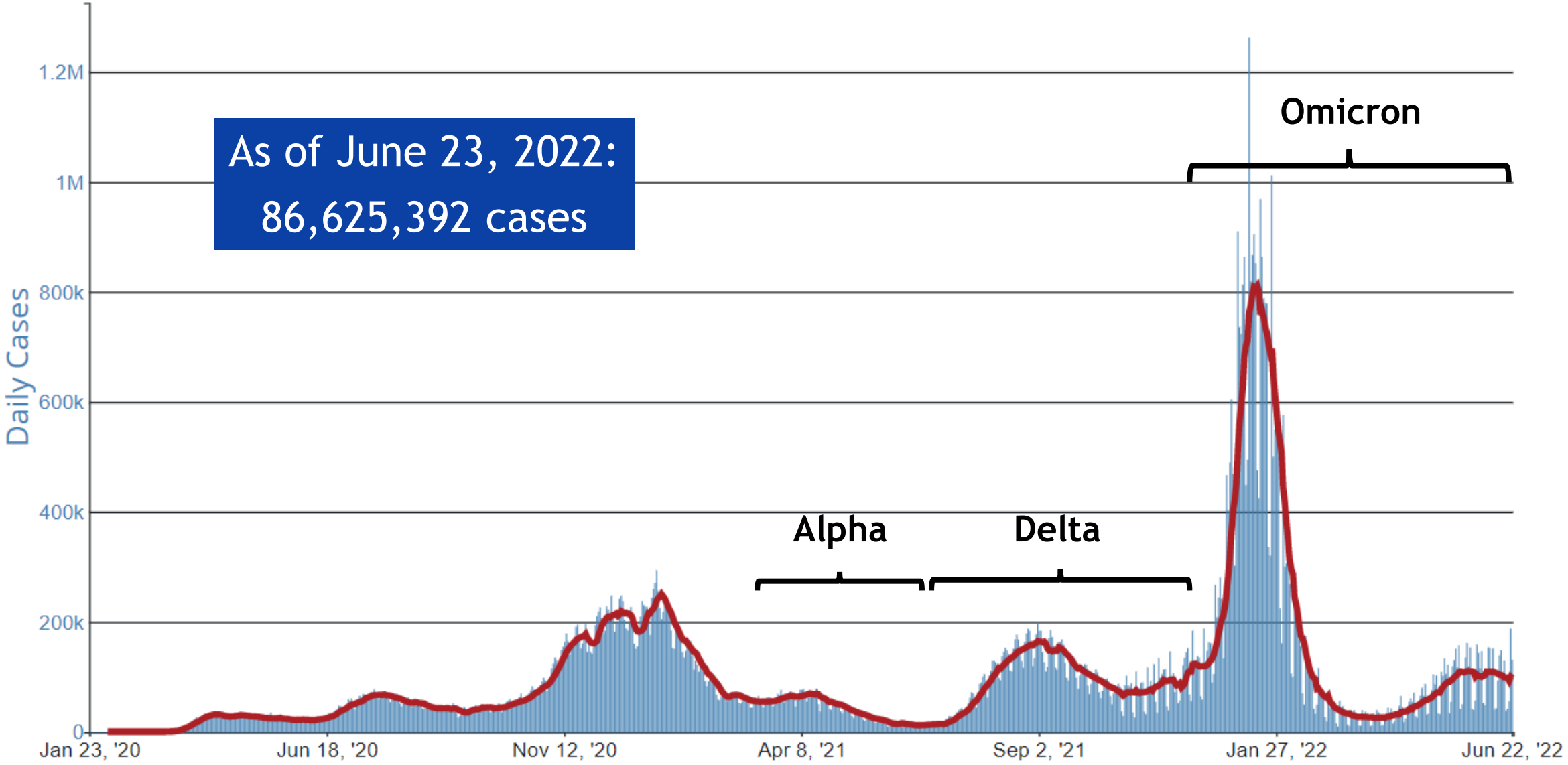
COVID-19 Disease Trends

COVID-19 Cases Reported Weekly by WHO Region, and Global Deaths as of 19 June 2022



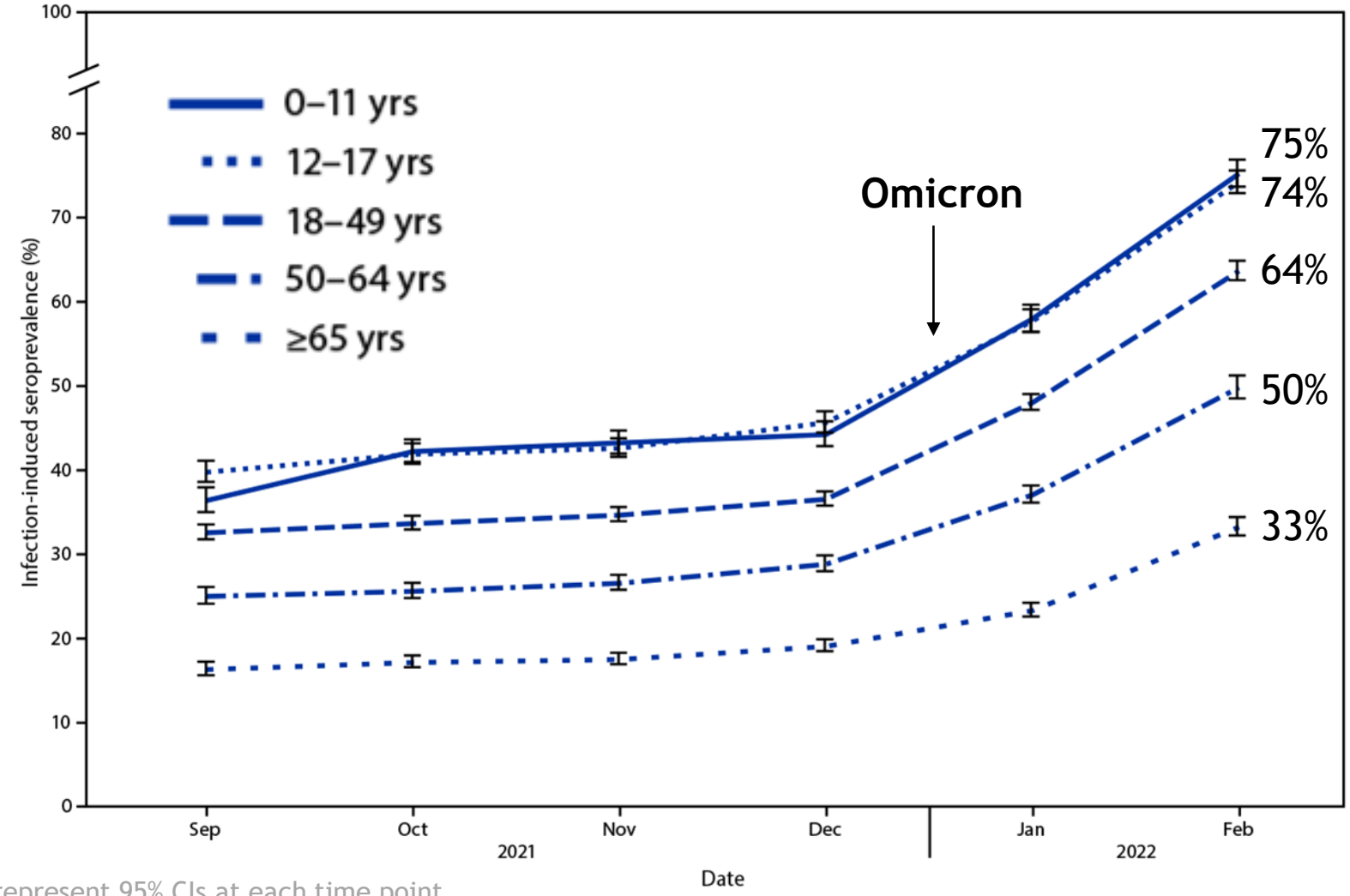
World Health Organization. https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---22-june-2022

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



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#trends_dailycases Accessed June 24, 2022

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



58% National seroprevalence in February 2022

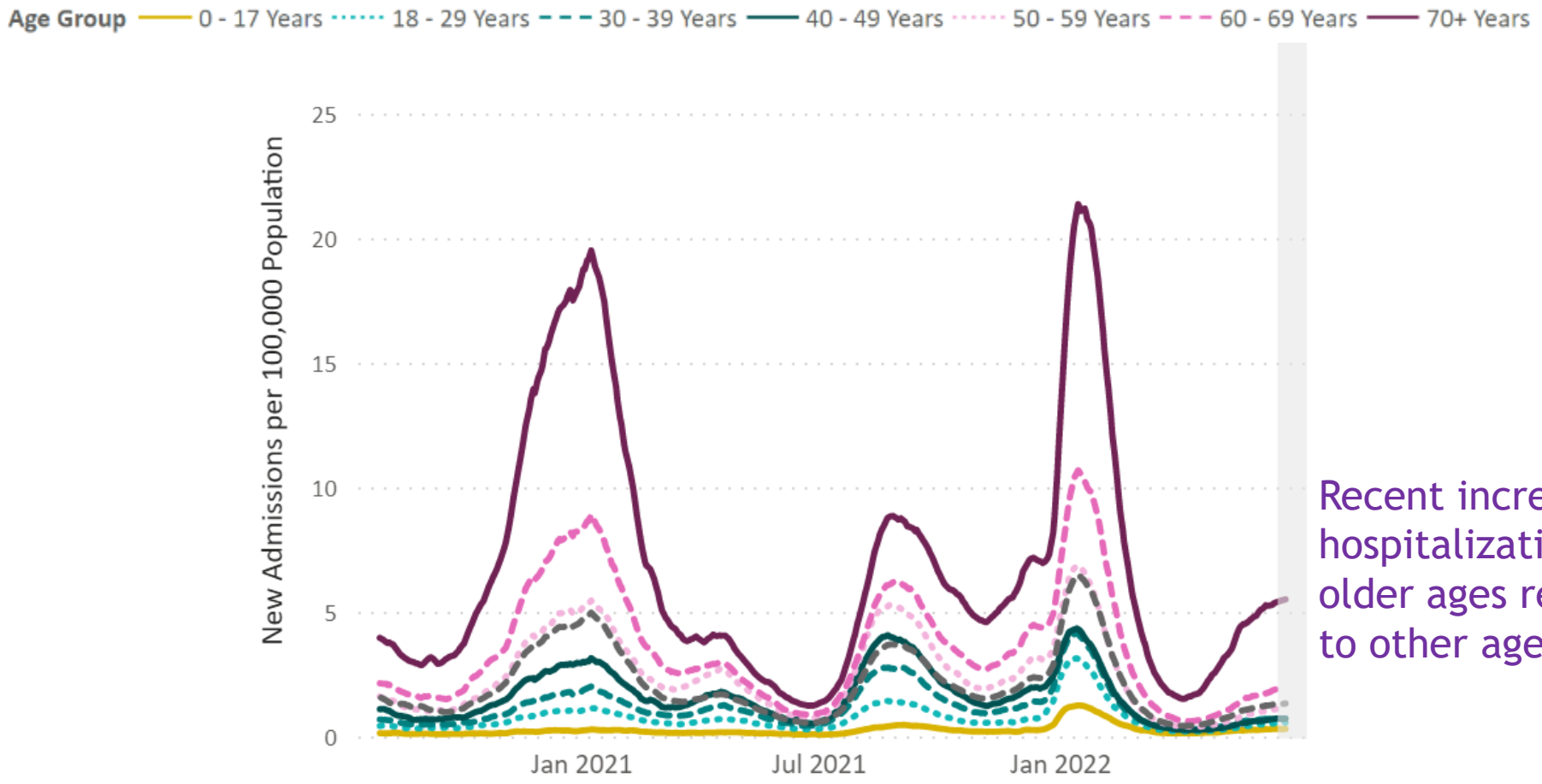
Does not indicate:

- 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

Weekly Trends in Rates of New Inpatient Admissions by Age Group, United States, August 1, 2020 – June 22, 2022

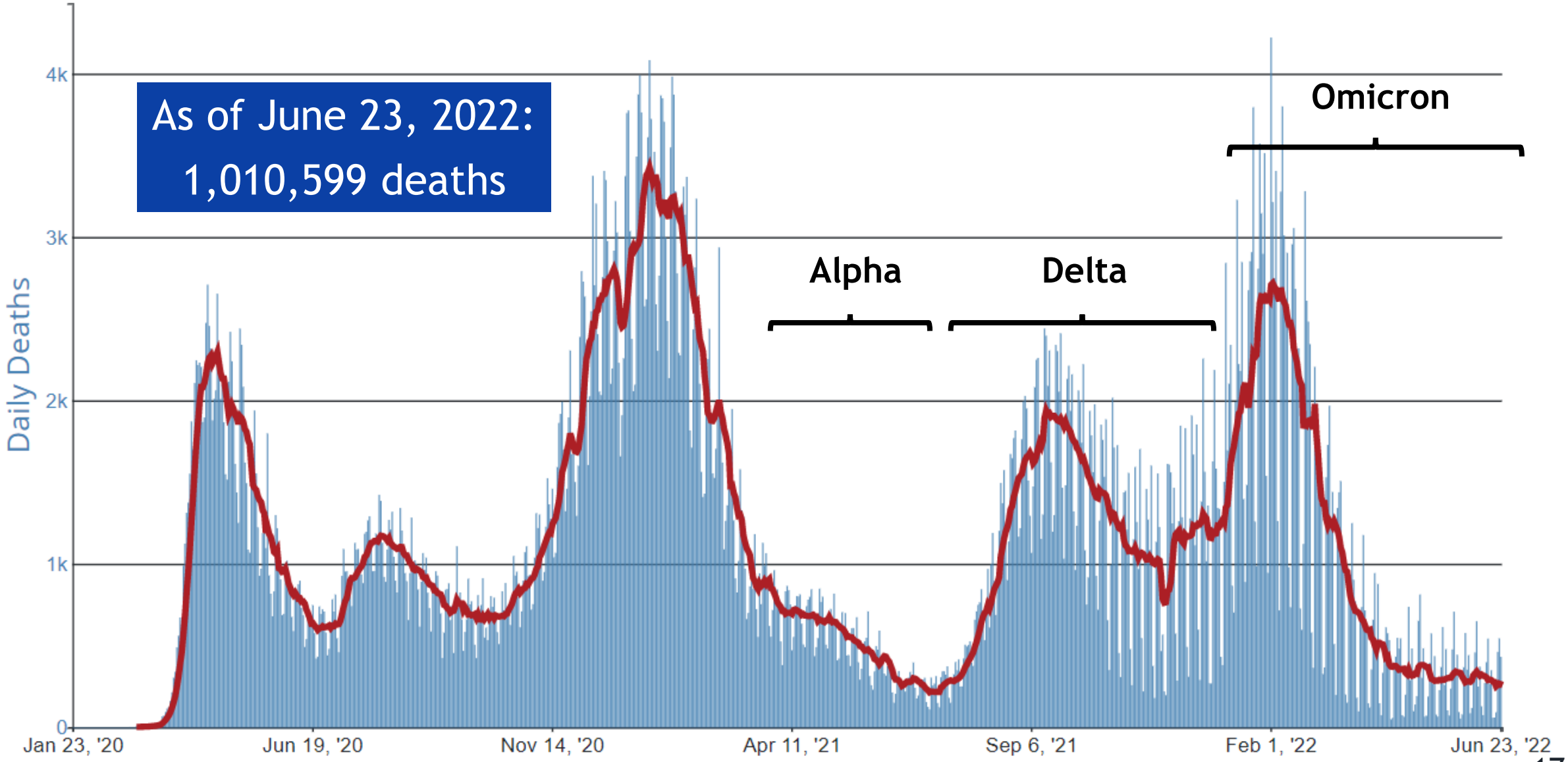


Recent increase in hospitalization rates in older ages relative to other age groups

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.

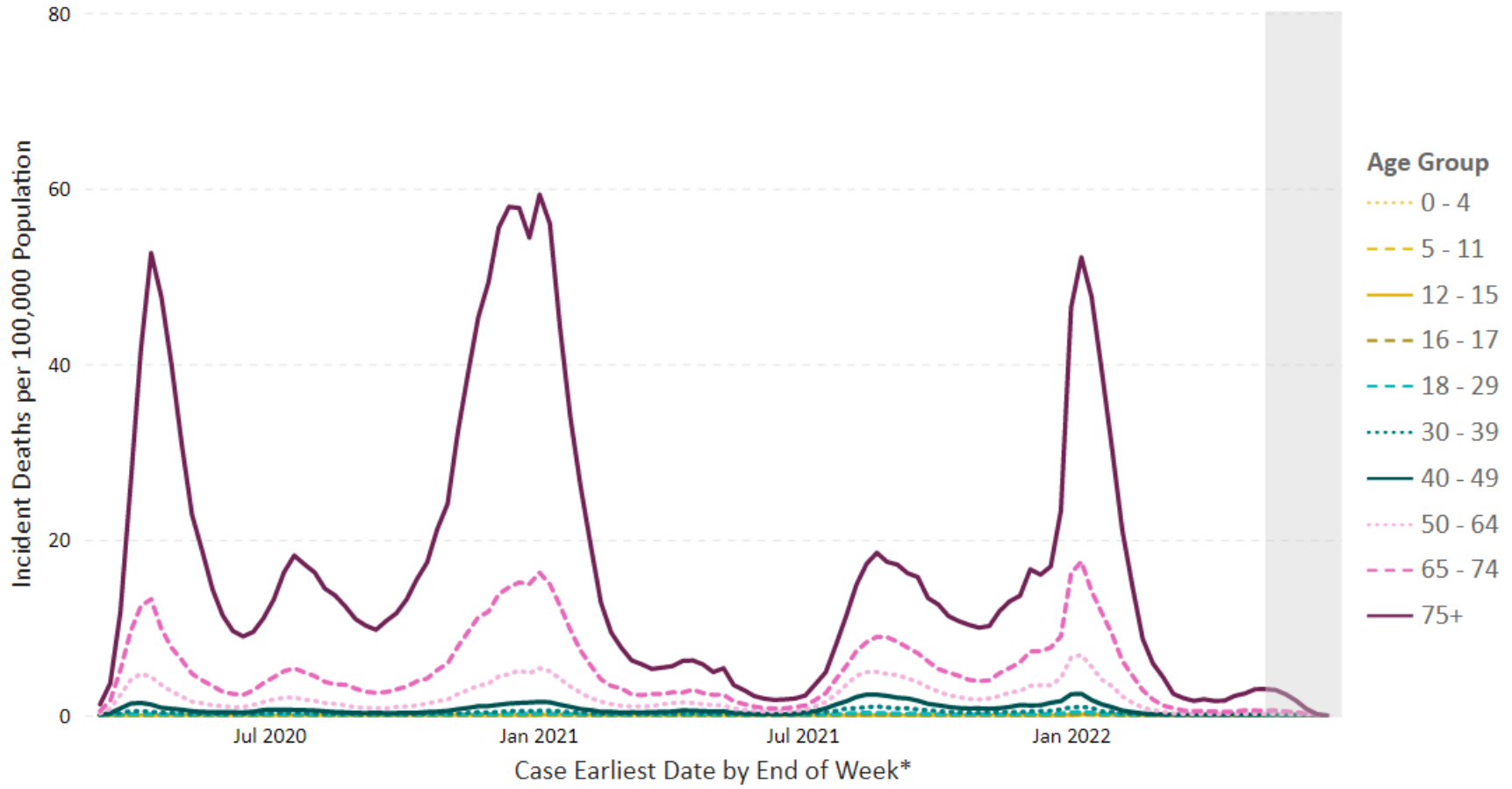
Unified Hospital Dataset: https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions. Accessed June 24, 2022

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



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths Accessed June 24, 2022

Weekly Trends in COVID-19 Mortality Rates by Age Group, United States, March 1, 2020 – June 25, 2022

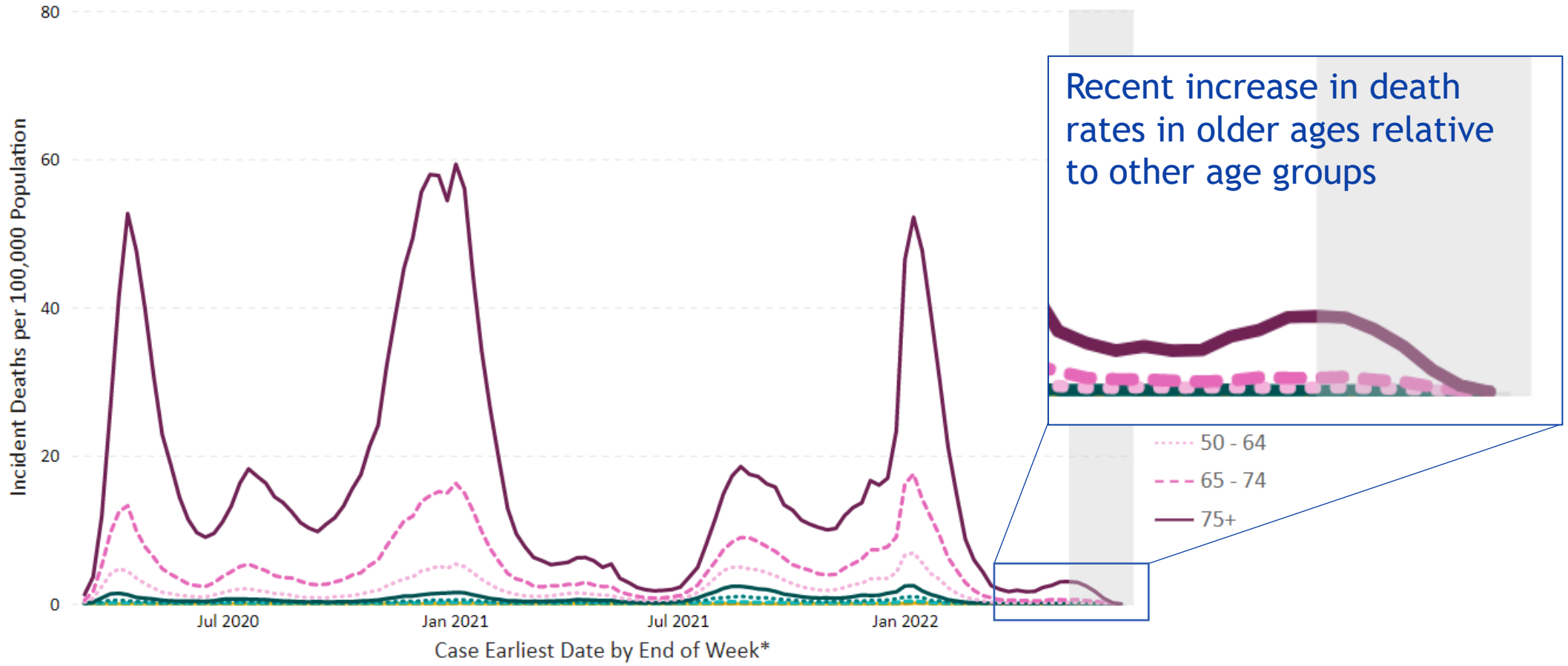


US: The most recent case record was reported during the week ending on Jun 25, 2022. Percentage of deaths among reported cases - 1.11%. Percentage of deaths reporting age by date - 99.91%.
US territories are included in case and death counts but not in population counts. Potential six-week delay in case 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

https://covid.cdc.gov/covid-data-tracker/#demographicsovertime Accessed June 24, 2022

Weekly Trends in COVID-19 Mortality Rates by Age Group, United States, March 1, 2020 – June 25, 2022



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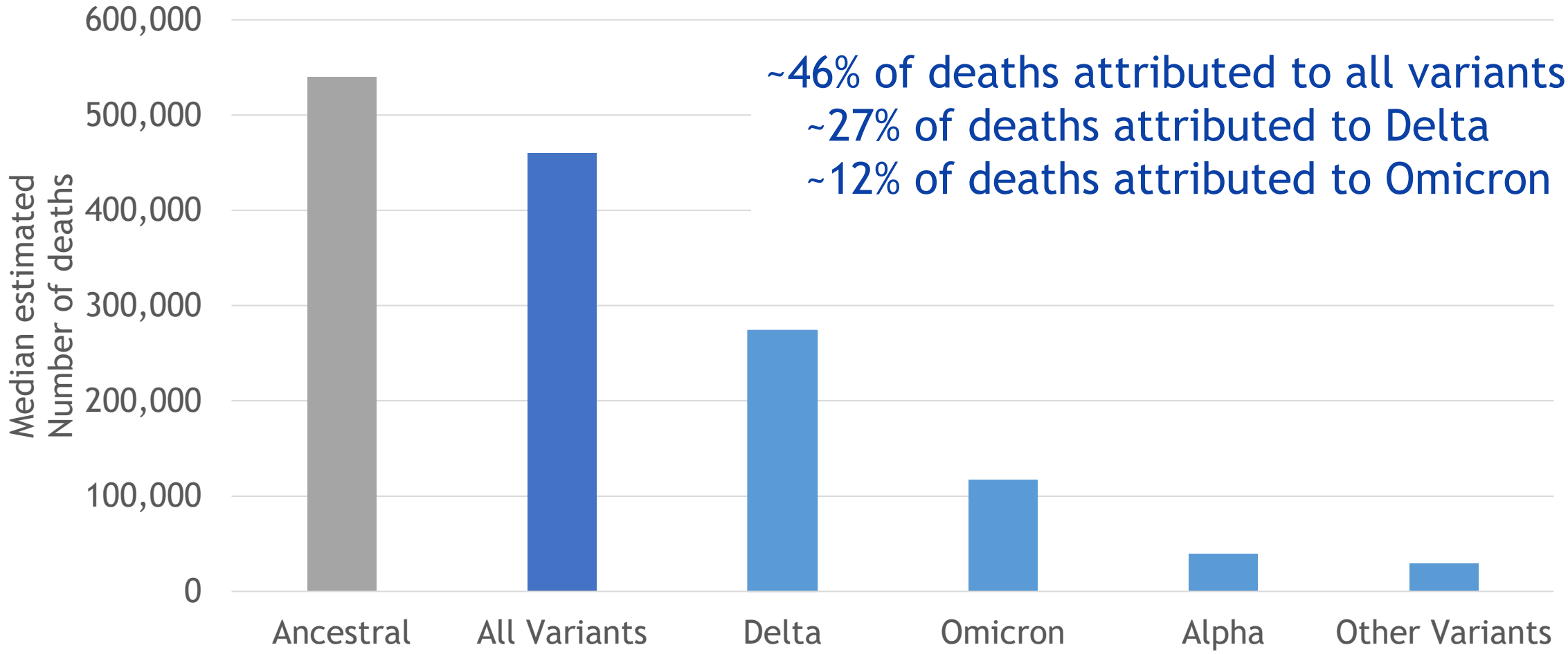
https://covid.cdc.gov/covid-data-tracker/#demographicsovertime Accessed June 24, 2022

Estimated Deaths Attributed to SARS-CoV-2 Variants

For the ~1M COVID-19 deaths recorded in the United States as of May 12, 2022



Walker et al. One Million and Counting: Estimates of Deaths in the United States from Ancestral SARS-CoV-2 and Variants MedRxiv: https://doi.org/10.1101/2022.05.31.22275835

COVID-19 Disease Complications

Multisystem Inflammatory Syndrome in Children (MIS-C)

- Since May 2020, reported 8,525 cases and 69 deaths of this rare but serious condition* in children associated with COVID-19

Post COVID-19 Conditions

- One in five COVID-19 survivors aged 18–64 years and one in four survivors aged ≥65 years experienced at least one new chronic condition that might be attributable to previous COVID-19
- Adult COVID-19 survivors have twice the risk for developing pulmonary embolism or respiratory conditions
- Less common in children than adults

*Characterized by fever, multisystem organ involvement, laboratory evidence of inflammation, and SARS-CoV-2 infection with no alternative plausible diagnosis occurring 2-6 weeks after acute SARS-CoV-2 infection. https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance

Bull-Otterson et al. http://dx.doi.org/10.15585/mmwr.mm7121e1

Trends in COVID-19 Vaccination and Disease by Vaccination Status

COVID-19 Vaccinations in the United States

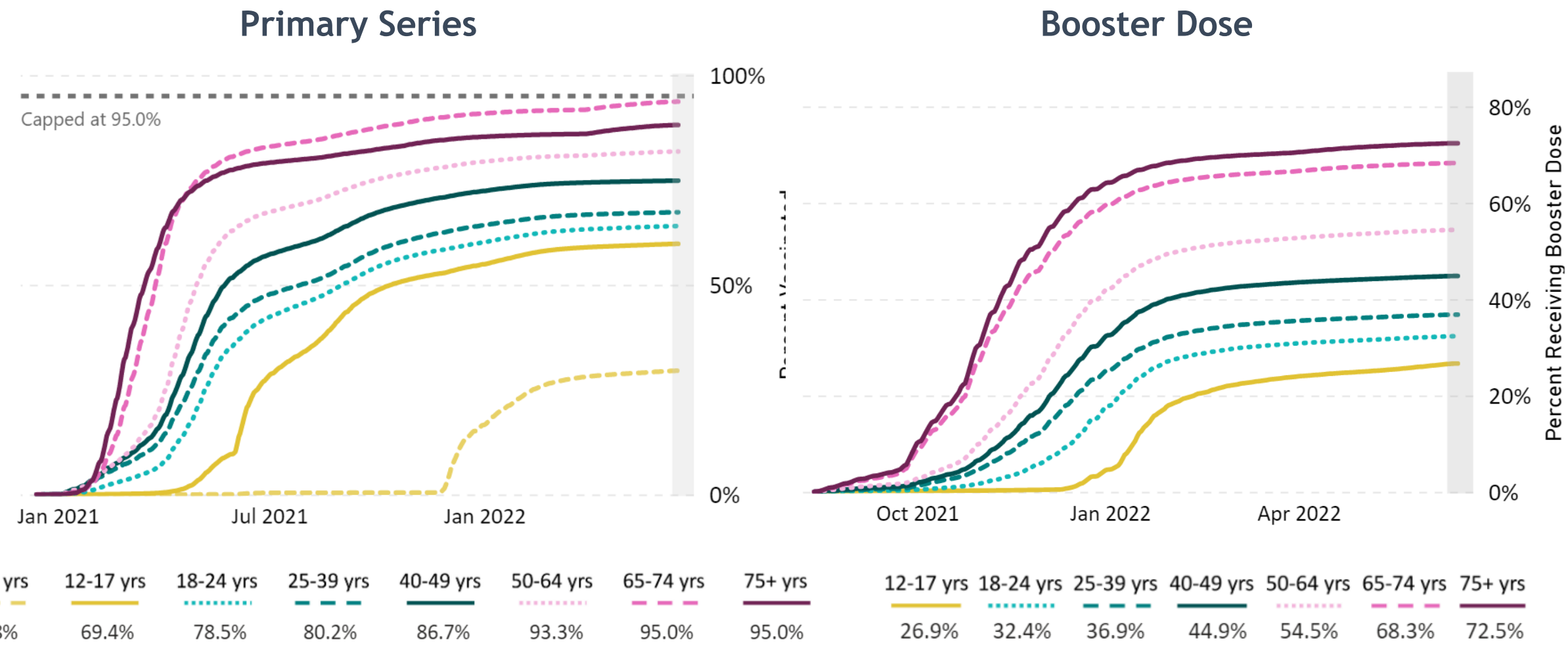
As of June 23, 2022

222.1M **People vaccinated with a primary series**	71% Population ≥5 Years of Age
105.1M **People received a first booster dose***	49% Population ≥12 Years of Age
17.4M **People received a second booster dose***	26% Population ≥50 Years of Age

***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 Accessed June 24, 2022

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



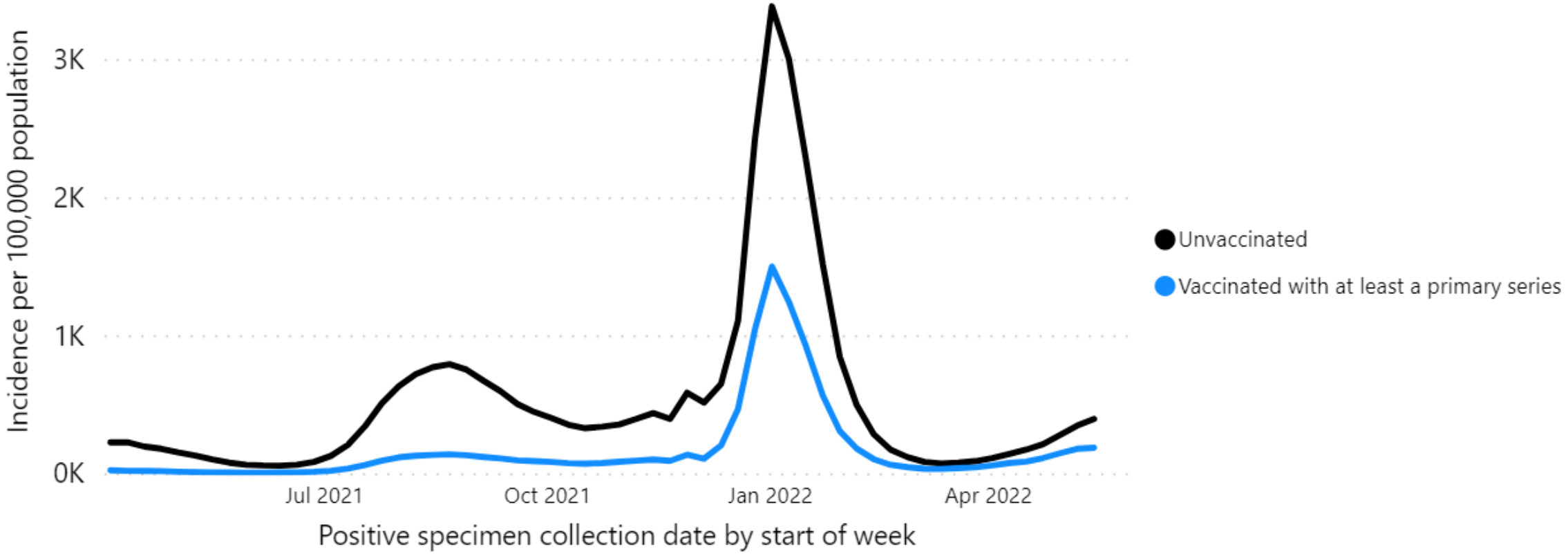
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Accessed June 24, 2022

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)
- Detailed data on serious illnesses in vaccinated persons available through COVID-NET, electronic health record, and vaccine effectiveness (VE) platforms
- 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

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

April 4, 2021 – May 21, 2022 (31 U.S. Jurisdictions)



Unvaccinated people aged 5 years and older had:

2.0X

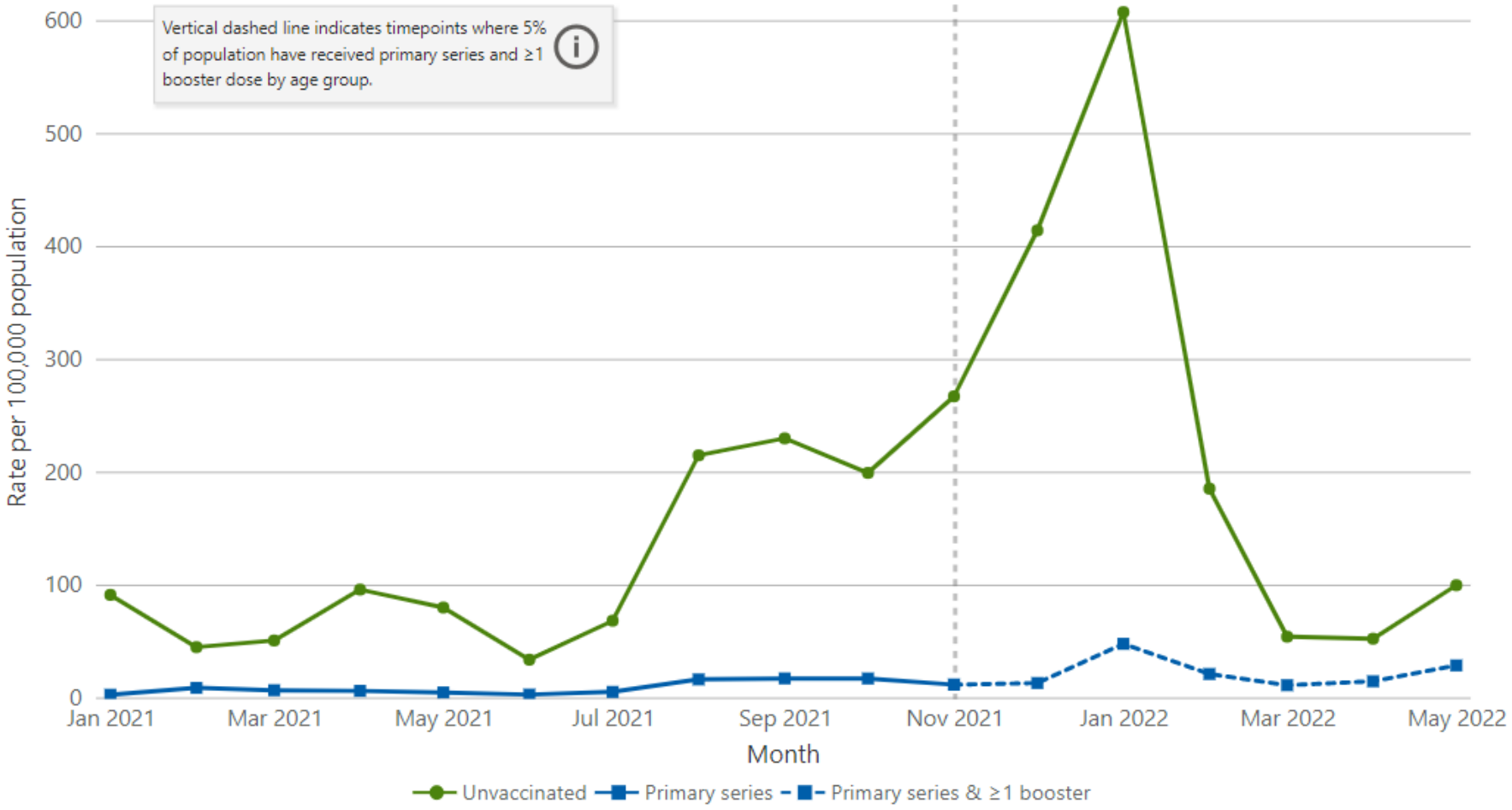
Risk of Testing Positive for COVID-19

in May 2022,* compared to people vaccinated with at least a primary series.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed June 18, 2022

Age-Adjusted Rates of COVID-19-Associated Hospitalization by Vaccination Status and Receipt of Booster Dose in Adults Ages ≥18 Years

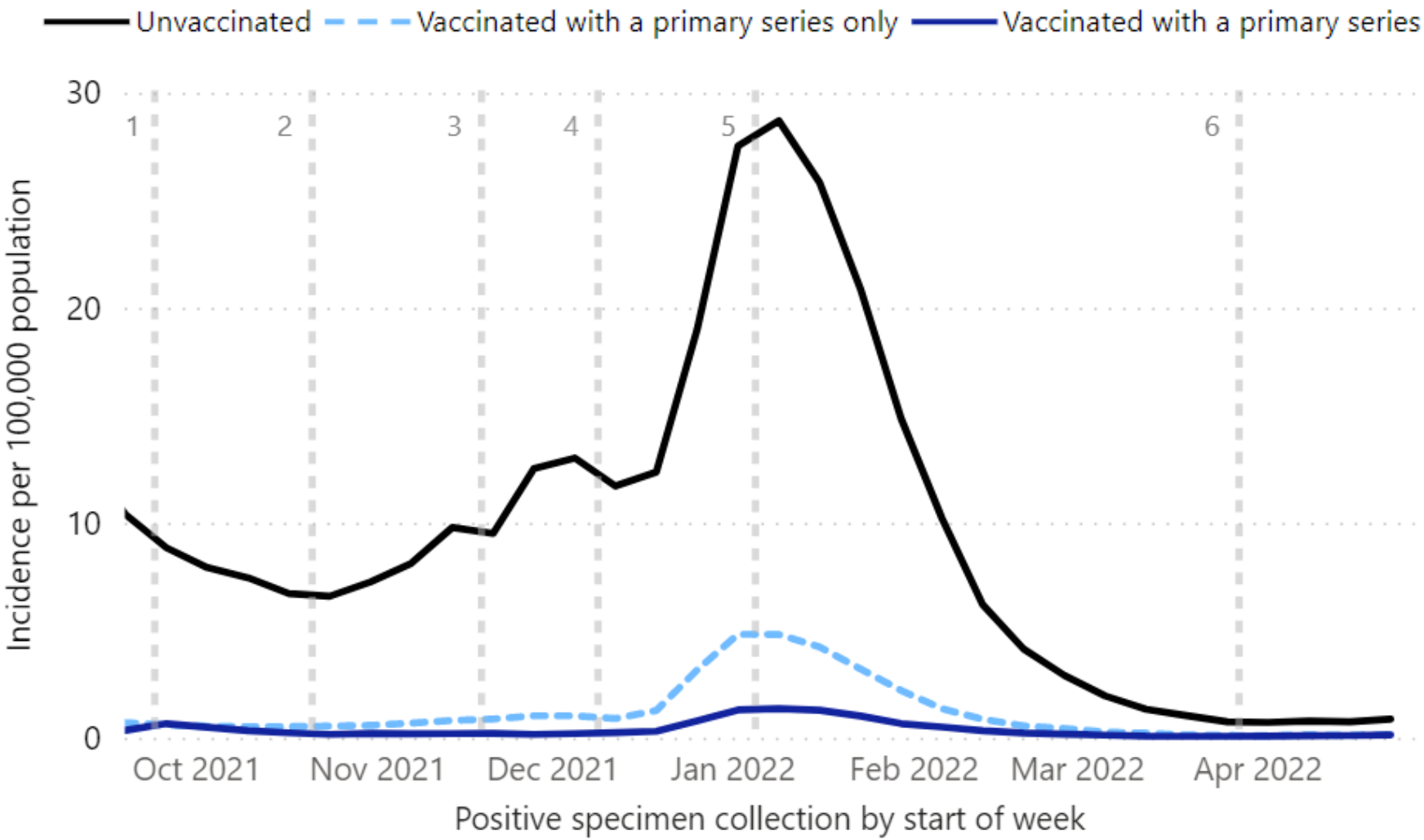
January 2021–May 2022



In May, unvaccinated adults ages ≥18 years had **3.5X higher** COVID-19-associated hospitalization rates compared to those vaccinated with a booster dose

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination Accessed June 27, 2022

Age-Adjusted Rates of COVID-19 Deaths by Vaccination Status and Receipt of Booster Dose,* September 19, 2021 – April 30, 2022 (30 U.S. Jurisdictions)



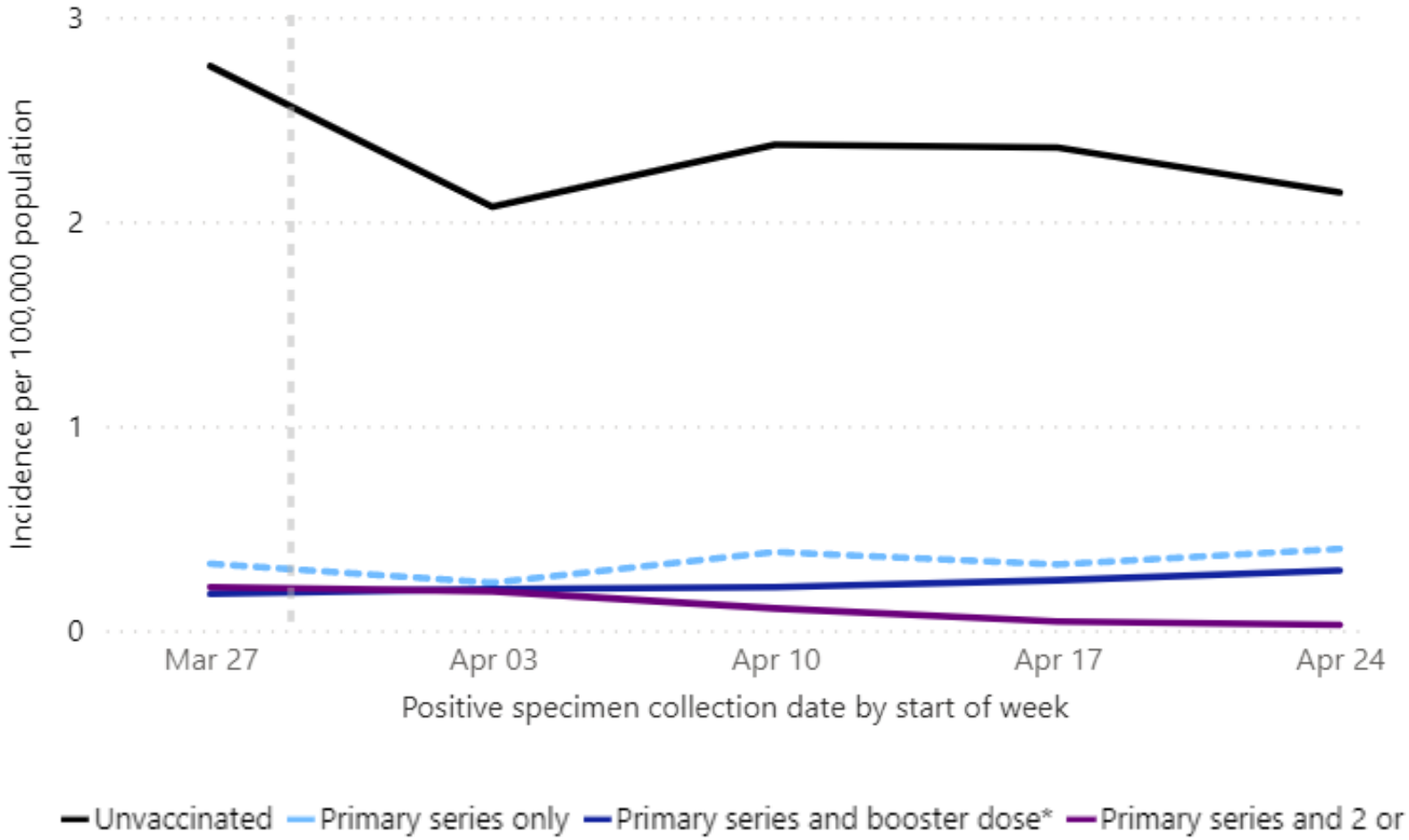
In April, unvaccinated people ages ≥12 years had **8X higher** COVID-19-associated death rates compared to those with a booster dose

This was a decrease from **17X** in March

*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 18, 2022

Death Rates by Vaccination Status and Receipt of 1st and 2nd Booster Doses Among People Ages 50+ Years, April 2022



Early analysis among people ages 50 years and older diagnosed with COVID-19 in April 2022:

- **Unvaccinated** people had **42 times** the risk of dying from COVID-19, compared those with **≥2 booster doses**
- People vaccinated with **one booster dose** had **4 times** the risk of dying from COVID-19, compared to those with **≥2 booster doses**

Dotted line denotes date when CDC recommended a 2nd booster dose in adults ages 50+ years and immunocompromised individuals.
*Includes either a booster or additional dose.
https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccinbooine-status. Accessed June 18, 2022

Risk of Severe COVID-19 Illness Among Vaccinated Persons

- Severe illness relatively rare in vaccinated persons compared with unvaccinated persons
- Most (75%) vaccinated persons with severe COVID-19 illness have multiple risk factors:
  - Older age
  - Underlying medical conditions
    - Immunosuppression
    - Diabetes mellitus
    - Chronic kidney disease
    - Chronic lung disease
    - Chronic cardiovascular disease
    - Chronic neurologic disease

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

Uptake of COVID-19 Antiviral Treatments During Omicron (BA.2/BA.2.12.1) Surge, New York City, April 23-May 8, 2022

- Among adults ≥18 years surveyed with recent SARS-CoV-2 infection, **29%** (95%CI 20%–39%) had risk factors* making them eligible to receive the antiviral Paxlovid (nirmatrelvir/ritonavir)
- Among those diagnosed with COVID-19 by a healthcare provider:
  - **55%** (95%CI 45%–67%) were not aware of Paxlovid
  - **15%** (95%CI 7%–23%) reported receiving it
  - **3%** (95%CI 0%–7%) reported being unable to access it
- Receipt was lower among people aged ≥65 years (2%), non-college graduates (3%), and unemployed (3%)

* Age ≥65 years or underlying medical conditions: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Qasmieh et al. MedRxiv. https://www.medrxiv.org/content/10.1101/2022.05.25.22275603v1.full.pdf

Summary

- CDC continues to monitor emerging variants, like the sub-lineages of Omicron, including prevalence and impact on disease incidence, severity, and vaccine effectiveness 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
- Need to educate prescribing clinicians and promote awareness and uptake of antiviral drugs among individuals at risk of severe COVID-19 illness

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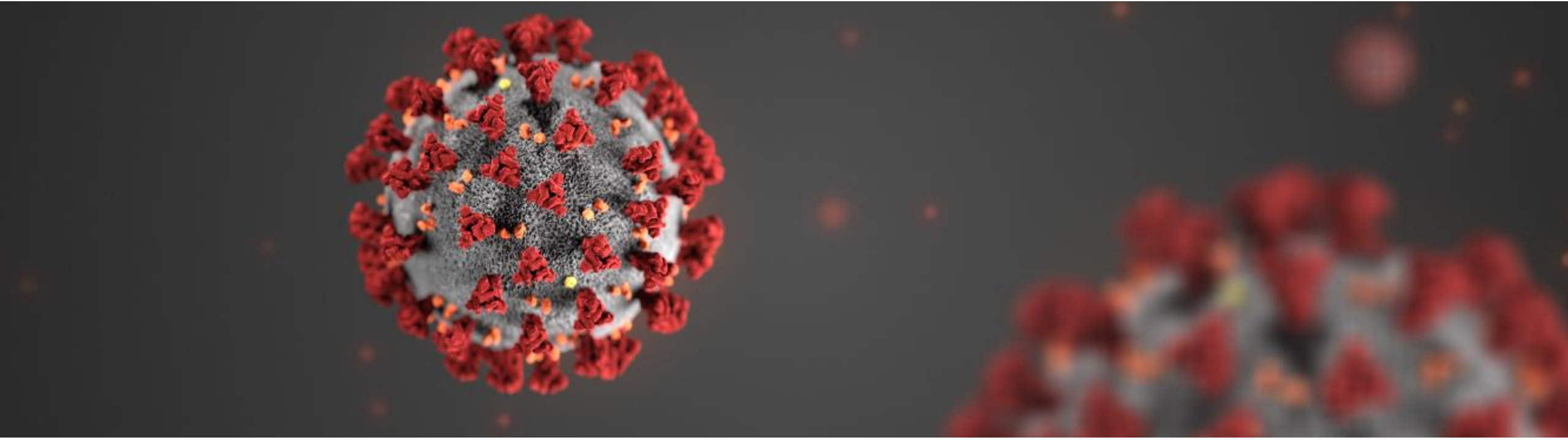
- Ruth Link-Gelles
- Sara Oliver
- Evelyn Twentyman
- Katherine Fleming-Dutra
- Aron Hall
- Rebecca Kondor
- Phillip Shirk
- Clint Paden
- Natalie Thornburg
- Bin Zhou
- Todd Davis
- Summer Galloway
- Dave Wentworth
- State and local health departments: AL, AR, AZ, CA, CO, CT, DC, FL, GA, ID, IN, IO, 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



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