COVID-19 Series for Free & Charitable Clinics

October 14, 2021

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AT THE FOREFRONT UChicago Medicine

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

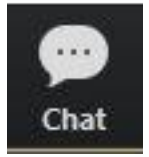
CDC's Strategy: **Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

Project Goal: Build and reinforce COVID-19 vaccine confidence among healthcare personnel in the safety net sector and, in turn, the patients they serve.

Partnerships: **The National Association of Free and Charitable Clinics** and **15 State Associations** and Federally Qualified Health Centers (FQHCs) in Puerto Rico and the U.S. Virgin Islands.

How: Provide tailored COVID-19 vaccine information to the free and charitable clinic sector through various channels and **give the FCC sector a direct line of communication to CDC**.

Reminders:

- Please use your first name and clinic name when you join the session
- Use the “chat” feature to ask questions 

- Please remember to mute your microphone 

- If you can’t connect audio via computer or you lose computer audio at anytime, you can call in to session at **(408) 638-0968, Meeting ID 932-6566-2201##**
- This activity has been approved for AMA PRA Category 1.25 Credit™ & Nursing CEUs

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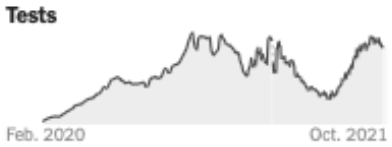
Disclosures

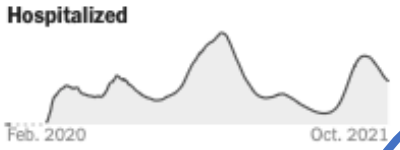
- We have no relevant financial interests to disclose.

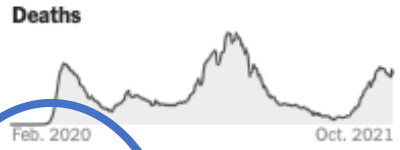
Coronavirus in the U.S.: Latest Map and Case Count

New reported cases

All time | Last 90 days

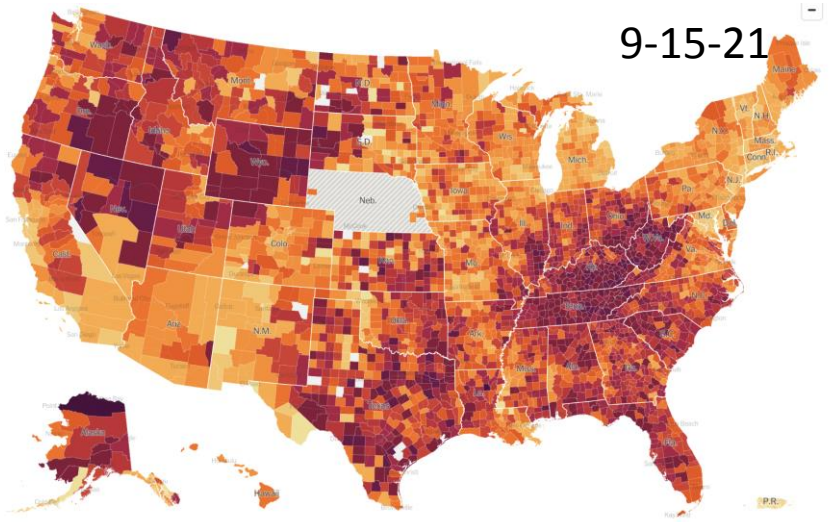




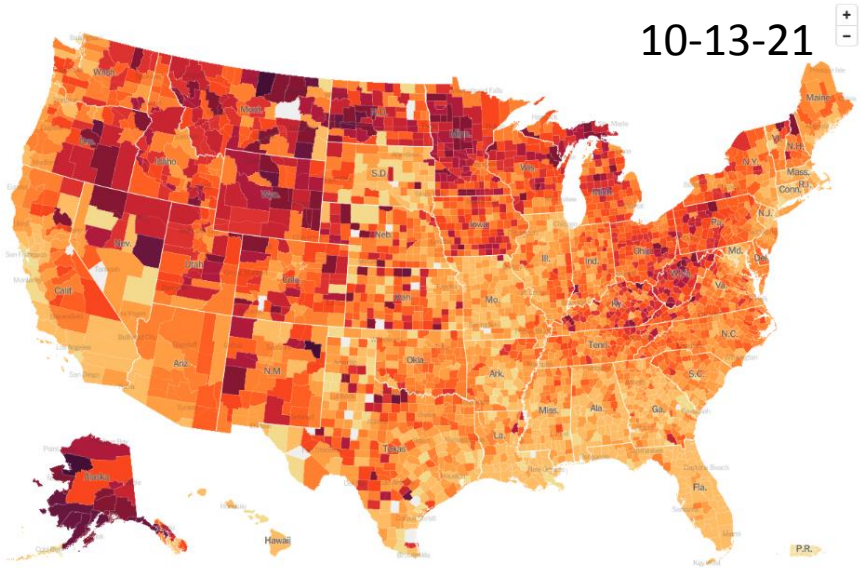


	DAILY AVG. ON OCT. 12	14-DAY CHANGE	TOTAL REPORTED
Cases	91,399	-21%	44,565,236
Tests	1,574,404	-10%	—
Hospitalized	65,943	-20%	—
Deaths	1,938	-4%	717,501

9-15-21

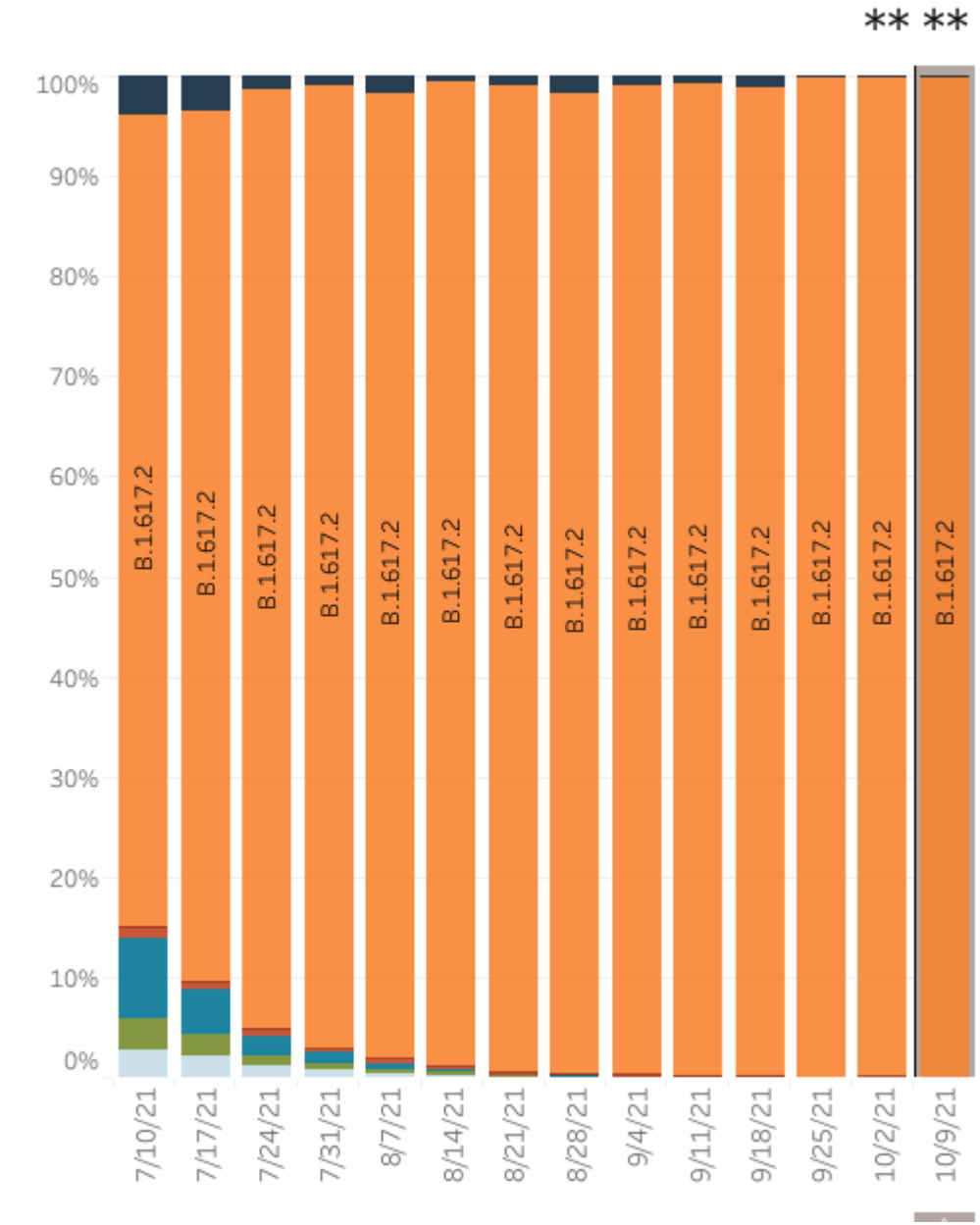


10-13-21



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

United States: 7/4/2021 – 10/9/2021



United States: 10/3/2021 – 10/9/2021 NOWC

USA

WHO label	Lineage #	US Class	%Total	95%PI
Alpha	B.1.1.7	VBM	0.0%	0.0-0.0%
Gamma	P.1	VBM	0.0%	0.0-0.0%
Delta	B.1.617.2	VOC	99.9%	99.8-99.
	AY.1	VOC	0.0%	0.0-0.1%
	AY.2	VOC	0.0%	0.0-0.0%
Mu	B.1.621	VBM	0.0%	0.0-0.0%
Other	Other*		0.0%	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.

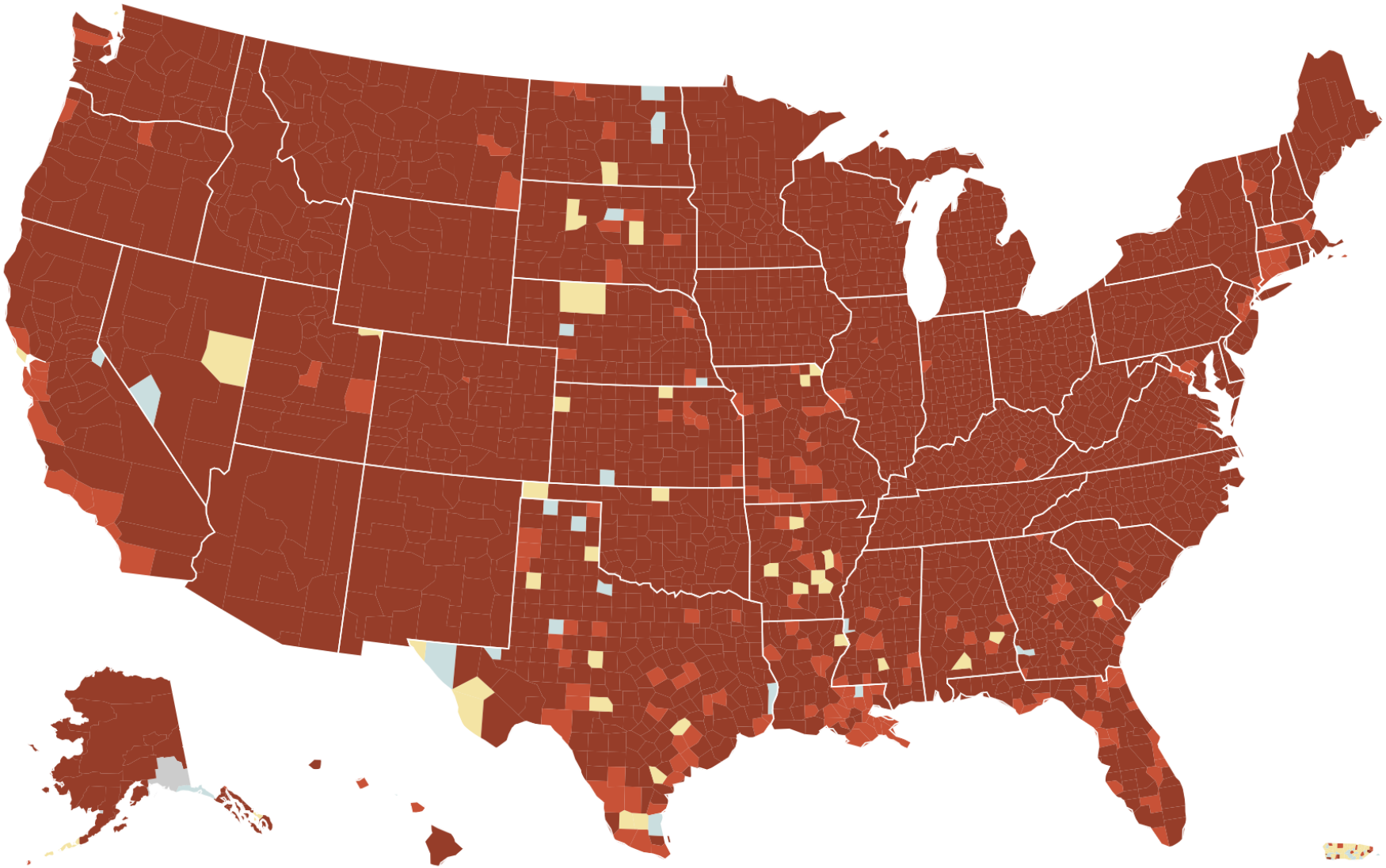
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

Sublineages of P.1 and B.1.621 are aggregated with the parent lineage and included in parent lineage's proportion. Q.1-Q.8 are aggregated with B.1.1.7. AY.3-AY.38 and their sublineages are aggregated with B.1.617.2.

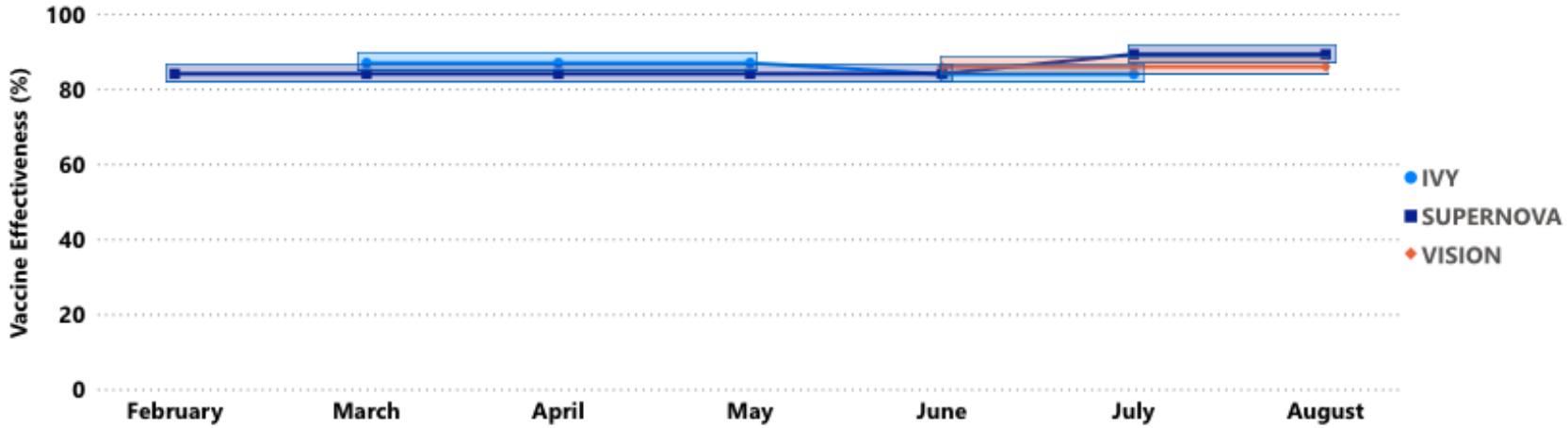
CDC advises masking indoors in counties with substantial or high coronavirus spread

Level of COVID-19 community transmission, as of Oct. 5-Oct. 11

No data | Low | Moderate | Substantial | High



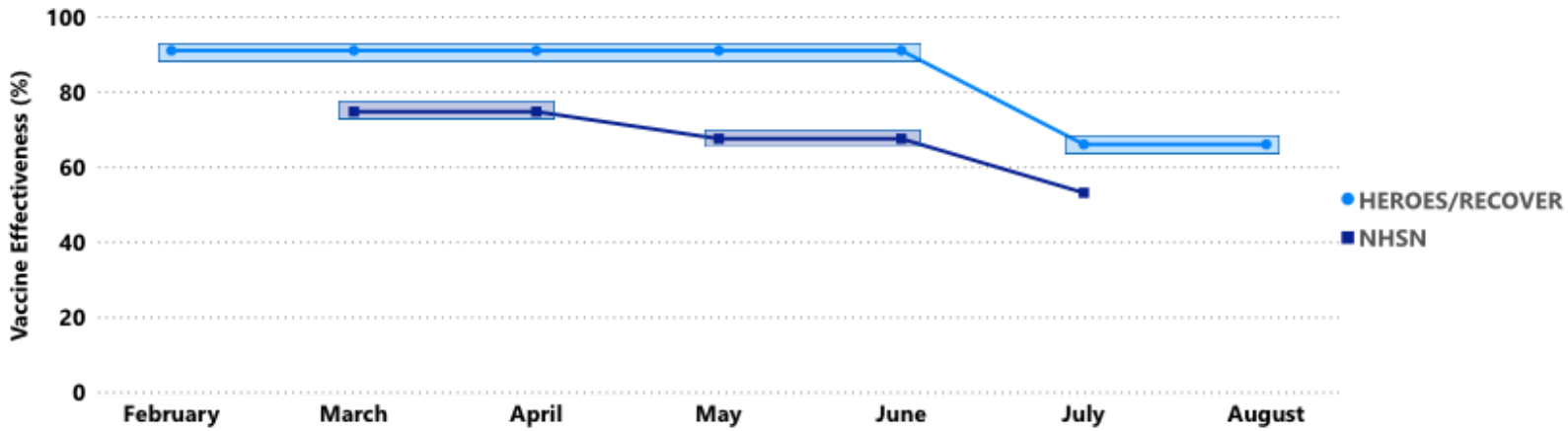
Vaccine effectiveness against **hospitalization**



COVID-19 vaccines are effective at protecting people from being hospitalized with COVID-19. The vaccines help protect against Delta and other variants and continue to prevent COVID-19 hospitalizations even though time has passed since many people got vaccinated.

Note: The horizontal bars indicate vaccine effectiveness estimates based on a study period of two or more months combined.

Vaccine effectiveness against **infection**



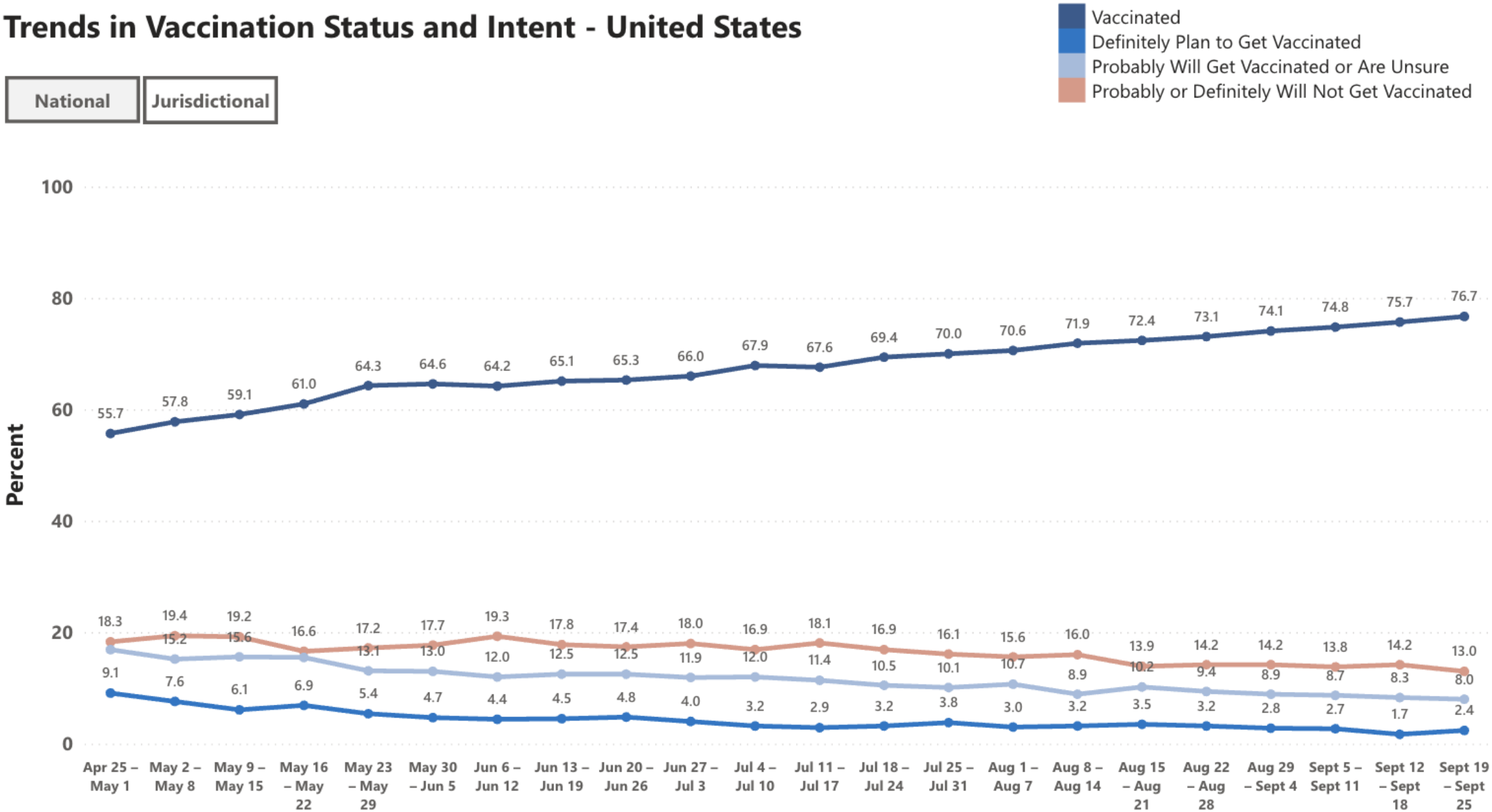
COVID-19 vaccines were less effective at preventing COVID-19 infection in July and August compared to earlier months. Time has passed since people got vaccinated, and Delta became the predominant variant during this time period.

Note: The horizontal bars indicate vaccine effectiveness estimates based on a study period of two or more months combined.

cdc.gov

Trends in Vaccination Status and Intent - United States

National | Jurisdictional



Vaccination Status and Intent by Demographics - United States

Data Collection Period: September 19 – September 25, 2021 (N= 18,196)

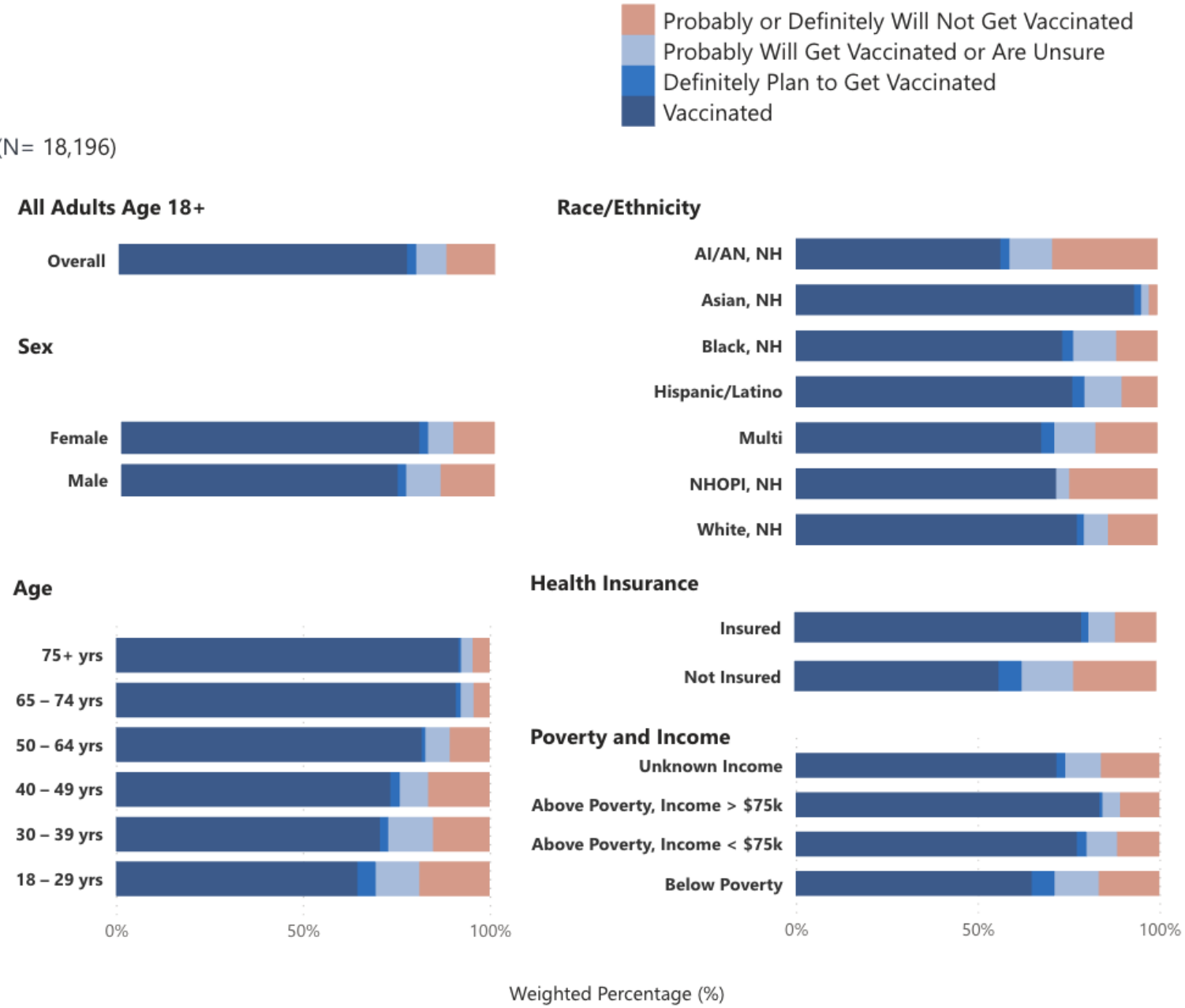
National | Jurisdictional

Overall

79.1% are **Vaccinated (76.7%)** or **Definitely Plan to Get Vaccinated (2.4%)**

8.0% **Probably Will Get Vaccinated or Are Unsure**

13.0% **Probably or Definitely Will Not Get Vaccinated**



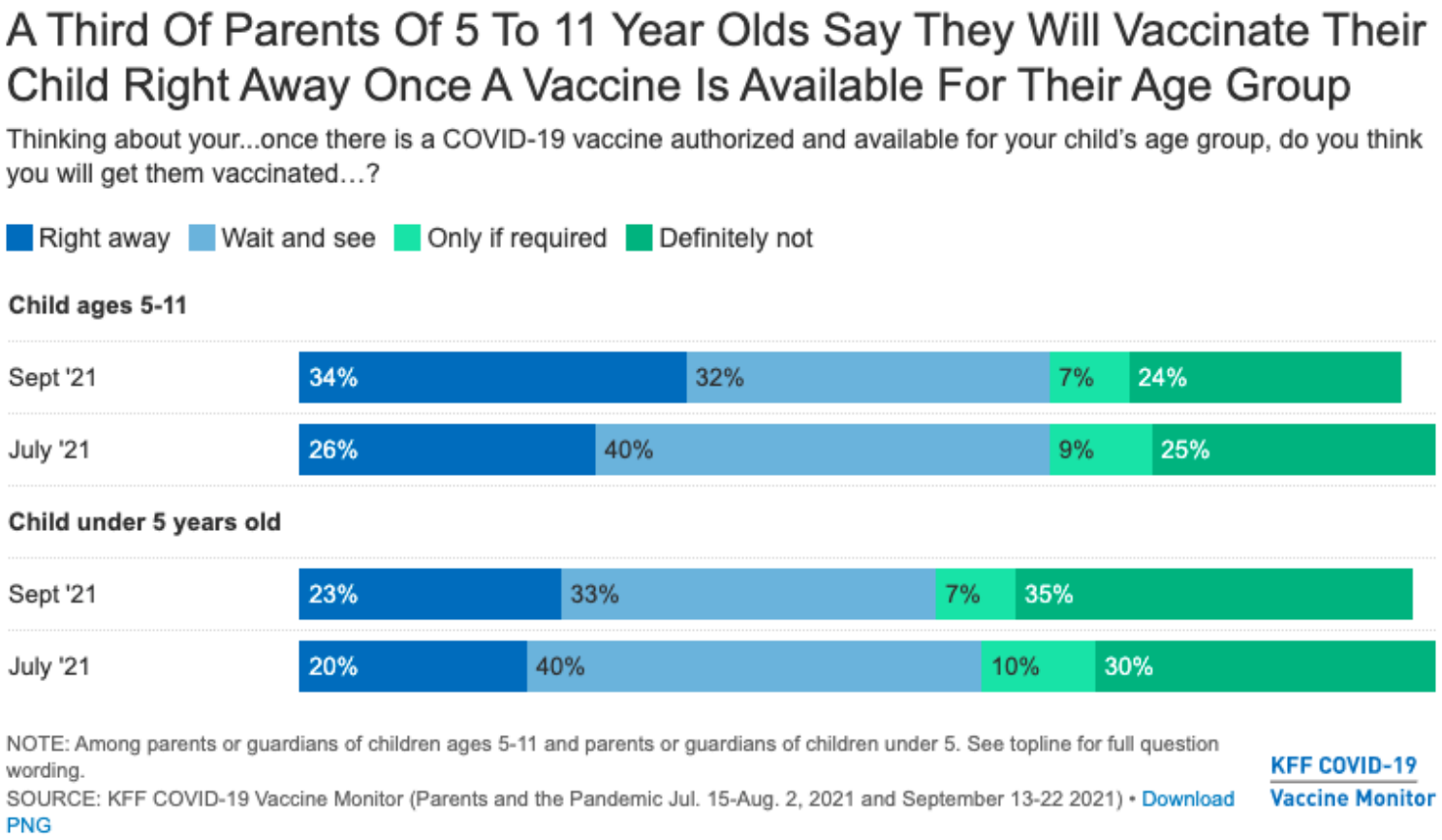
The number of eligible people still weighing whether to get a Covid vaccine has sharply dwindled, leaving an unvaccinated population that is mostly hard-core refusers

- Alison Buttenheim, a behavioral health expert at the University of Pennsylvania, noted that although primary care doctors, as trusted sources for patients, had been playing a crucial role in this phase of vaccine uptake, ***"it definitely raises the question of what happens to people who don't have a usual source of care."***
- Millions of holdouts have decided to get vaccinated over the past couple months, many prodded at the last minute by mandates or anxiety over the highly transmissible Delta variant. The decline of new cases recently in many states is another marker of the success of the vaccine campaigns, public health officials say.
- But millions of adults are not covered by mandates. Experts in vaccine behavior fear that the country is bumping up against the ceiling of persuadable people, one that is significantly lower than the threshold needed for broad immunity from Delta and, possibly, future variants.

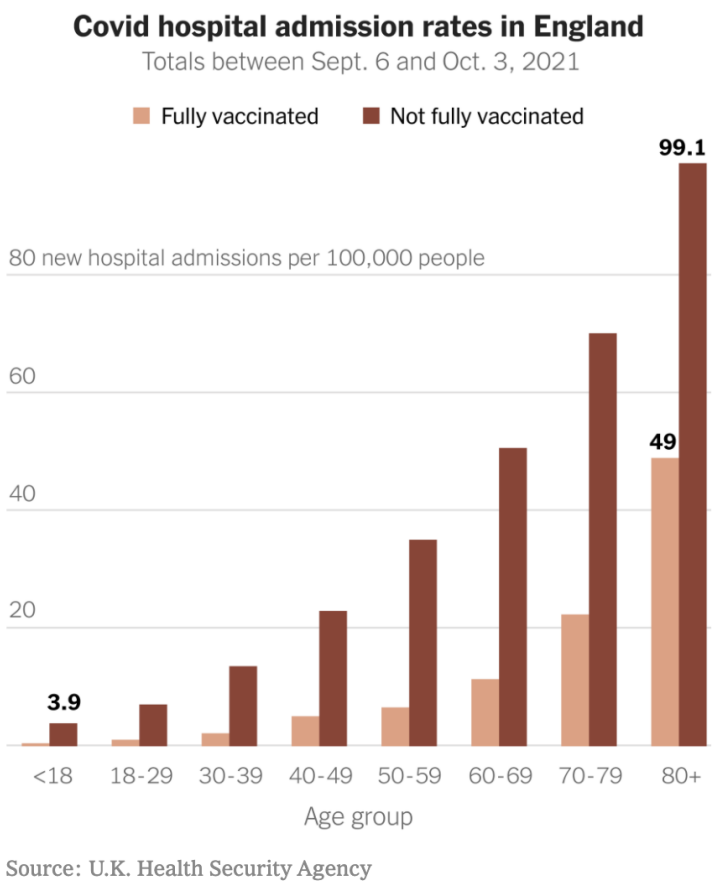
https://www.nytimes.com/2021/10/11/health/covid-boosters-unvaccinated.html

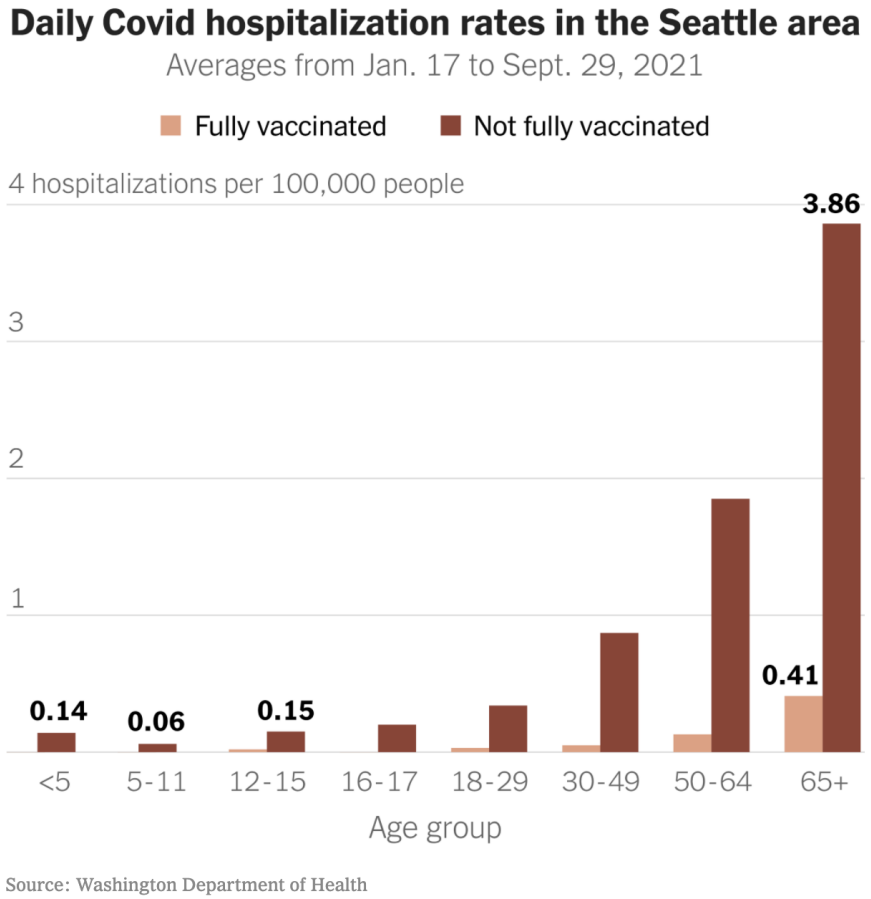
What about the children?

- FDA to meet on 10/26 to further debate this and decide on EUA expansion to children ages 5-11



“Your Unvaccinated Kid Is Much Safer Than a Vaccinated Grandma.”





https://www.nytimes.com/2021/10/12/briefing/covid-age-risk-infection-vaccine.html

Pfizer Boosters

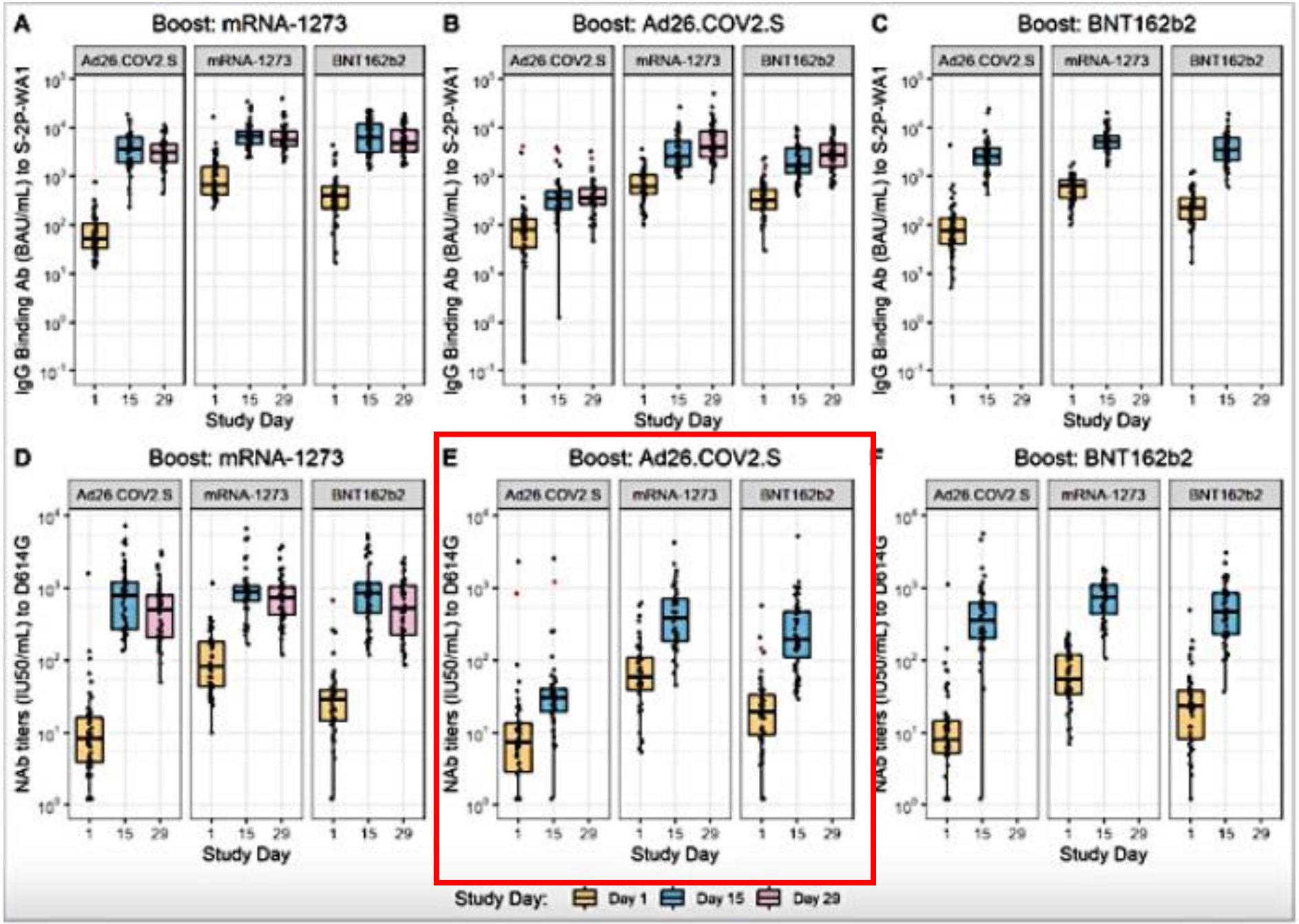
- CDC recommends:
  - **People 65 years and older and residents in long-term care settings** *should receive a booster* shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
  - **People aged 50–64 years with underlying medical conditions** *should receive a booster* shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
  - **People aged 18–49 years with underlying medical conditions** *may receive a booster* shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
  - **People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting** *may receive a booster* shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html

Heterologous SARS-CoV-2 Booster Vaccinations – Preliminary Report

- Phase 1/2 open-label clinical trial conducted at ten U.S. sites, adults who received one of three EUA Covid-19 vaccines at least 12 weeks prior to enrollment and had no reported history of SARS-CoV-2 infection received a booster injection with one of three vaccines (Moderna mRNA-1273 100-µg, Janssen Ad26.COV2.S 5×1010 virus particles, or Pfizer-BioNTech BNT162b2 30-µg; nine combinations).
- The primary outcomes were safety, reactogenicity, and humoral immunogenicity on study days 15 and 29.
- 458 individuals were enrolled: 154 received mRNA-1273, 150 received Ad26.CoV2.S, and 154 received BNT162b2 booster vaccines. Reactogenicity was similar to that reported for the primary series. Injection site pain, malaise, headache, and myalgia occurred in more than half the participants. Booster vaccines increased the neutralizing activity against a D614G pseudovirus (4.2-76-fold) and binding antibody titers (4.6-56-fold) for all combinations; **homologous boost increased neutralizing antibody titers 4.2-20-fold whereas heterologous boost increased titers 6.2-76-fold**. Day 15 neutralizing and binding antibody titers varied by 28.7-fold and 20.9-fold, respectively, across the nine prime-boost combinations.

doi.org/10.1101/2021.10.10.21264827;

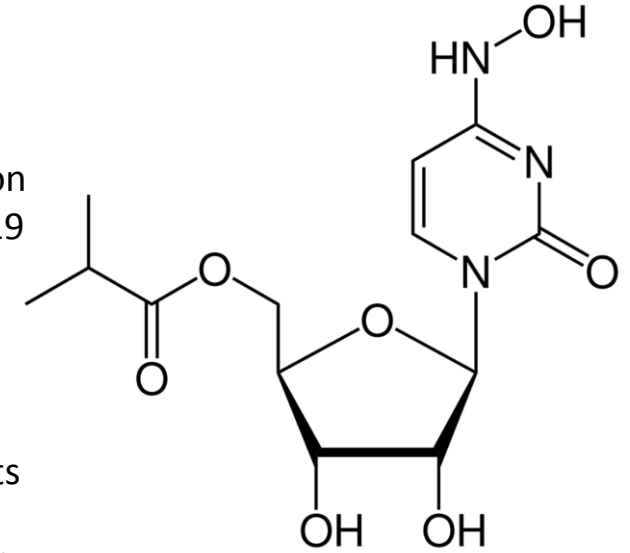


- mRNA vaccine boosters seem to increase antibody levels more than J & J
- No clear difference between a boost with Moderna or Pfizer

FDA to meet to consider Moderna and J & J boosters

- An independent advisory panel of experts will examine the available data on both Moderna and Johnson & Johnson boosters in a two-day meeting later this week.
- Moderna argued that a third injection is needed because the potency of its vaccine wanes over time, with levels of neutralizing antibodies falling six to eight months after a second dose. The company also cited “real world evidence of reduced effectiveness against the Delta variant,” although the F.D.A. noted that the studies diverge on whether Moderna’s protection weakened over time against symptomatic infection or against the Delta variant. The company did not argue that a booster was necessary to prevent severe disease or hospitalization, but concentrated its arguments on preventing infection and mild to moderate disease.
- Moderna said the mean antibody level of participants in its study was 1.8 times higher after the booster than it was after the second shot. In another measurement, the booster raised neutralizing antibodies at least fourfold in 87.9 percent of people compared to after the second dose, thus narrowly failing to meet the agency’s requirement of 88.4 percent.
- Johnson & Johnson argued that booster shots of its vaccine increased protection against Covid-19, including against severe forms of the disease, and increased the strength of the body’s immune response against virus variants. Johnson & Johnson said that a booster shot could be administered as early as two months after the first dose, but recommended doing so at least six months after, when it said recipients had been shown to have a more robust immune response.

Molnupiravir (mall-new-peer-a-veer)



- Merck has submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for molnupiravir, an investigational oral antiviral medicine, for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.
- Phase 3 MOVe-OUT clinical trial, which evaluated molnupiravir in non-hospitalized adult patients with mild-to-moderate COVID-19 who were at risk for progressing to severe COVID-19 and/or hospitalization.
- Interim analysis: molnupiravir reduced the risk of hospitalization or death by approximately 50%; 7.3% of patients who received molnupiravir were either hospitalized or died through Day 29 following randomization (28/385), compared with 14.1% of placebo-treated patients (53/377); p=0.0012. Through Day 29, no deaths were reported in patients who received molnupiravir, as compared to 8 deaths in patients who received placebo.
- The incidence of any adverse event was comparable in the molnupiravir and placebo groups (35% and 40%, respectively). The incidence of drug-related adverse events was also comparable (12% and 11%, respectively), and fewer subjects in the molnupiravir group discontinued therapy due to an adverse event compared to the placebo group (1.3% and 3.4%, respectively).
- It's a prodrug of N4-hydroxycytidine (NHC), a nucleoside analog.. Like many nucleoside analogs these compounds can cause trouble (in several ways) for viral RNA-dependent RNA polymerase, an absolutely critical enzyme for the replication of any RNA virus. A common mechanism is what's called an "error catastrophe". These enzymes are notoriously error-prone to start with, and viruses over the eons have added several mechanisms to try to keep that under control - but remember, a background mutation rate is also a survival advantage (throwing off new variants), just so long as it doesn't get out of control. Nucleoside analogs, in many cases, work by doing just that - pushing the RNA replication step into making so many errors that the end result can't even produce a competent virus.

Will Molnupiravir help?

- Clinical trials showed that the drug reduced the risk of hospitalization and death in at-risk patients by 50 percent, according to the company's interim analysis.
- Molnupiravir will need to be used early in the course to be successful
- This means increase in rapid testing is important
- Studies looking at Molnupiravir for post-exposure prophylaxis is ongoing
- Think of this drug as "Tamiflu for COVID"
- However, a course of Molnupiravir is slated to cost $700!

Questions?

Thank you!

Next Session: Thursday, November 11th,12-1:15pm CST

Resources & recording of the session

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

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