COVID-19 Series for Free & Charitable Clinics

August 26, 2021

ECHO CHICAGO

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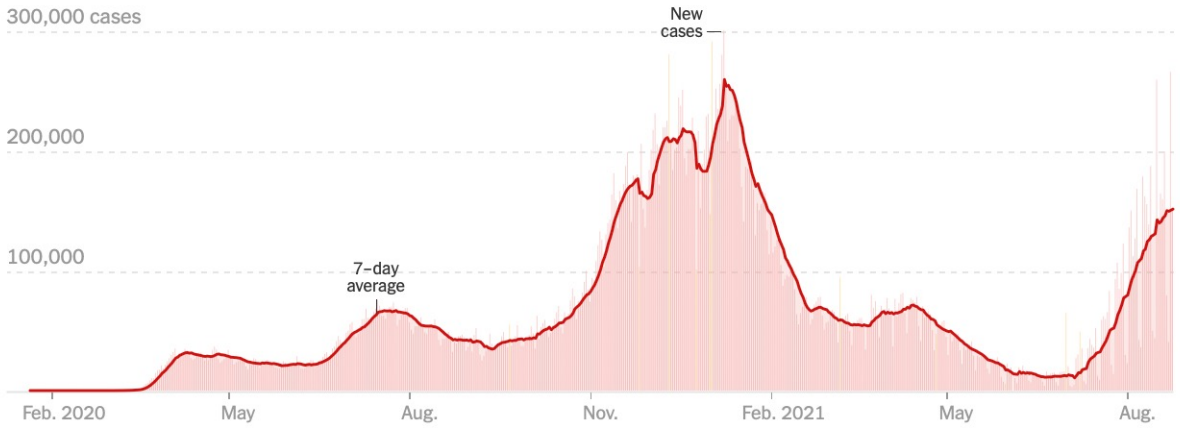
AT THE FOREFRONT UChicago Medicine

Disclosures

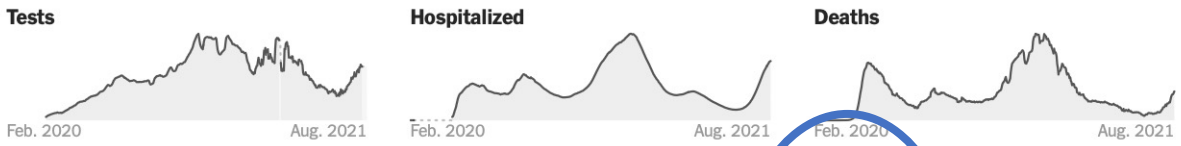
- We have no relevant financial interests to disclose.

Coronavirus in the U.S.: Latest Map and Case Count

New reported cases

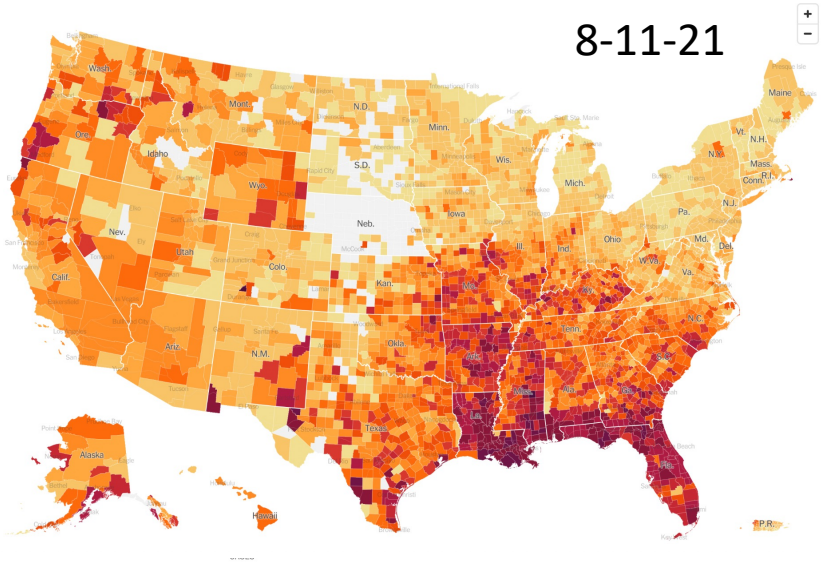


These are days with a reporting anomaly. Read more here.

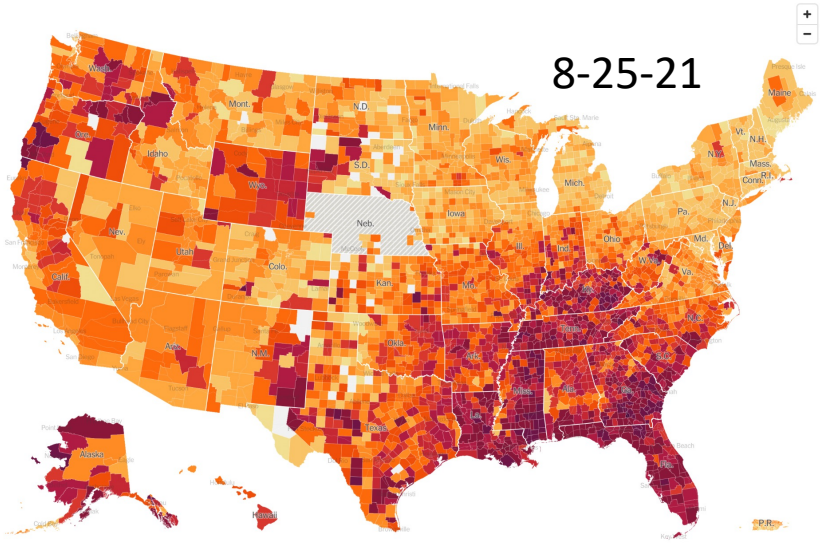


	DAILY AVG. ON AUG. 24	14-DAY CHANGE	TOTAL REPORTED
Cases	151,441	+28%	38,193,758
Tests	1,152,222	+23%	—
Hospitalized	94,082	+35%	—
Deaths	1,116	+84%	631,050

8-11-21



8-25-21



https://www.nytimes.com/interactive/2021/us/covid-cases.html?action=click&module=Top%20Stories&pgtype=Homepage

United States: 5/16/2021 – 8/21/2021

United States: 8/15/2021 – 8/21/2021 NOWC

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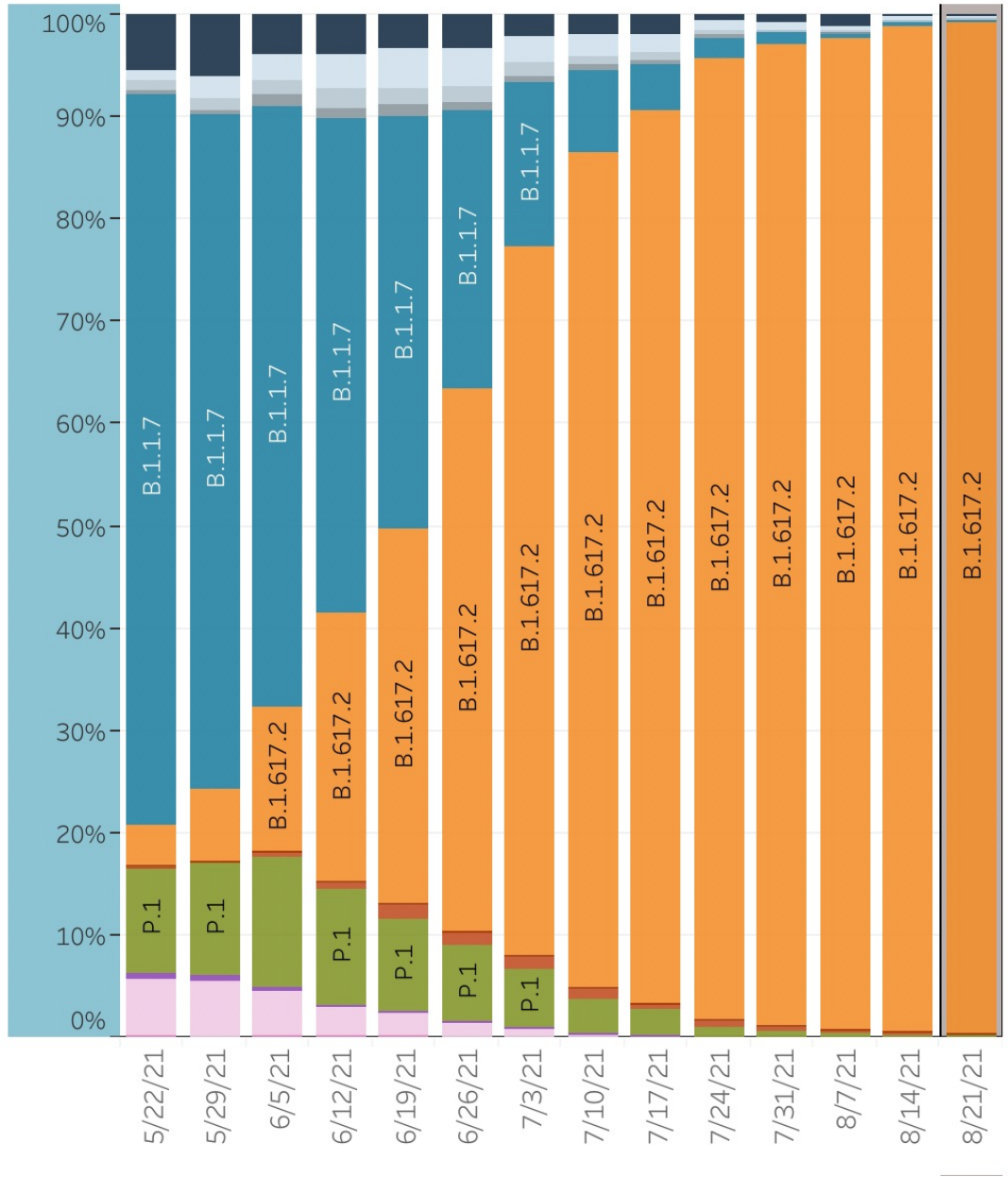


USA

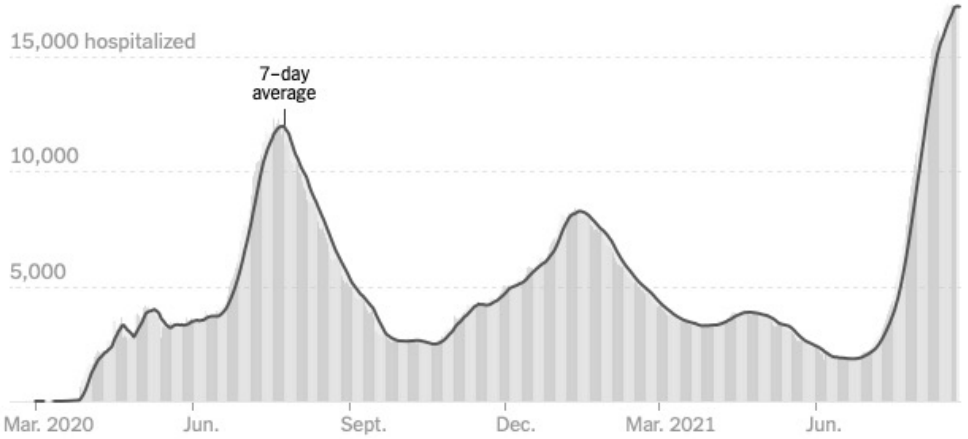
WHO label	Lineage #	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.2%	0.0-0.7%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.1%	0.0-0.5%
Delta	B.1.617.2	VOC	98.8%	97.6-99.8
	AY.2	VOC	0.2%	0.0-0.7%
	AY.1	VOC	0.1%	0.0-0.5%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
N/A	B.1.621		0.3%	0.0-0.7%
	B.1.621.1		0.1%	0.0-0.5%
	B.1.628		0.1%	0.0-0.5%
Other	Other*		0.1%	0.0-0.5%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Sublineages of P.1 and B.1.351 are aggregated with the parent lineage and included in parent lineage's proportion. AY.3-AY.12 are aggregated with B.1.617.2

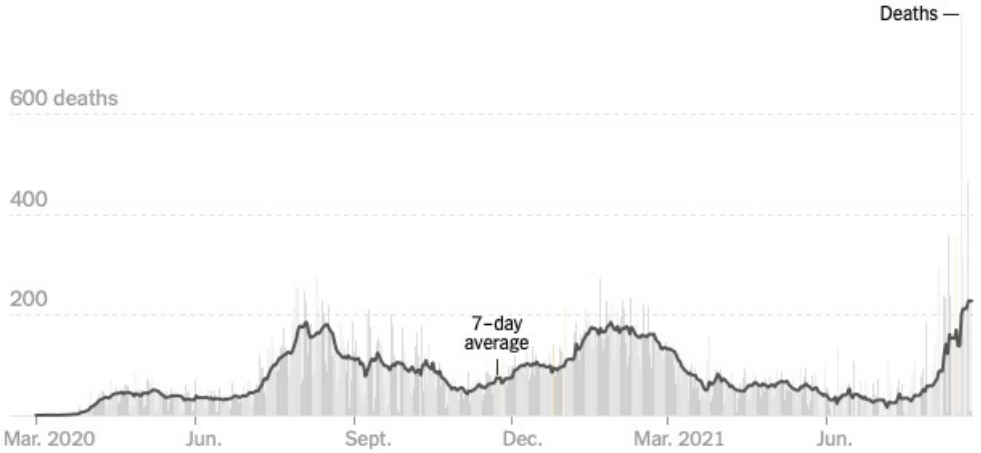
Cases and Deaths in Florida Hit Record Highs

- This week, 227 virus deaths were being reported each day in Florida, on average, as of Tuesday, a record for the state and by far the most in the United States right now
- The average for new known cases reached 23,314 a day on the weekend, 30 percent higher than the state's previous peak in January, according to a New York Times database
- Across the country, new deaths have climbed to more than 1,000 a day, on average
- A growing proportion of the people inundating hospitals and dying in Florida now are coming from younger segments of the population, particularly those ages 40 to 59, which were less vulnerable in earlier waves of the pandemic. The Delta variant is spreading among younger people, many who thought they were healthy and did not get vaccinated

Florida Covid-19 Hospitalizations ›



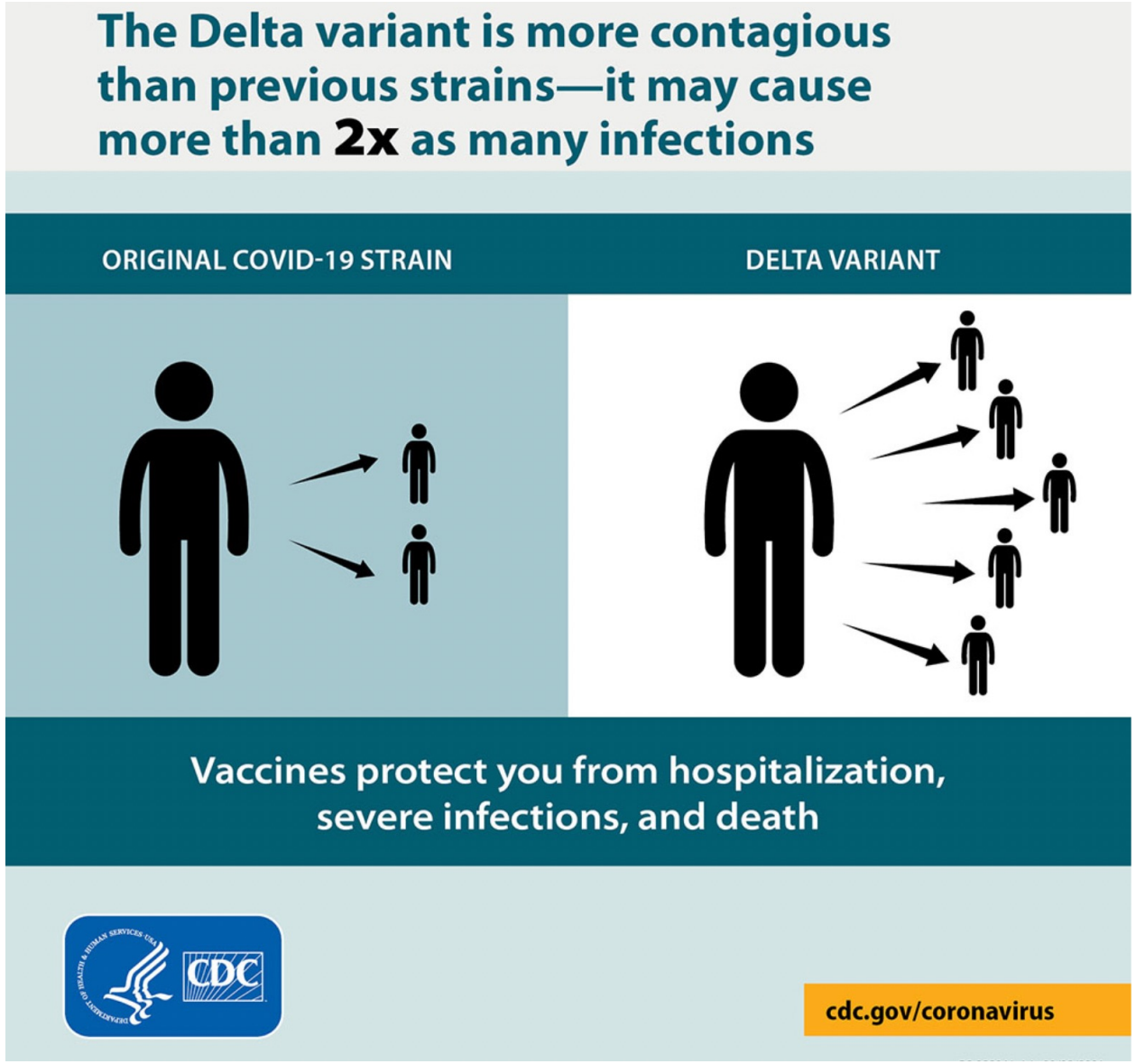
Florida Coronavirus Deaths ›



https://www.nytimes.com/live/2021/08/26/world/covid-delta-variant-vaccine

Delta Variant

- **The Delta variant is more contagious:** The Delta variant is highly contagious, nearly twice as contagious as previous variants.
- **Some data suggest the Delta variant might cause more severe illness than previous strains in unvaccinated persons.** In two different studies from Canada and Scotland, patients infected with the Delta variant were more likely to be hospitalized than patients infected with Alpha or the original virus strains.
- **Unvaccinated people remain the greatest concern:** Although breakthrough infections happen much less often than infections in unvaccinated people, individuals infected with the Delta variant, including fully vaccinated people with symptomatic breakthrough infections, can transmit it to others. CDC is continuing to assess data on whether fully vaccinated people with asymptomatic breakthrough infections can transmit. However, the greatest risk of transmission is among unvaccinated people who are much more likely to contract, and therefore transmit the virus.
- **Fully vaccinated people with Delta variant breakthrough infections can spread the virus to others. However, vaccinated people appear to be infectious for a shorter period:** Previous variants typically produced less virus in the body of infected fully vaccinated people (breakthrough infections) than in unvaccinated people. In contrast, the Delta variant seems to produce the same high amount of virus in both unvaccinated and fully vaccinated people. However, like other variants, the amount of virus produced by Delta breakthrough infections in fully vaccinated people also goes down faster than infections in unvaccinated people. This means fully vaccinated people are likely infectious for less time than unvaccinated people.



*Comirnaty (*koe-mir'-na-tee) is now FDA Approved

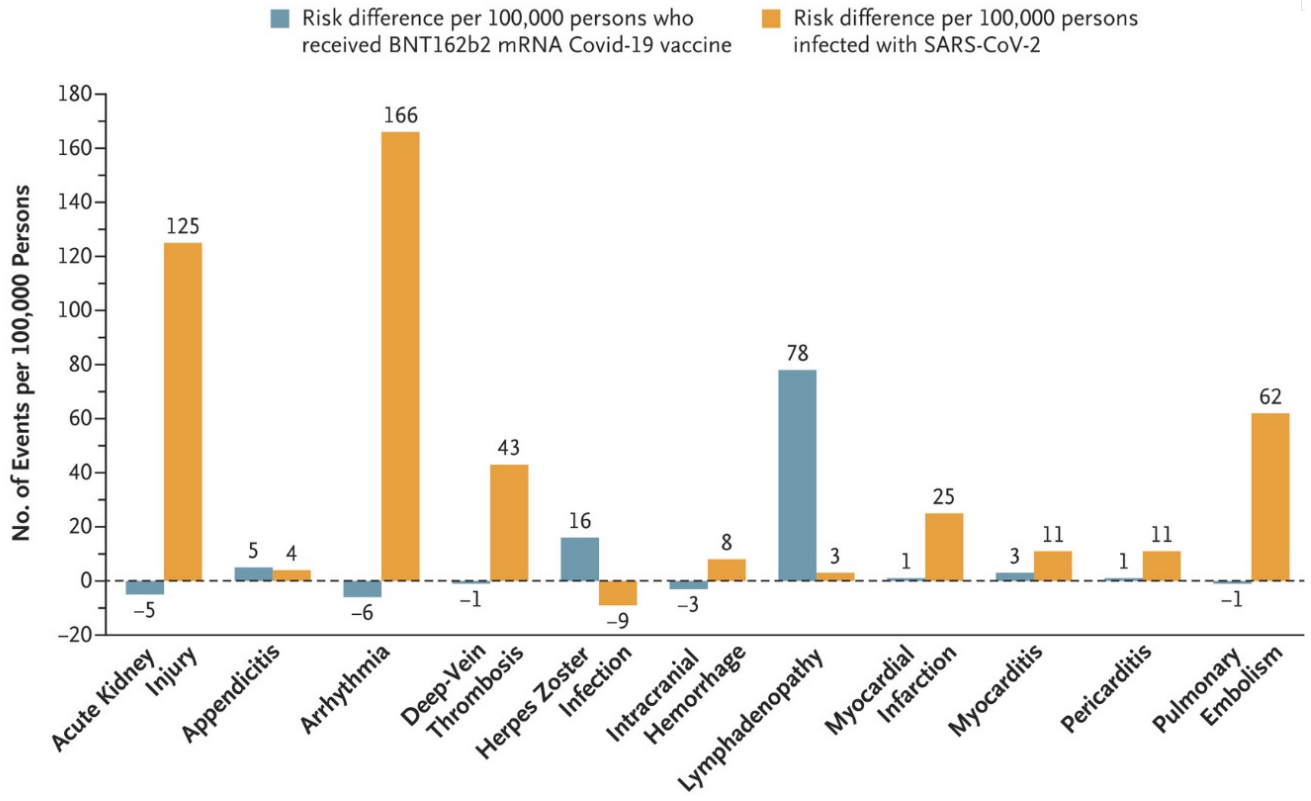
- The two-dose vaccine (formerly Pfizer/BioNTech BNT162b2) is now fully approved for people ages 16 and older
- For those who are ages 12 to 15 and for those who are immunocompromised and need a booster shot, the vaccine is still available under an FDA emergency use authorization (EUA)
- "While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated," Woodcock of the FDA said
- A Kaiser Family Foundation survey from June showed that roughly 30% of unvaccinated adults who felt hesitant about the vaccine said a full approval would mean they would be more likely to get vaccinated.
- Moderna (Spikevax) is still awaiting full FDA approval

ORIGINAL ARTICLE

Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting

Noam Barda, M.D., Noa Dagan, M.D., Yatir Ben-Shlomo, B.Sc., Eldad Kepten, Ph.D., Jacob Waxman, M.D., Reut Ohana, M.Sc., Miguel A. Hernán, M.D., Marc Lipsitch, D.Phil., Isaac Kohane, M.D., Doron Netzer, M.D., Ben Y. Reis, Ph.D., and Ran D. Balicer, M.D.

- Data from the largest health care organization in Israel to evaluate the safety of the BNT162b2 mRNA vaccine
- The vaccinated and control groups each included a mean of 884,828 persons.
- Vaccination was most strongly associated with an elevated risk of myocarditis (risk ratio, 3.24; 95% confidence interval [CI], 1.55 to 12.44; risk difference, 2.7 events per 100,000 persons; 95% CI, 1.0 to 4.6)
- Other events:
  - Lymphadenopathy (risk ratio, 2.43; 95% CI, 2.05 to 2.78; risk difference, 78.4 events per 100,000 persons; 95% CI, 64.1 to 89.3),
  - Appendicitis (risk ratio, 1.40; 95% CI, 1.02 to 2.01; risk difference, 5.0 events per 100,000 persons; 95% CI, 0.3 to 9.9)
  - Herpes zoster infection (risk ratio, 1.43; 95% CI, 1.20 to 1.73; risk difference, 15.8 events per 100,000 persons; 95% CI, 8.2 to 24.2). SARS-CoV-2 infection was associated with a
  - **INFECTION substantially increased risk of myocarditis** (risk ratio, 18.28; 95% CI, 3.95 to 25.12; risk difference, 11.0 events per 100,000 persons; 95% CI, 5.6 to 15.8) and of additional serious adverse events, including pericarditis, arrhythmia, deep-vein thrombosis, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia.



NEJM Aug 25, 2021 DOI: 10.1056/NEJMoa2110475

Boosters!

- Why do we need them?
  - Evidence of waning effectiveness
  - Evidence that Delta is on the rise, but success seen in reduced hospitalizations in the vaccinated
  - Evidence of success of boosting dose leading to improved levels of neutralizing antibody
- FDA has already granted an EUA for a 3rd dose in immunocompromised patients
  - CDC recommends that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose
- Starting September 20, 3rd dose will be available to be given 8 months after second dose (maybe 6 months – Stay tuned!)

Waning effectiveness?

- Study at Mayo clinic, Puranik et al.
- January to July 2021, during which either the Alpha or Delta variant was highly prevalent. Defined cohorts of vaccinated and unvaccinated individuals from Minnesota (n = 25,589 each) matched on age, sex, race, history of prior SARS-CoV-2 PCR testing, and date of full vaccination
- Both vaccines were highly effective during this study period against SARS-CoV-2 infection (mRNA-1273: 86%, 95%CI: 81-90.6%; BNT162b2: 76%, 95%CI: 69-81%) and COVID-19 associated hospitalization (mRNA-1273: 91.6%, 95% CI: 81-97%; BNT162b2: 85%, 95% CI: 73-93%).
- However … July, 2021:
  - Effectiveness against infection was considerably lower for mRNA-1273 (76%, 95% CI: 58-87%)
  - Even more pronounced reduction in effectiveness for BNT162b2 (42%, 95% CI: 13-62%).
  - Delta variant prevalence in Minnesota increased from 0.7% in May to over 70% in July whereas the Alpha variant prevalence decreased from 85% to 13% over the same time period.
  - Comparing rates of infection between matched individuals fully vaccinated with mRNA-1273 versus BNT162b2 across Mayo Clinic Health System sites in multiple states (Minnesota, Wisconsin, Arizona, Florida, and Iowa), mRNA-1273 conferred a two-fold risk reduction against breakthrough infection compared to BNT162b2 (IRR = 0.50, 95% CI: 0.39-0.64).
  - In Florida, which is currently experiencing its largest COVID-19 surge to date, the risk of infection in July after full vaccination with mRNA-1273 was about 60% lower than after full vaccination with BNT162b2 (IRR: 0.39, 95% CI: 0.24-0.62).
- Observational study highlights that while both mRNA COVID-19 vaccines strongly protect against infection and severe disease, further evaluation of mechanisms underlying differences in their effectiveness such as dosing regimens and vaccine composition are warranted.

doi: https://doi.org/10.1101/2021.08.06.21261707

Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021

Ashley Fowlkes, ScD[1]; Manjusha Gaglani, MBBS[2]; Kimberly Groover, PhD[3]; Matthew S. Thiese, PhD[4]; Harmony Tyner, MD[5]; Katherine Ellingson, PhD[6]; HEROES-RECOVER Cohorts

TABLE. Effectiveness of COVID-19 vaccines against any SARS-CoV-2 infection among frontline workers, by B.1.617.2 (Delta) variant predominance and time since full vaccination — eight U.S. locations, December 2020–August 2021

Period and vaccination status	No. of contributing participants*	Total no. of person-days	Median days (IQR)	No. of SARS-CoV-2 infections	Adjusted VE,† % (95% CI)
Full cohort to date					
Unvaccinated	4,136	181,357	20 (8–45)	194	N/A
Fully vaccinated§	2,976	454,832	177 (115–195)	34	80 (69–88)
14–119 days after full vaccination	2,923	284,617	106 (106–106)	13	85 (68–93)
120–149 days after full vaccination	2,369	66,006	30 (30–30)	3	81 (34–95)
≥150 days after full vaccination	2,129	104,174	52 (37–64)	18	73 (49–86)
Pre-Delta variant predominance					
Unvaccinated	4,137	156,626	19 (8–43)	175	N/A
Fully vaccinated	2,875	329,865	124 (95–149)	10	91 (81–96)
Delta variant predominance					
Unvaccinated	488	24,871	43 (37–69)	19	N/A
Fully vaccinated	2,352	119,218	49 (35–56)	24	66 (26–84)

The VE point estimates declined from 91% before predominance of the SARS-CoV-2 Delta variant to 66% since the SARS-CoV-2 Delta variant became predominant at the HEROES-RECOVER cohort study sites; however, this trend should be interpreted with caution because VE might also be declining as time since vaccination increases and because of poor precision in estimates due to limited number of weeks of observation and few infections among participants.

MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e4

Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021

TABLE. Effectiveness of full vaccination* with Pfizer-BioNTech or Moderna vaccines in preventing SARS-CoV-2 infection among nursing home residents, by period of B.1.617.2 (Delta) variant circulation — National Healthcare Safety Network, March 1–August 1, 2021

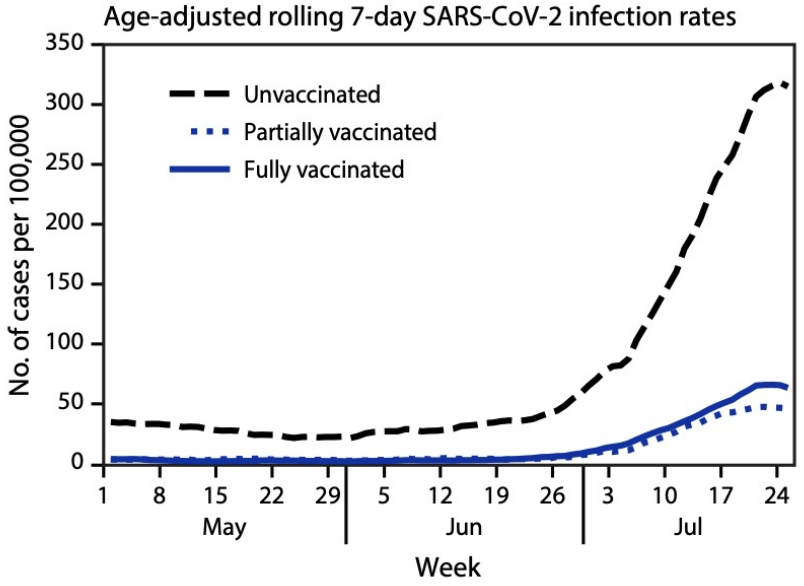
Vaccine type/Period†	Aggregate weekly count of residents	No. of cases	Vaccine effectiveness, % (95% CI)		
			Unadjusted§	Adjusted¶	p-value**
Any mRNA vaccine					
Period 1: pre-Delta	936,123	466	74.3 (69.5–78.4)	74.7 (70.0–78.8)	Ref
Period 2: intermediate	1,859,929	440	65.8 (58.5–71.9)	67.5 (60.1–73.5)	0.06
Period 3: Delta	5,011,746	2,999	52.8 (48.8–56.5)	53.1 (49.1–56.7)	<0.001
Pfizer-BioNTech					
Period 1: pre-Delta	679,288	348	74.7 (69.5–79.0)	74.2 (68.9–78.7)	Ref
Period 2: intermediate	1,246,078	316	63.5 (54.9–70.5)	66.5 (58.3–73.1)	0.07
Period 3: Delta	3,248,732	1,939	52.2 (47.7–56.3)	52.4 (48.0–56.4)	<0.001
Moderna					
Period 1: pre-Delta	256,835	118	72.6 (66.1–77.8)	74.7 (66.2–81.1)	Ref,
Period 2: intermediate	613,851	124	73.2 (66.8–78.3)	70.4 (60.1–78.0)	0.45
Period 3: Delta	1,763,014	1,060	48.4 (42.3–53.8)	50.6 (45.0–55.7)	<0.001
Unvaccinated					
Period 1: pre-Delta	217,534	447	Ref		NA
Period 2: intermediate	360,051	269			
Period 3: Delta	953,861	1,397			

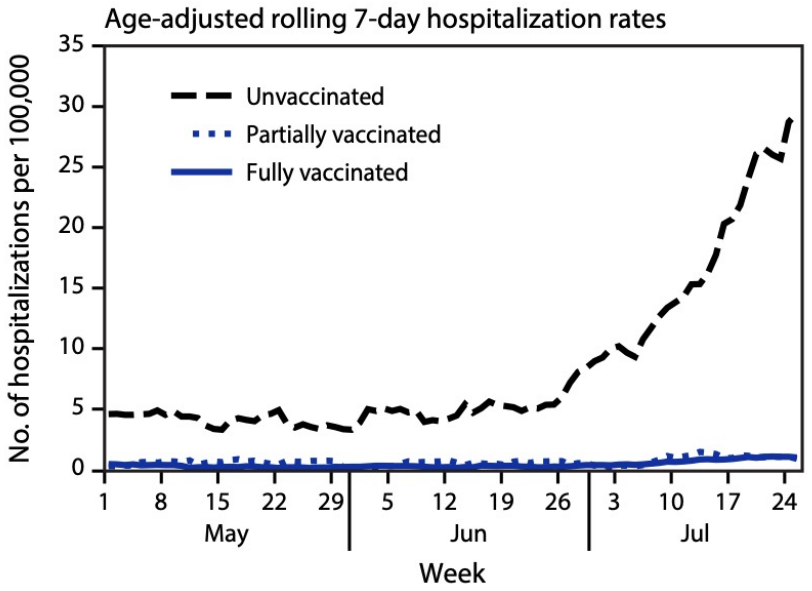
2 doses of mRNA vaccines were 74.7% effective against infection among nursing home residents early in the vaccination program (March–May 2021). During June–July 2021, when B.1.617.2 (Delta) variant circulation predominated, effectiveness declined significantly to 53.1%.

MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e3

SARS-CoV-2 Infections and Hospitalizations Among Persons Aged ≥16 Years, by Vaccination Status — Los Angeles County, California, May 1–July 25, 2021

Jennifer B. Griffin, PhD[1]; Meredith Haddix, MPH[1]; Phoebe Danza, MPH[1]; Rebecca Fisher, MPH[1]; Tae Hee Koo, MPH[1]; Elizabeth Traub, MPH[1]; Prabhu Gounder, MD[1]; Claire Jarashow, PhD[2]; Sharon Balter, MD[1]





During May 1–July 25, 2021, among 43,127 SARS-CoV-2 infections in residents of Los Angeles County, California, 10,895 (25.3%) were in fully vaccinated persons, 1,431 (3.3%) were in partially vaccinated persons, and 30,801 (71.4%) were in unvaccinated persons. On July 25, infection and hospitalization rates among unvaccinated persons were 4.9 and 29.2 times, respectively, those in fully vaccinated persons. In July, when the Delta variant was predominant, cycle threshold values were similar for unvaccinated, partially vaccinated, and vaccinated persons.

MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7034e5

Durability of mRNA-1273 vaccine–induced antibodies against SARS-CoV-2 variants

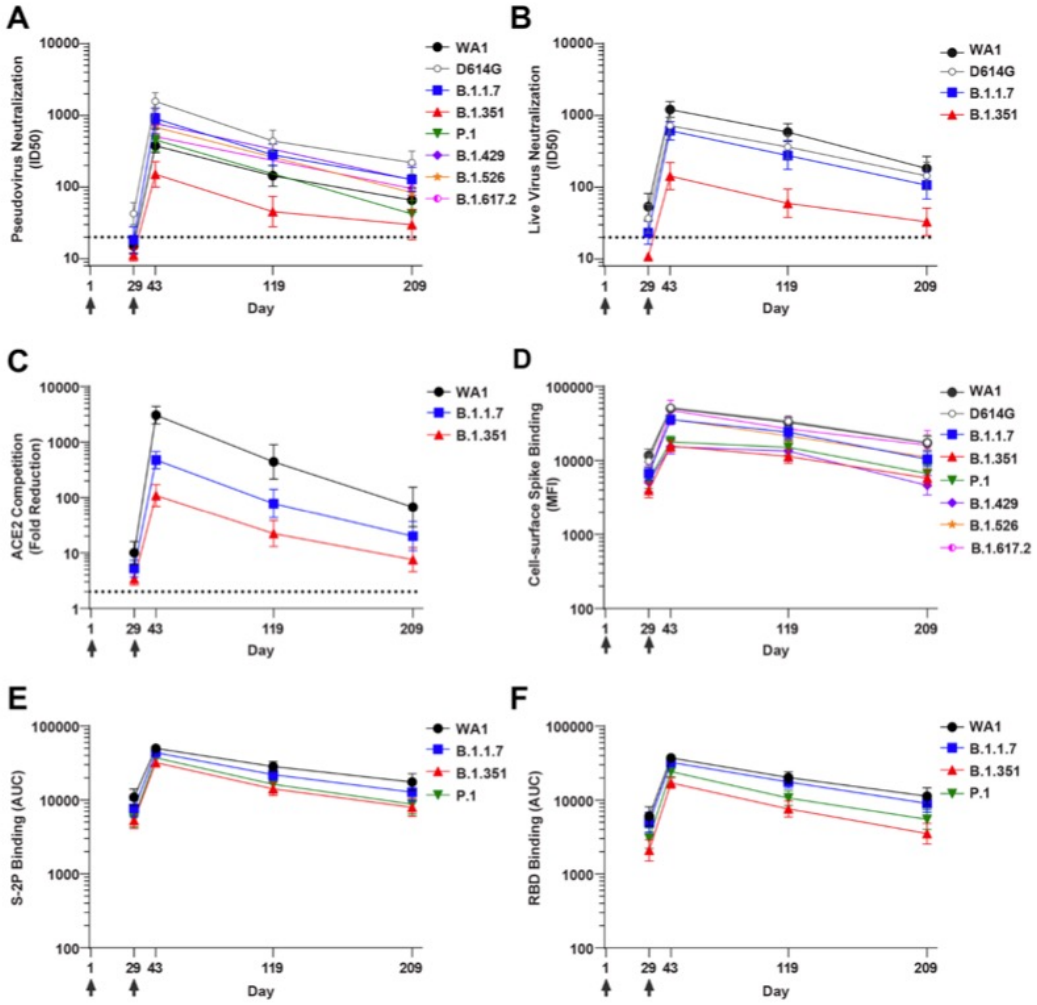
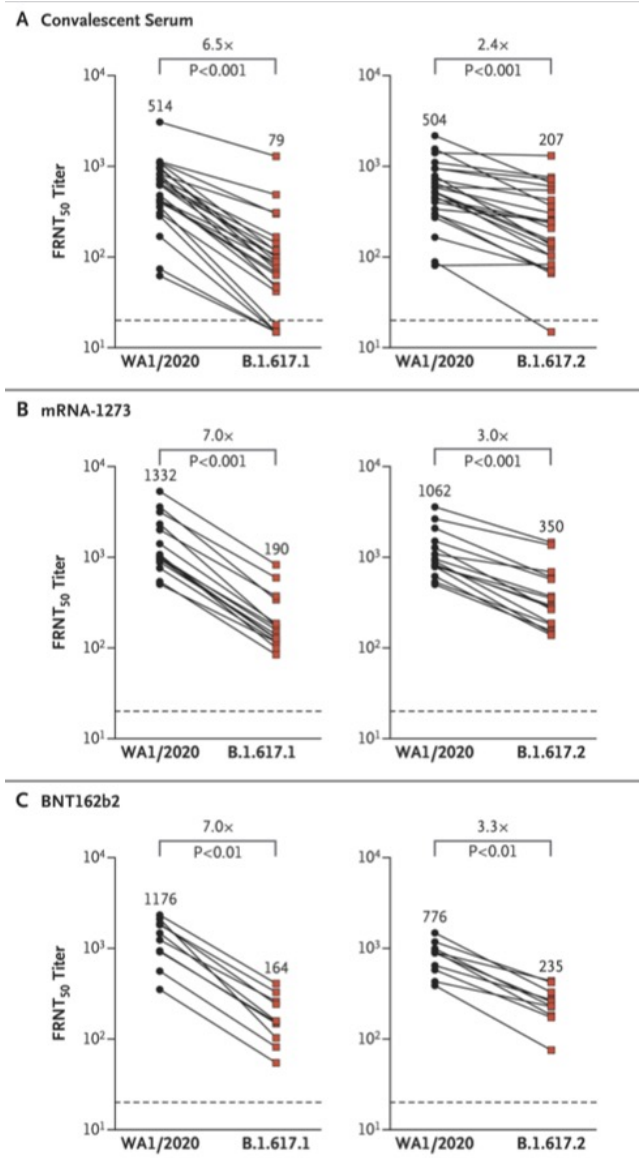


Fig. 1. Binding and functional antibodies persist for 6 months following the second dose of the mRNA-1273 vaccine. For all assays, sera from n=24 individuals were sampled at 4 timepoints.

- SARS-CoV-2 mutations may diminish vaccine-induced protective immune responses, particularly as antibody titers wane over time.
- Cross-reactive neutralizing responses were rare after a single dose. At the peak of response to the second vaccine dose, all individuals had responses to all variants.
- Binding and functional antibodies against variants persisted in most subjects, albeit at low levels, for 6-months after the primary series of the mRNA-1273 vaccine.
- Across all assays, B.1.351 had the lowest antibody recognition.
- These data complement ongoing studies to inform the potential need for additional boost vaccinations.

A. Pegu et al., Science 10.1126/science.abj4176 (2021)

Infection and Vaccine-Induced Neutralizing-Antibody Responses to the SARS-CoV-2 B.1.617 Variants

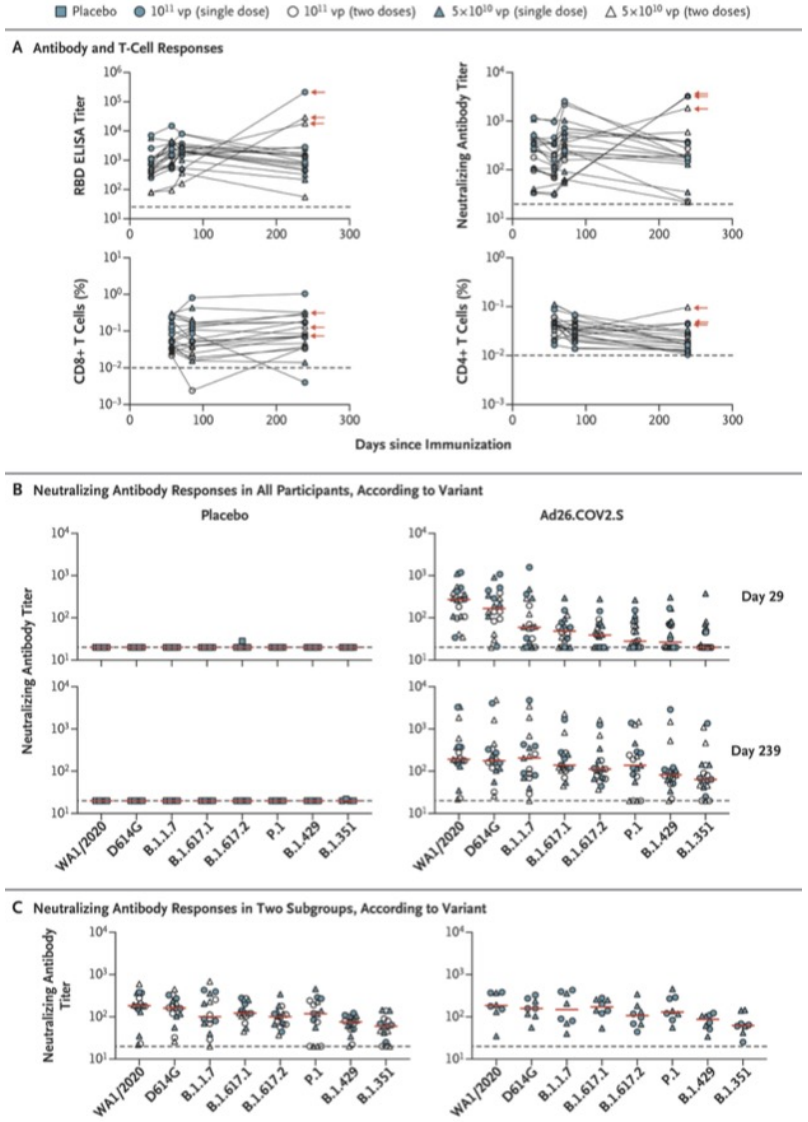


- B.1.617.1 variant was 6.8 times less susceptible, and the B.1.617.2 variant was 2.9 times less susceptible, to neutralization by serum from persons who had recovered from Covid-19 and from vaccinated persons than was the WA1/2020 variant.
- Despite this finding, a majority of the convalescent serum samples (79% [19 of 24 samples] against B.1.617.1 and 96% [23 of 24 samples] against B.1.617.2) and all serum samples from vaccinated persons still had detectable neutralizing activity above the threshold of detection against both variants through 3 months after infection or after the second dose of vaccine.
- Thus, protective immunity conferred by the mRNA vaccines is most likely retained against the B.1.617.1 and B.1.617.2 variants.

August 12, 2021 N Engl J Med 2021; 385:664-666
DOI: 10.1056/NEJMc2107799

Johnson & Johnson Announces Data to Support Boosting its Single-Shot COVID-19 Vaccine

- New interim data from these studies demonstrate that a booster dose of the Johnson & Johnson COVID-19 vaccine generated a rapid and robust increase in spike-binding antibodies, nine-fold higher than 28 days after the primary single-dose vaccination. Significant increases in binding antibody responses were observed in participants between ages 18 and 55, and in those 65 years and older who received a lower booster dose.
- Ad26.COV2.S vaccine elicited durable humoral and cellular immune responses with minimal decreases for at least 8 months after immunization
- Observed an expansion of neutralizing antibody breadth against SARS-CoV-2 variants over this time period, including B.1.617.2 variant and the partially neutralization-resistant B.1.351 and P.1 variants, which suggests maturation of B-cell responses even without further boosting

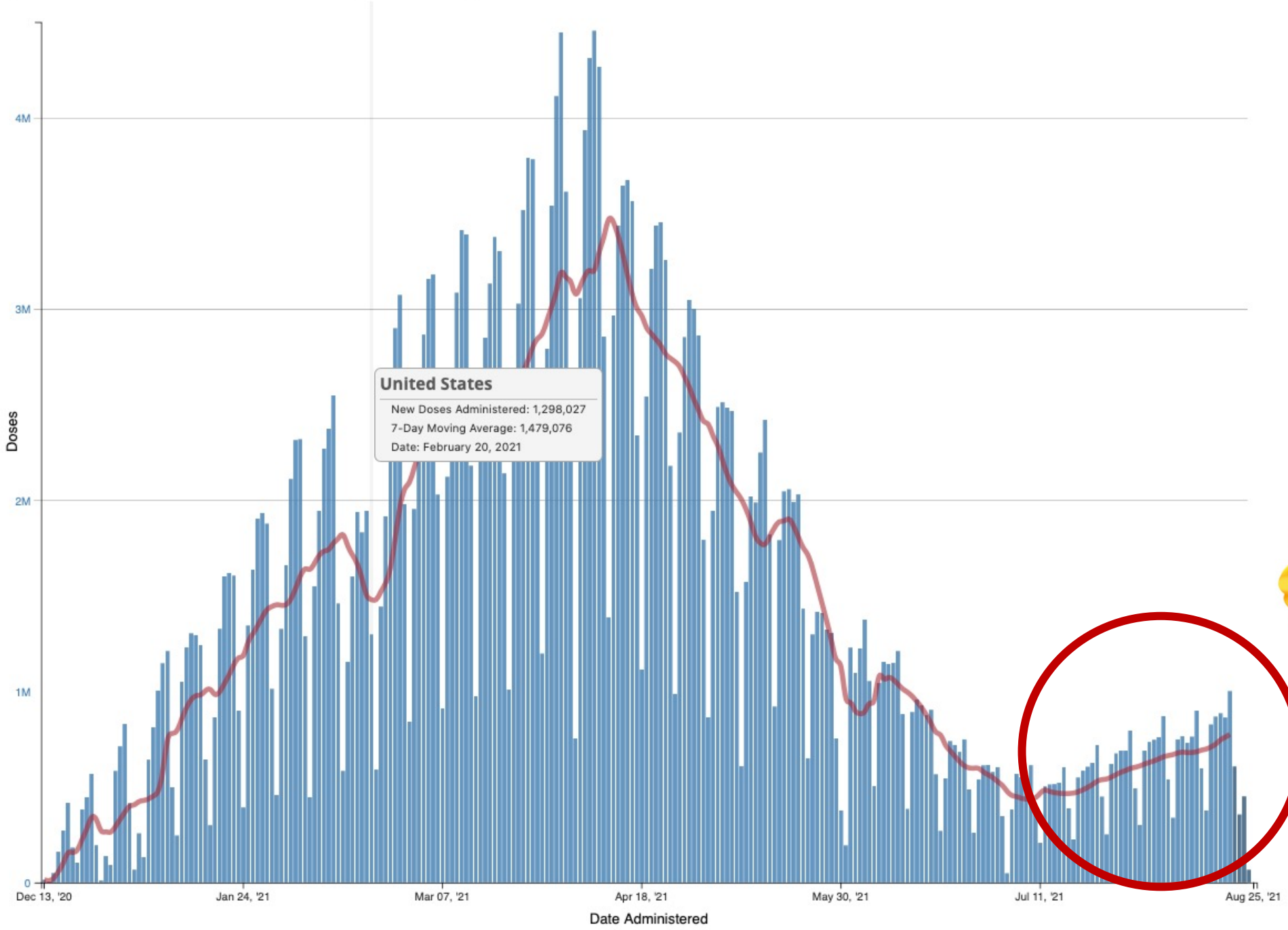


DOI: 10.1056/NEJMc2108829

ADE Is Still Not a Problem With COVID Vaccines

- Conspiracy theories about antibody-dependent enhancement (ADE) with COVID-19 vaccines are swirling yet again
- Essentially, the idea with ADE is that certain antibodies actually make it easier for viruses to get inside cells
- Some have theorized the vaccines are actually accelerating the pandemic
- Some recent papers based on modelling have suggested this, but no empirical evidence in the lab or the real world has actually supported this hypothesis

Daily Count of Total Doses Administered and Reported to CDC by Date Administered, United States



Questions?

Thank you!

Next Session: Thursday, September 16th,12-1pm CST

Resources & recording of the session

https://www.echo-chicago.org/resources/covid19/

This project was funded in part by a cooperative agreement with the Centers for Disease Control and Prevention grant number 1 NU50CK000588-01-00. The Centers for Disease Control and Prevention is an agency within the Department of Health and Human Services (HHS). The contents of this resource center do not necessarily represent the policy of CDC or HHS and should not be considered an endorsement by the Federal Government.

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AT THE FOREFRONT UChicago Medicine

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