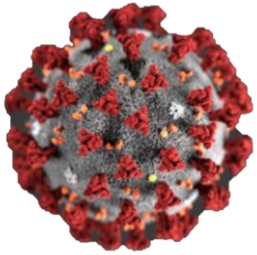
New Hampshire COVID-19 Healthcare Provider and Public Health Partner Call

March 24, 2022



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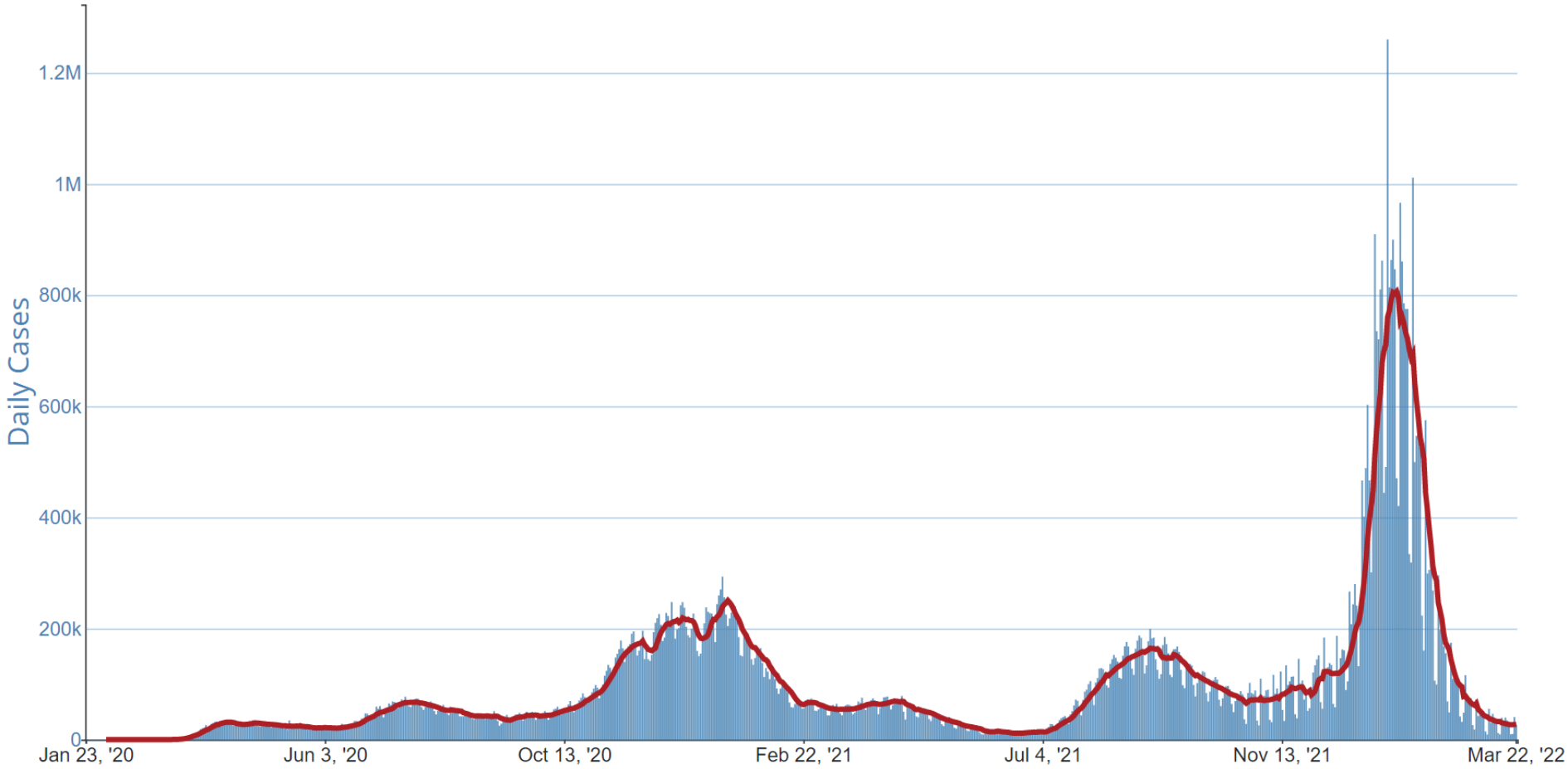
Agenda

- Epidemiology update
- Booster doses (will a 2nd booster dose be needed?)
- Vaccine protection against severe disease
- BA.2 variant (subvariant of “Omicron”)
- Q&A

Epidemiology Update

U.S. National Daily Incidence of COVID-19



https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

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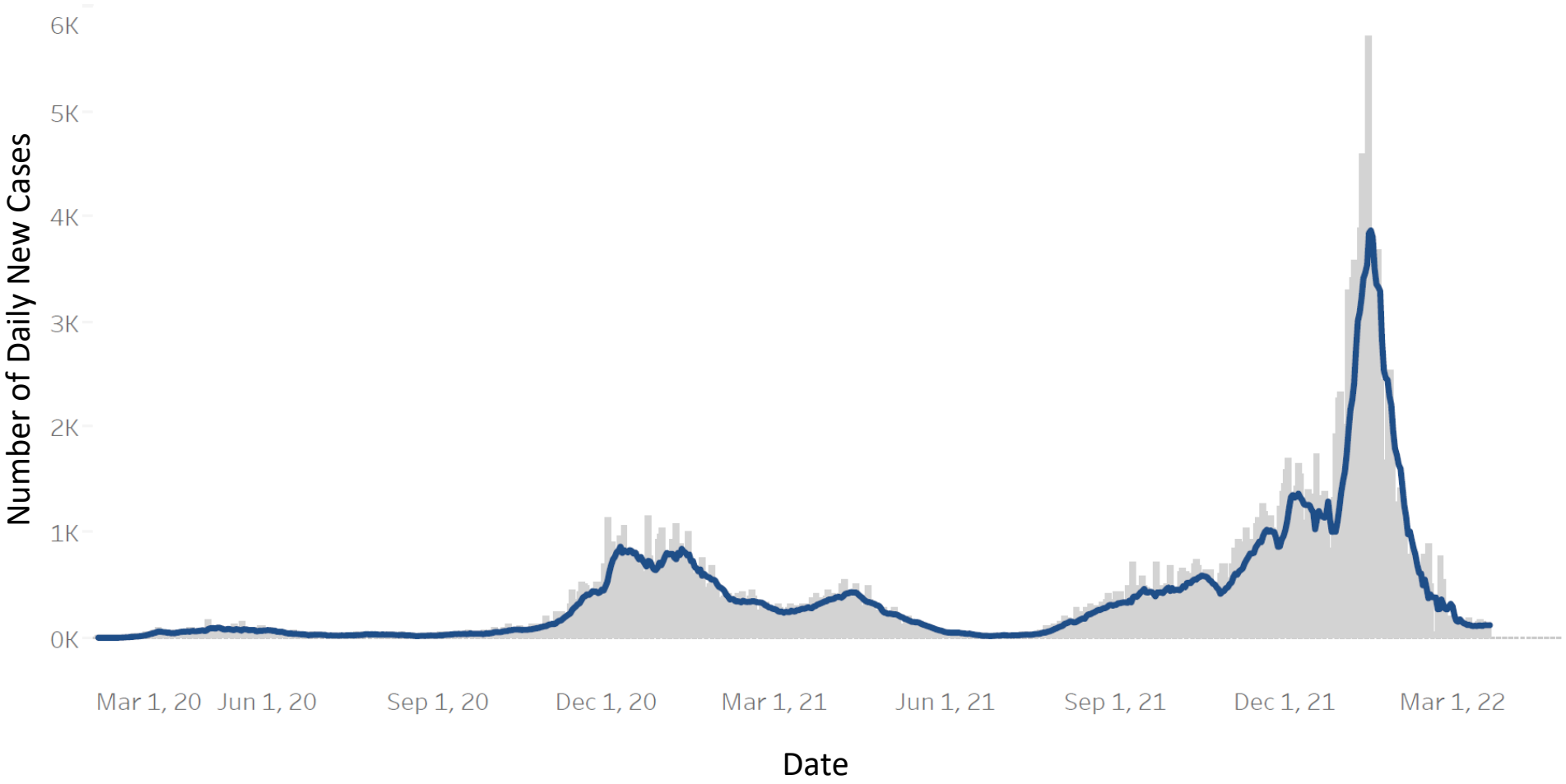
Number of New COVID-19 Cases per Day in NH



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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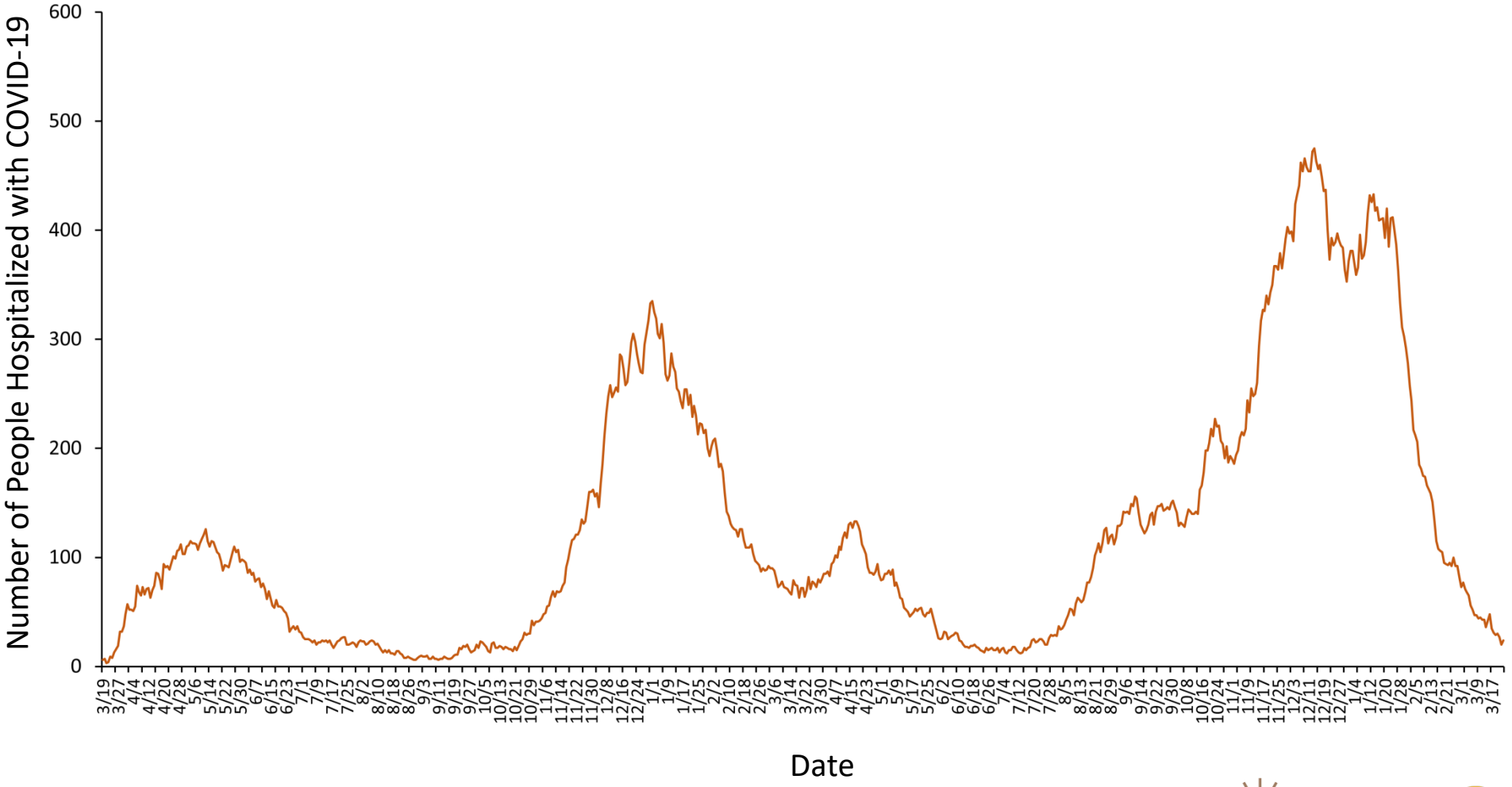
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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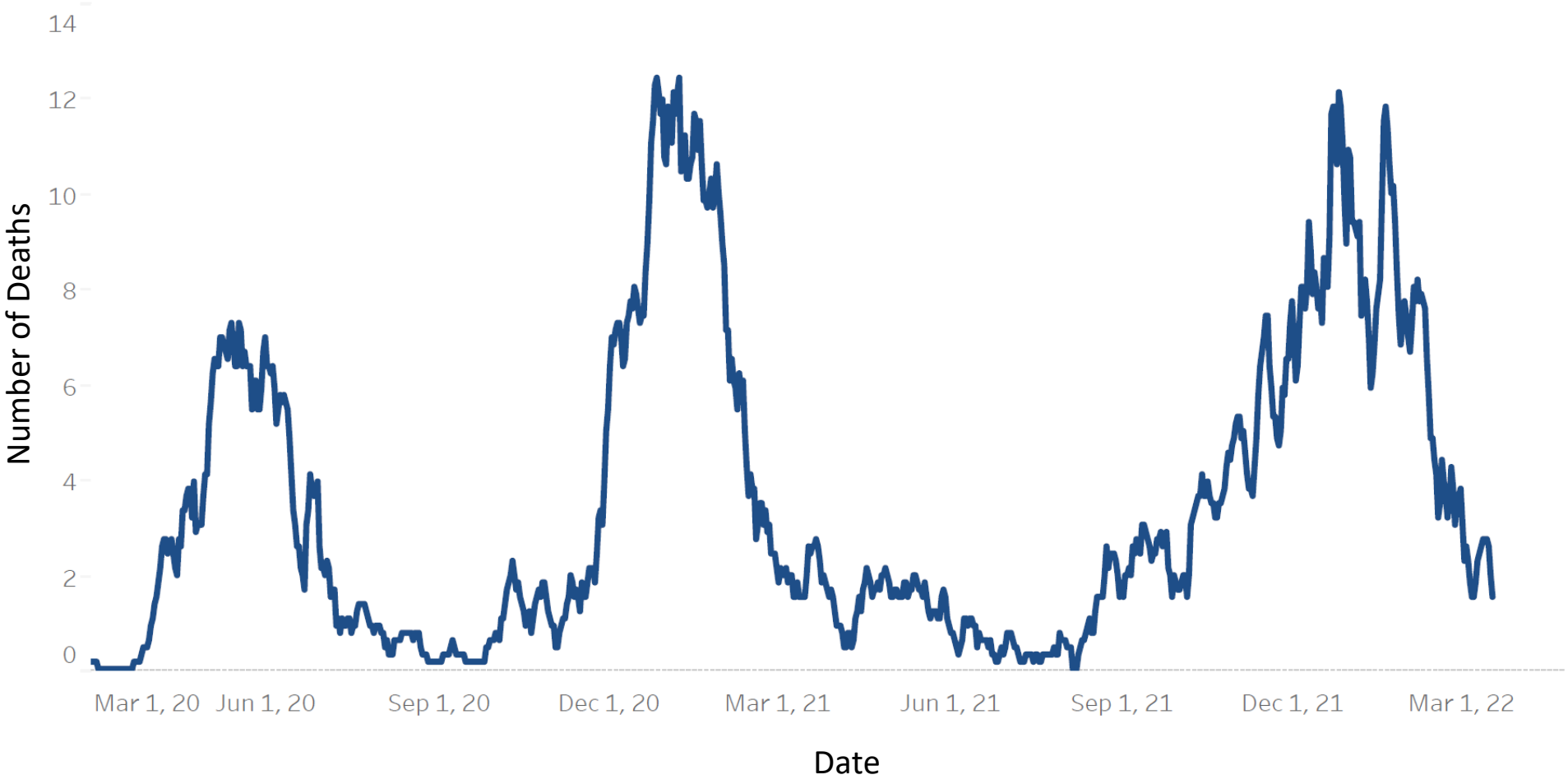
Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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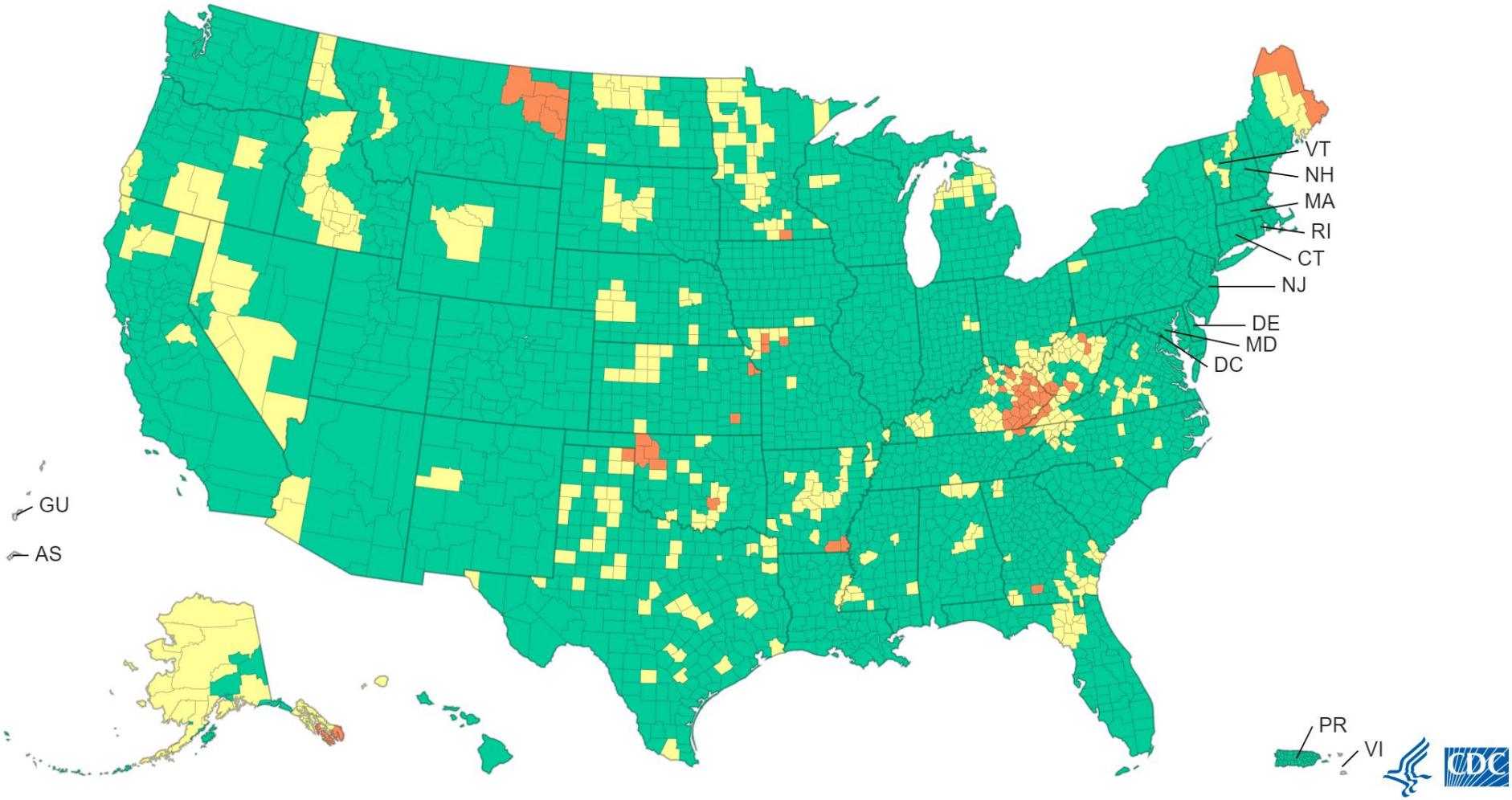
CDC's COVID-19 Community Levels



https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html

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Will a 2nd COVID-19 Vaccine Booster Be Needed?

Authorization of an Additional Booster Dose of their COVID-19 Vaccine for Older Adults

Tuesday, March 15, 2022 - 04:41pm

- See Pfizer media release
- Pfizer-BioNTech submitted an application to the FDA for EUA of an additional booster dose (2nd booster) for adults 65 years of age and older
- Based on data from Israel showing that “an additional mRNA booster increases immunogenicity and lowers rates of confirmed infections and severe illness.”

moderna

MODERNA SUBMITS AMENDMENT TO THE EMERGENCY USE AUTHORIZATION FOR AN ADDITIONAL BOOSTER DOSE OF ITS COVID-19 VACCINE IN THE U.S.

MARCH 17, 2022

- See Moderna media release
- Moderna submitted a request to the U.S. FDA to amend their COVID-19 vaccine EUA to allow for a 4th dose (2nd booster) in adults 18 years of age and older
- To provide flexibility for the CDC and healthcare providers to determine the appropriate use of additional Moderna booster doses for those at higher risk due to age or comorbidities

CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines

Additional considerations

People can self-attest to their moderately to severely immunocompromised status and receive COVID-19 vaccine doses wherever vaccines are offered. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.

On a case-by-case basis, providers of moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient. However, providers should not routinely administer additional doses of COVID-19 vaccine beyond those recommended in this guidance. Providers should consult treatment guidelines for use of monoclonal antibodies as pre-exposure prophylaxis for moderately or severely immunocompromised people who may not mount an immune response to COVID-19 vaccination.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

FDA VRBPAC to Meet April 6th

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA to Hold Advisory Committee Meeting on COVID-19 Vaccines to Discuss Future Boosters

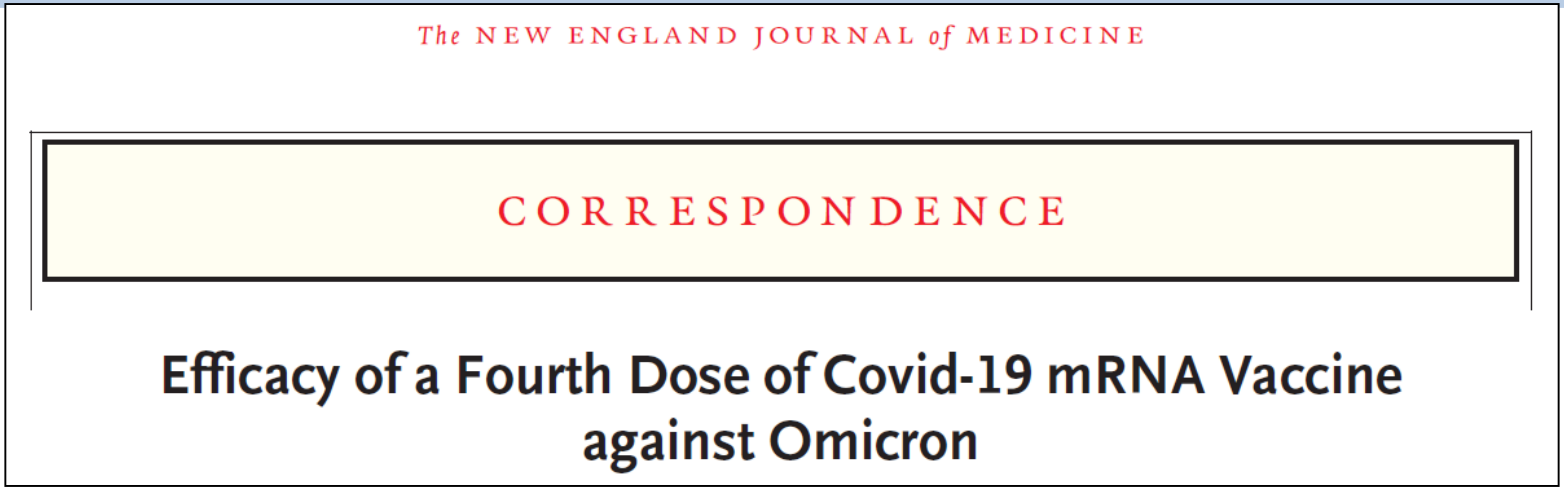
For Immediate Release: March 21, 2022

The April 6 VRBPAC meeting is intended to assist the agency in developing a general framework that will inform its regulatory decision-making on:

- What might warrant updating the composition of COVID-19 vaccines to address specific variants.
- Timing and populations for COVID-19 vaccine booster doses in the coming months.

No vote is planned at this meeting and there will not be any discussion of any product-specific applications.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-hold-advisory-committee-meeting-covid-19-vaccines-discuss-future



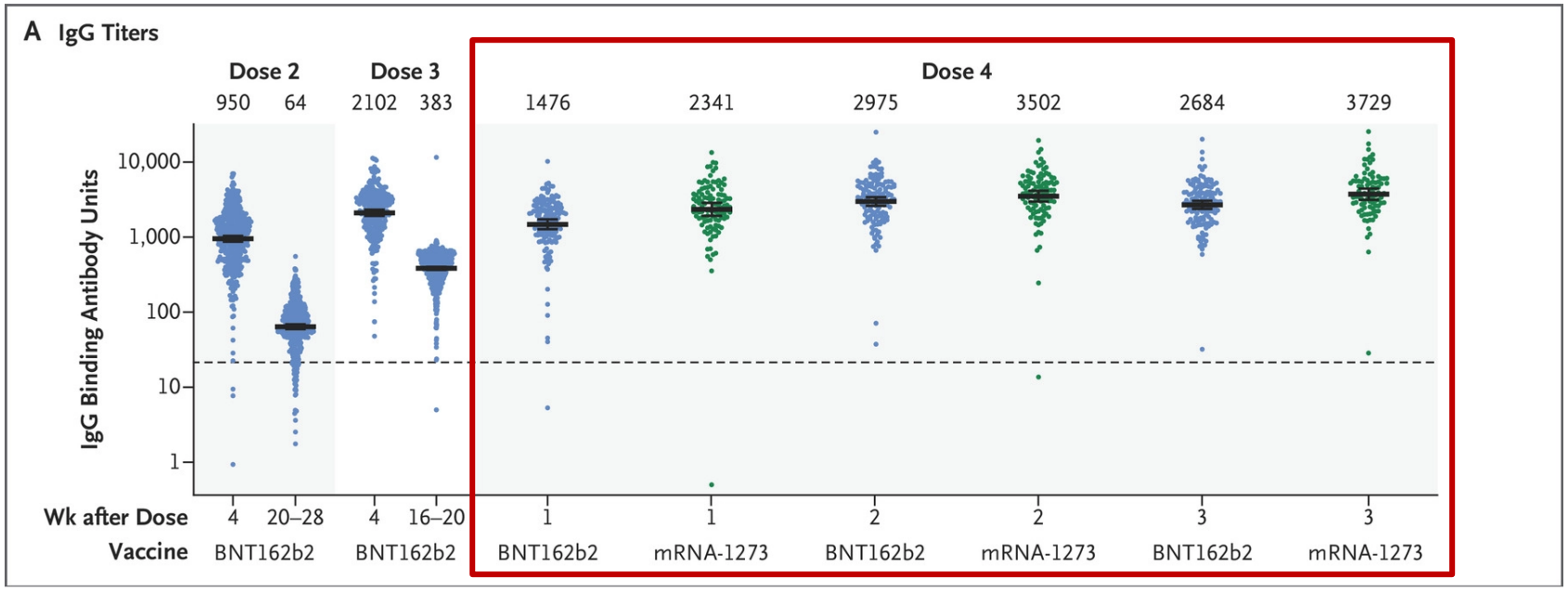
- Assessed immunogenicity and safety of a 4th dose (2nd booster) of either the Pfizer-BioNTech or Moderna COVID-19 vaccine
  - Administered 4 months after the 3rd dose (1st booster) in a 3-dose Pfizer-BioNTech series
  - Conducted during Omicron surge
- 1050 eligible HCWs from Sheba Medical Center in Israel
  - 154 received a 4th dose of the Pfizer-BioNTech vaccine
  - 120 received a 4th dose of the Moderna vaccine
  - Two age-matched controls for each participant were selected

https://www.nejm.org/doi/full/10.1056/NEJMc2202542

Study Results

- Results “suggest that maximal immunogenicity of mRNA vaccines is achieved after three doses and that antibody levels can be restored by a fourth dose”
- No new safety concerns identified, a 4th dose caused expected mild systemic and local symptoms
- Study was conducted in healthy young health care workers, NOT older and vulnerable populations
- Cohort was too small to allow accurate determination of vaccine efficacy

https://www.nejm.org/doi/full/10.1056/NEJMc2202542



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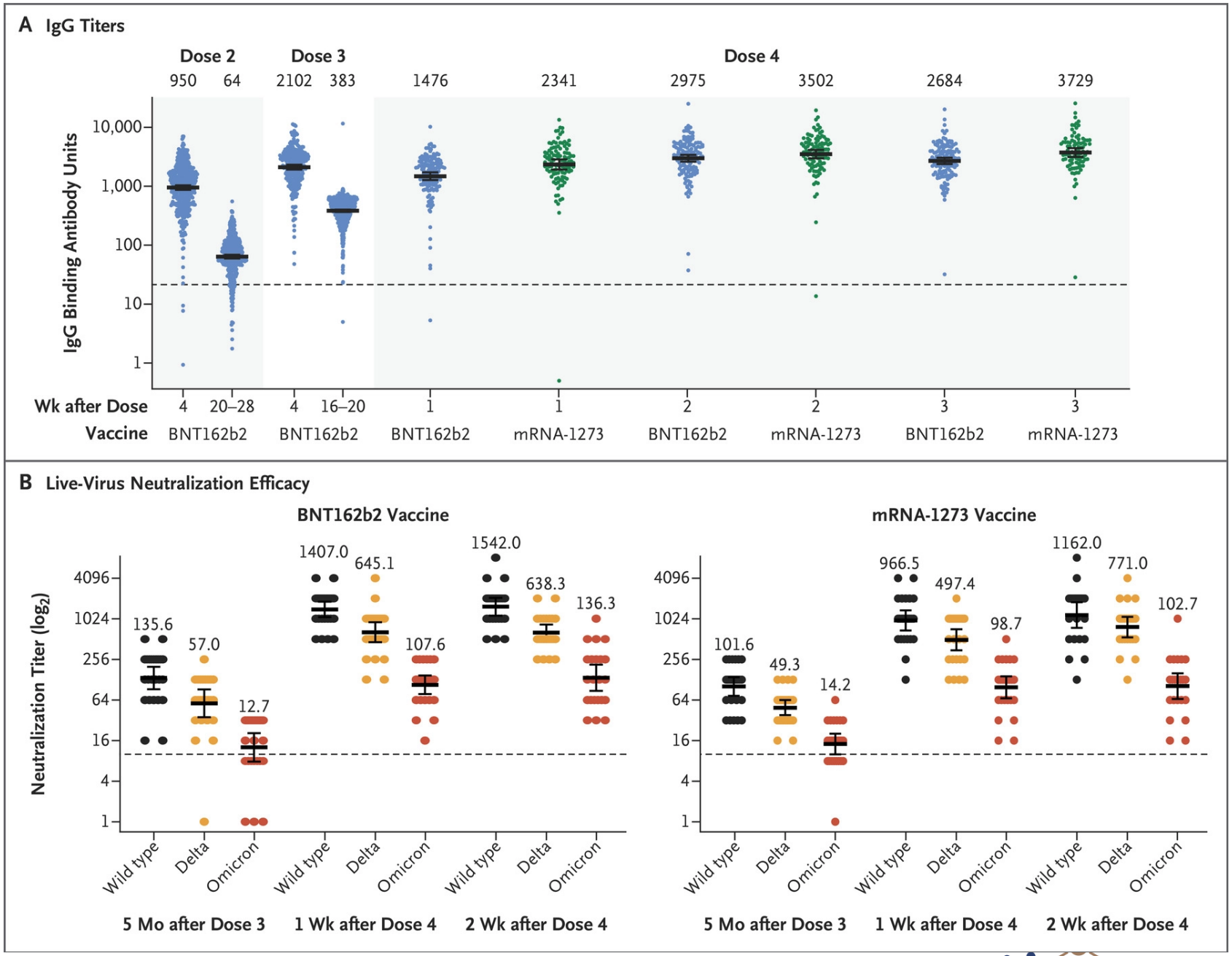


https://www.nejm.org/doi/full/10.1056/NEJMc2202542

Summary

- Currently only a single “booster dose” is recommended
- We know that vaccine protection against infection decreases over time (still strong protection against severe disease)
- Future variants may emerge that could be more likely to escape vaccine immunity
- It’s possible that a future booster dose may be needed (FDA VRBPAC is meeting to discuss), but the formulation of the vaccine and timing is uncertain
- The need for a booster will likely increase with increasing time from vaccination, and as we enter higher risk periods for increasing COVID-19

COVID-19 vaccination schedule*

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month	6 month	7 month
Pfizer-BioNTech (ages 5–11 years)	1st dose	2nd dose (3 weeks after 1st dose						
Pfizer-BioNTech (ages 12 years and older)	1st dose	2nd dose† (3-8 weeks after 1st dose)					Booster dose‡ (at least 5 months after 2nd dose)	
Moderna (ages 18 years and older)	1st dose	2nd dose† (4-8 weeks after 1st dose)					Booster dose‡ (at least 5 months after 2nd dose)	
Janssen (ages 18 years and older)	1st dose		Booster dose‡ (at least 2 months after 1st dose)					

COVID-19 vaccination schedule for people who are moderately or severely immunocompromised

Vaccine	0 month	1 month	2 month	3 month	4 month	5 month
Pfizer-BioNTech (ages 5–11 years)	1st dose	2nd dose (3 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)			
Pfizer-BioNTech (ages 12 years and older)	1st dose	2nd dose (3 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)			Booster dose* (at least 3 months after 3rd dose)
Moderna (ages 18 years and older)	1st dose	2nd dose (4 weeks after 1st dose)	3rd dose (at least 4 weeks after 2nd dose)			Booster dose* (at least 3 months after 3rd dose)
Janssen (ages 18 years and older)	1st dose	2nd (additional) dose† using an mRNA COVID-19 vaccine (at least 4 weeks after 1st dose)		Booster dose* (at least 2 months after additional dose)		

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#recommendations

Primary Series Vaccination + Single Booster Dose is Protective Against Severe Disease

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 71
March 18, 2022

Effectiveness of mRNA Vaccination in Preventing COVID-19–Associated Invasive Mechanical Ventilation and Death — United States, March 2021–January 2022

- Case-control study involving 21 medical centers in 18 states
- Studied vaccine effectiveness at preventing COVID-19 associated invasive mechanical ventilation (IMV) or death within 28 days of hospitalization
- Case patients: hospitalized adults with COVID-19 like illness who tested positive for SARS-CoV-2, AND who had the outcome of IMV or death
- Control patients: hospitalized adults with/without COVID-19 like illness who tested negative for SARS-CoV-2

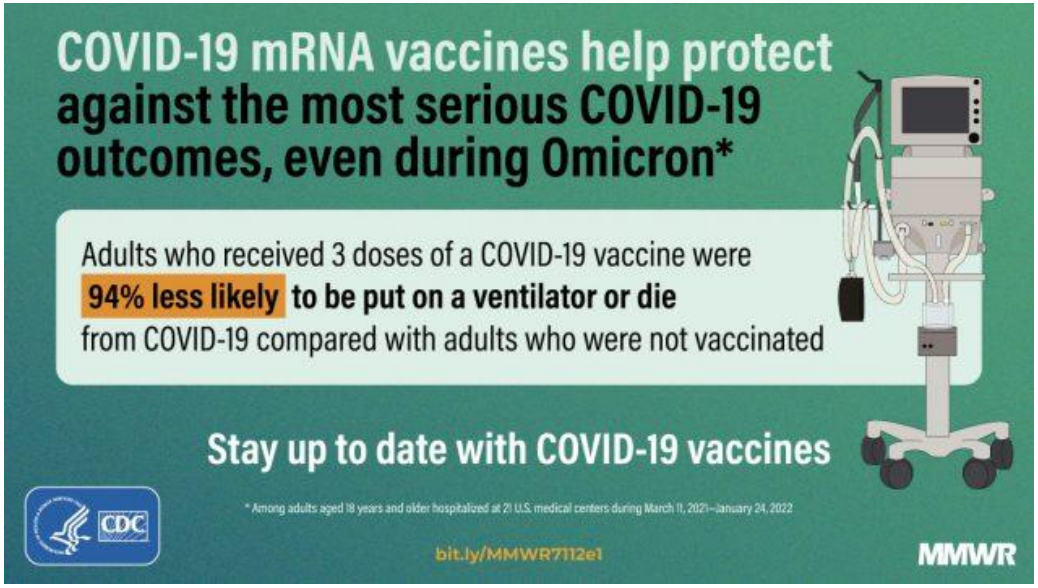
https://www.cdc.gov/mmwr/volumes/71/wr/mm7112e1.htm?s_cid=mm7112e1_x

Study Results: Vaccine Effectiveness

TABLE 2. Effectiveness of COVID-19 mRNA vaccines against COVID-19–associated invasive mechanical ventilation or in-hospital death — 21 hospitals, 18 states,*,† March 2021–January 2022

Group/Characteristic	No. of vaccinated case-patients with IMV or death/ total no. of case-patients (%)	No. of vaccinated control-patients/ total no. of control-patients (%)	Vaccine effectiveness, % (95% CI)
Pre-Delta, 2 doses	13/259 (5.0)	893/1,738 (51.4)	95 (90–97)
Delta, 2 or 3 doses	235/1,027 (22.9)	2,741/3,865 (70.9)	89 (87–91)
2 doses, median = 159 days after dose 2	218/1,010 (21.6)	2,402/3,526 (68.1)	88 (86–90)
3 doses, median = 35 days after dose 3	17/809 (2.1)	339/1,463 (23.2)	95 (91–97)
Omicron, 2 or 3 doses	59/154 (38.3)	386/501 (77.0)	86 (79–91)
2 doses, median = 256 days after dose 2	46/141 (32.6)	193/308 (62.7)	79 (66–87)
3 doses, median = 60 days after dose 3	13/108 (12.0)	193/308 (62.7)	94 (88–97)

Abbreviations: IMV = invasive mechanical ventilation; VE = vaccine effectiveness.



https://www.cdc.gov/mmwr/volumes/71/wr/mm7112e1.htm?s_cid=mm7112e1_x

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 71
March 18, 2022

COVID-19–Associated Hospitalizations Among Adults During SARS-CoV-2 Delta and Omicron Variant Predominance, by Race/Ethnicity and Vaccination Status — COVID-NET, 14 States, July 2021–January 2022

- COVID-NET data was analyzed to compare COVID-19 associated hospitalization rates in adults during Delta and Omicron surges
  - COVID-NET covers 99 counties across 14 states
  - Catchment area includes about 10% of U.S. population

https://www.cdc.gov/mmwr/volumes/71/wr/mm7112e2.htm

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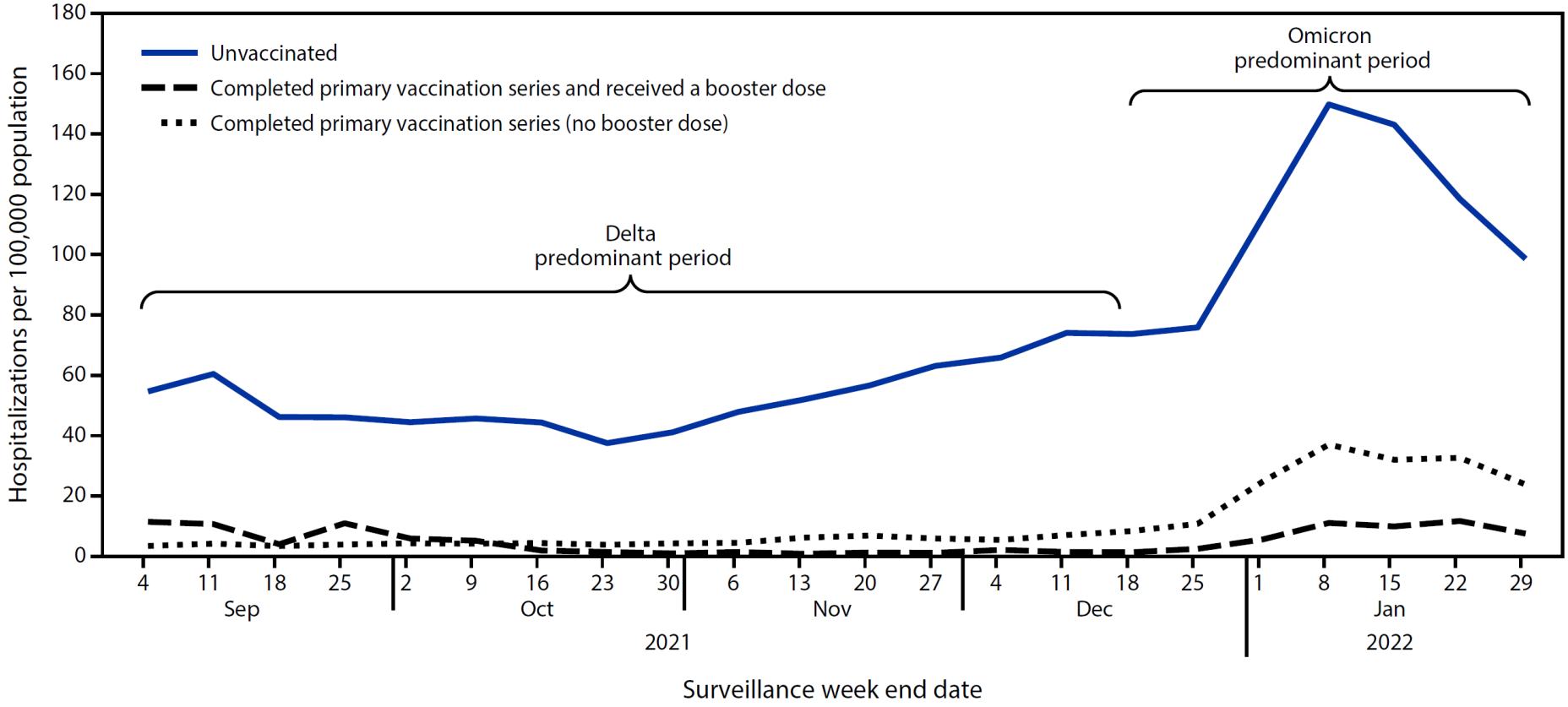
FIGURE 2. Weekly age-adjusted rates of COVID-19–associated hospitalizations among adults aged ≥18 years, by vaccination status* — COVID-19–Associated Hospitalization Surveillance Network, 13 states,† September 4, 2021–January 29, 2022§



January 2022 rate of COVID-19 associated hospitalizations:

- Unvaccinated *vs.* primary series + booster: 12x higher
- Unvaccinated *vs.* primary series only (no booster): 4x higher

https://www.cdc.gov/mmwr/volumes/71/wr/mm7112e2.htm

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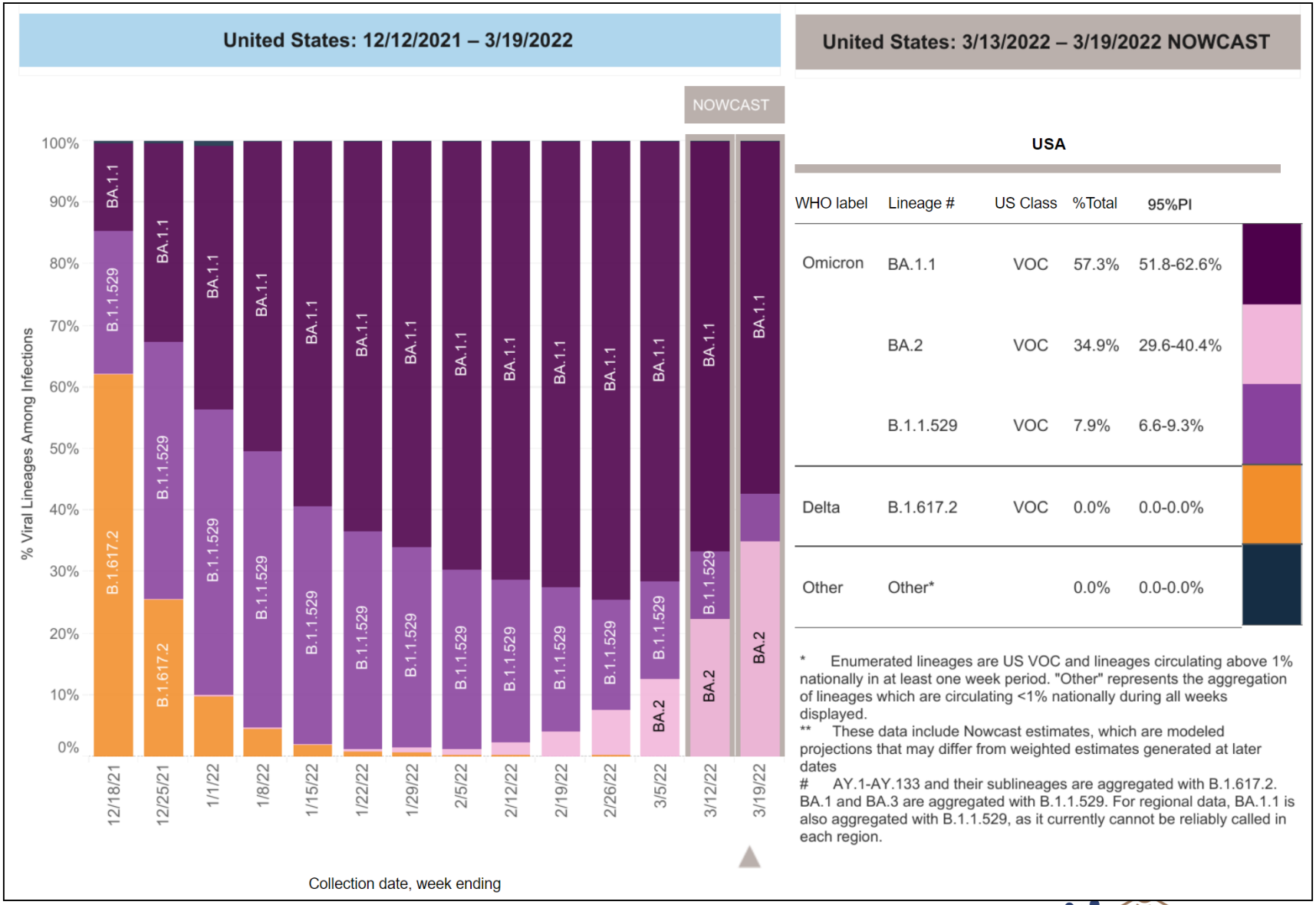
Summary

- CDC routinely publishes and updates data about infection, hospitalization, and death by vaccination status on their website:
  - Infection and death rates: https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status
  - Hospitalization rates: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

- A COVID-19 vaccine primary series + booster remains highly protective against severe disease, including hospitalization and death from COVID-19

Is the BA.2 Subvariant of Omicron More Likely to Evade Immunity?

CDC's Genomic Surveillance Data (U.S.)



United States: 3/13/2022 – 3/19/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.1.1	VOC	57.3%	51.8-62.6%
	BA.2	VOC	34.9%	29.6-40.4%
	B.1.1.529	VOC	7.9%	6.6-9.3%
Delta	B.1.617.2	VOC	0.0%	0.0-0.0%
Other	Other*		0.0%	0.0-0.0%

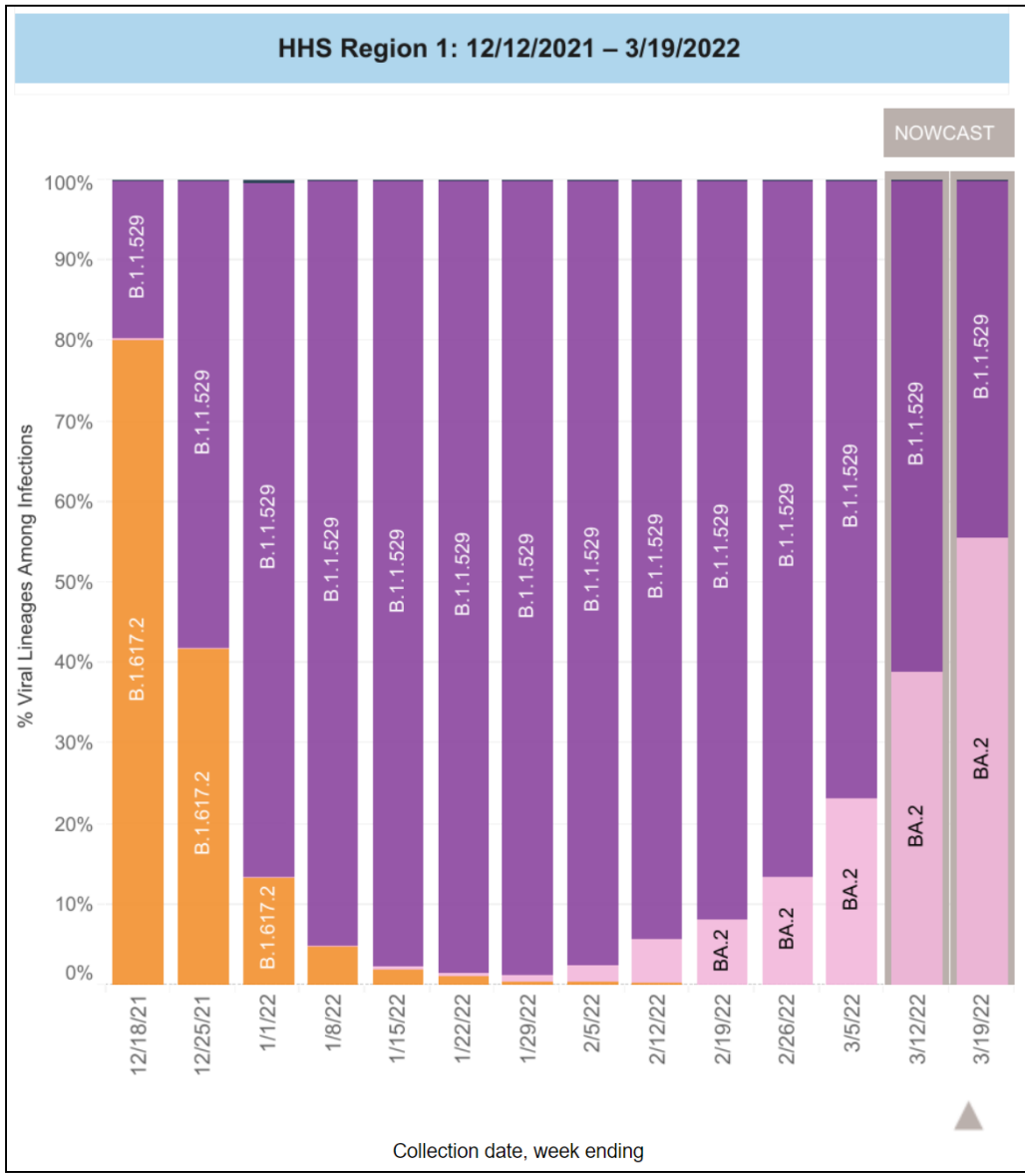
* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.

** 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.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

CDC's Genomic Surveillance Data (Region 1)



HHS Region 1: 3/13/2022 – 3/19/2022 NOWCAST

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2	VOC	55.4%	41.7-68.3%
	B.1.1.529	VOC	44.6%	31.7-58.3%
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.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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CDC's State-Level Genomic Surveillance Data

(Estimated variant proportions by state for the 4 weeks ending 2/26/2022)

State/Jurisdiction	Total Sequences	B.1.1.529 (Omicron)	BA.2 (Omicron)	B.1.617.2 (Delta)	Other
Connecticut	2,132	97.63% (95.1-99.1%)	2.32%† (0.9-4.8%)	0.05%† (0.0-0.4%)	0.00%† (NA)
Maine	977	97.98% (96.9-98.8%)	1.58% (0.8-2.7%)	0.44%† (0.1-1.1%)	0.00%† (NA)
Massachusetts	11,065	93.27% (92.5-93.9%)	6.58% (5.8-7.4%)	0.14%† (0.1-0.3%)	0.00%† (NA)
New Hampshire	752	97.17% (95.7-98.2%)	2.67% (1.6-4.1%)	0.16%† (0.0-0.8%)	0.00%† (NA)
Rhode Island	1,416	75.72%† (48.4-93.1%)	24.19%† (6.8-51.7%)	0.09%† (0.0-0.7%)	0.00%† (NA)
Vermont	2,801	95.61% (91.8-96.3%)	4.13% (3.1-7.9%)	0.26%† (0.1-0.5%)	0.00%† (NA)

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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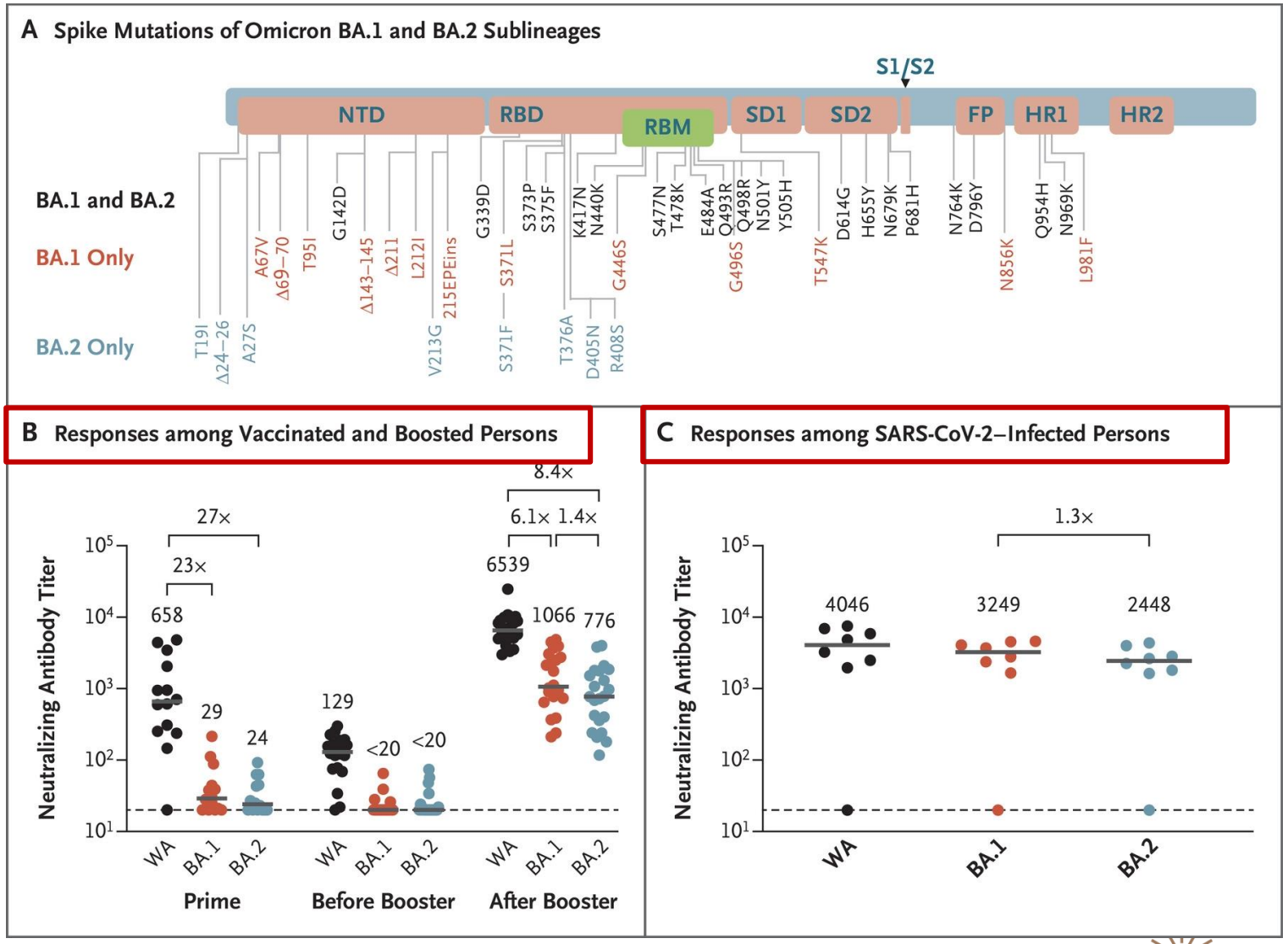
The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Neutralization of the SARS-CoV-2 Omicron BA.1 and BA.2 Variants

- Compared neutralizing antibody responses against:
  - Original/parent stain (WA1/2020)
  - Omicron BA.1 (dominant “Omicron” variant)
  - Omicron BA.2 (account for an increasing proportion of infections due to selective advantage)
- Compared neutralizing antibody responses in:
  - 24 persons without prior infection who were vaccinated and boosted:
  - 8 persons with a history of SARS-CoV-2 infection (during Omicron surge), irrespective of vaccination status (only 1 person was unvaccinated)

https://www.nejm.org/doi/full/10.1056/NEJMc2201849



https://www.nejm.org/doi/full/10.1056/NEJMc2201849

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Summary

- The BA.2 variant (subvariant of “Omicron”) is expected to increase in proportion because of increased infectiousness
- However, even as BA.2 infections have increased in the U.S., the COVID-19 Community Levels have continued to decrease
- There is no evidence that BA.2 causes more severe disease
- BA.2 does NOT appear to be more likely to evade COVID-19 vaccine- or infection-induced immunity compared to the original Omicron variant (which caused the winter surge)
- Staying Up To Date With COVID-19 Vaccines remains the most important way to protect oneself and family from COVID-19, including the BA.2 variant

Q&A