COVID-19 Series for Free & Charitable Clinics

July 14, 2022

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AT THE FOREFRONT UChicago Medicine

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

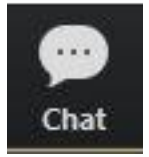
CDC's Strategy: **Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

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 Credit™ & Nursing CEUs

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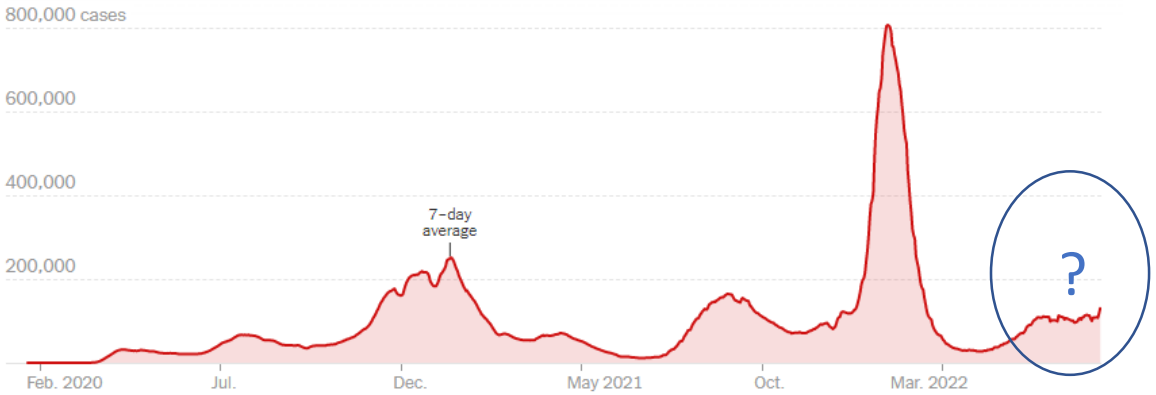
Disclosures

- We have no relevant financial interests to disclose.

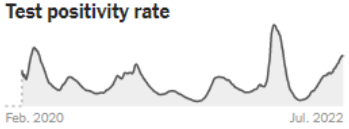
Coronavirus in the U.S.: Latest Map and Case Count

New reported cases

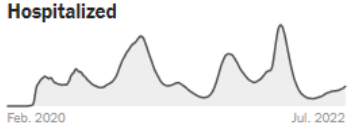
All time | Last 90 days



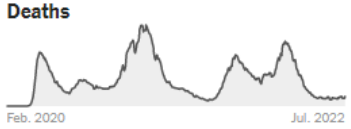
Test positivity rate



Hospitalized

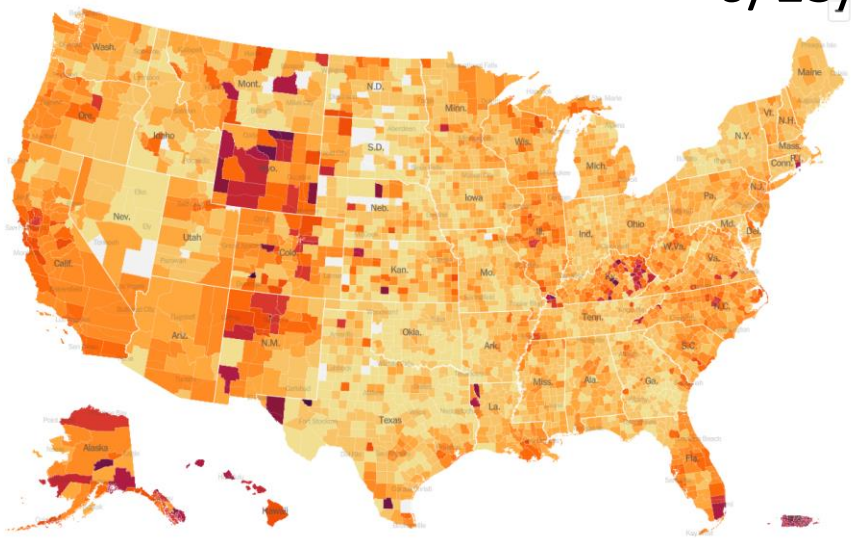


Deaths

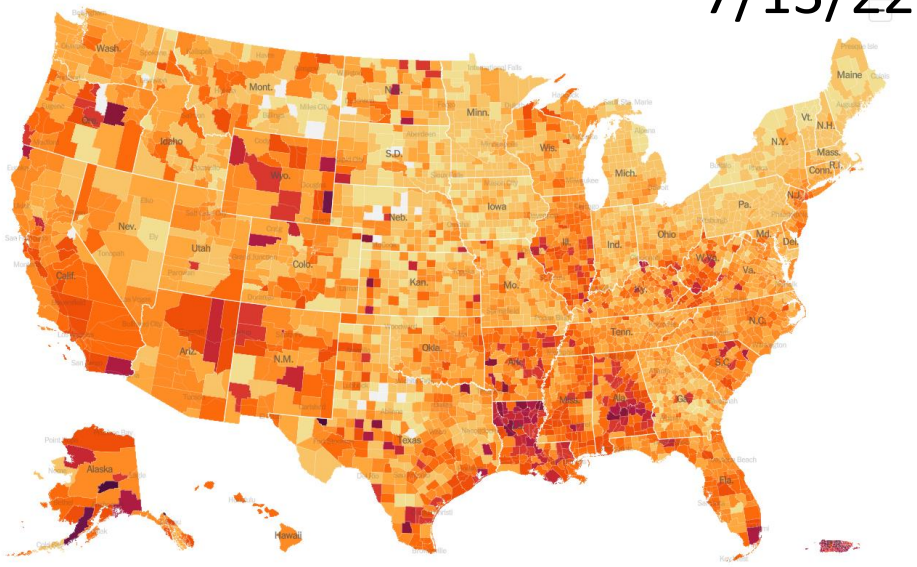


	DAILY AVG. ON JUL. 12	14-DAY CHANGE	TOTAL REPORTED
Cases	129,858	+19%	88,800,868
Test positivity	18%	—	—
Hospitalized	38,517	+18%	—
In I.C.U.s	4,330	+22%	—
Deaths	396	+5%	1,018,360

6/15/22

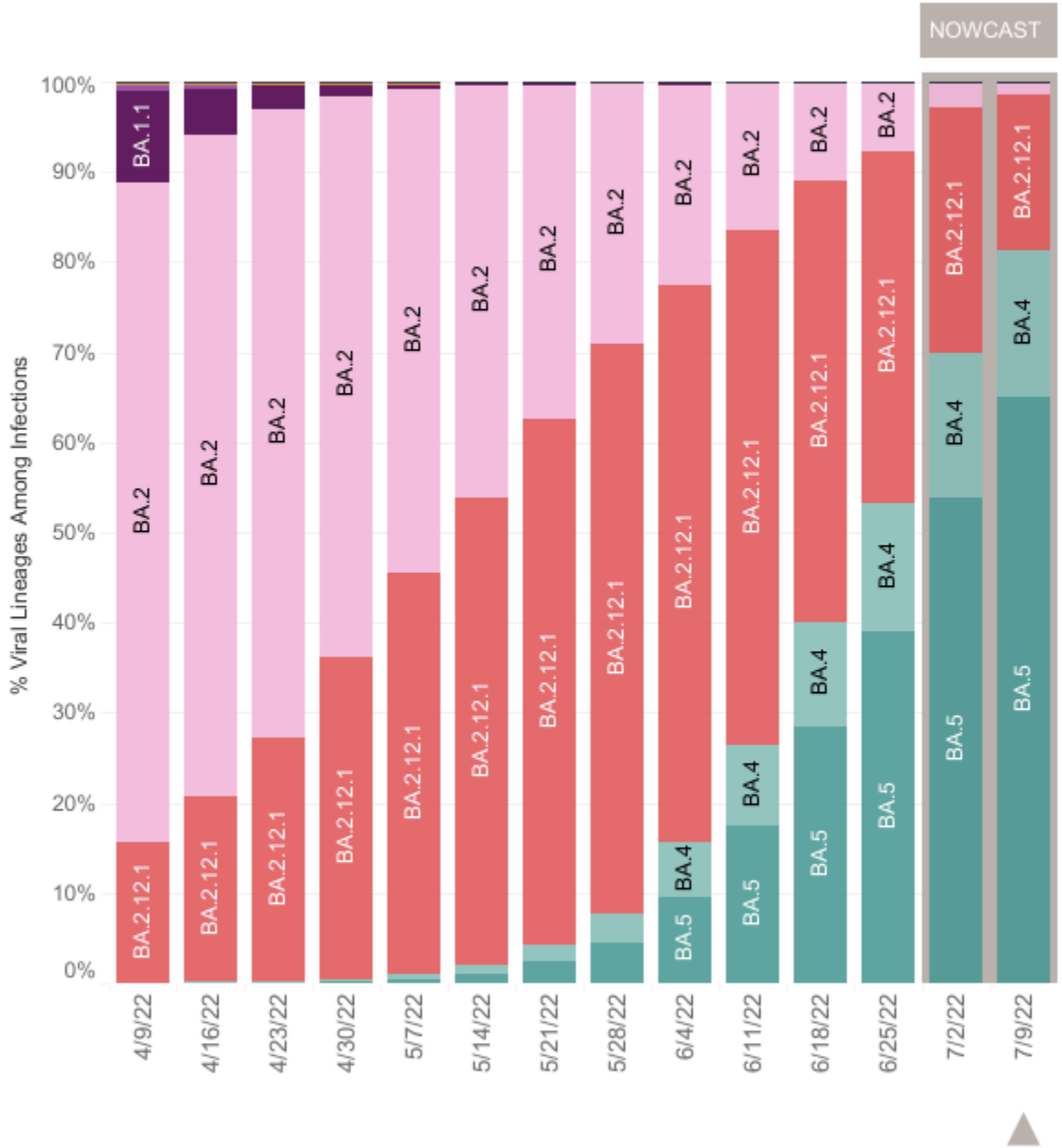


7/13/22



https://www.nytimes.com/interactive/2021/us/coronavirus-us-cases.html

United States: 4/3/2022 – 7/9/2022



United States: 7/3/2022 – 7/9/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.5	VOC	65.0%	62.2-67.7%
	BA.2.12.1	VOC	17.3%	15.7-19.0%
	BA.4	VOC	16.3%	14.5-18.3%
	BA.2	VOC	1.4%	1.3-1.6%
	B.1.1.529	VOC	0.0%	0.0-0.0%
	BA.1.1	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.

BA.5 becomes dominant among new U.S. cases, reduced state reporting is blurring the real-time look at the virus

- Public testing sites run by state and local governments have winnowed, more states have also stopped giving daily data updates, creating a foggier look at the state of virus across the country
- Vast majority of the positive results from popular home test kits are not included in official data, and not everyone who gets infected knows or gets tested. Many Americans appear to be moving even further away from focusing on daily case counting
- Some scientists estimate that the current wave of cases is the second largest of the pandemic
- More important metric is hospitalizations deaths which are relatively stable COVID is still killing an average of 314 people daily, one-tenth the number who were dying every day in January 2021
- The virus is killing more than twice as many Americans every day as suicide or car crashes are. And many of those who survive the virus are debilitated, some of them for long after their infections

Feature	BA.1	BA.2	BA.2.12.1	BA.4 and BA.5
Transmissibility Increase	Reference	30% increase	25% over BA.2	~10% over BA.2
Immune Escape	Reference	+	+++	+++
Ability to infect cells	Reference	+	++	Like BA.1
Key Mutations	Reference	T367A, D405N, R408S	L452Q	L452R, F486V, R493Q, Δ 69-70
Cross-Immunity w/ BA.1	Reference	Mostly preserved	Reduced	Reduced
Resistance to Monoclonal Antibodies	Reference	++	+++	+++
Places Where Dominant	Outcompeted	>100 countries	United States Region 2	~~South Africa~~ Worldwide incl. US
3-Shot Vaccine Effectiveness vs Hospitalization*	81% (95% CI 75,85)	83% (95% CI 71,91)	TBD	TBD
2-Shot Vaccine Effectiveness vs Hospitalization^	32% (95% CI 11,49)	50% (95% CI 7,73)	TBD	TBD

*UKHSA reports, up to 70 days, ^ past 6 months, TBD-to be determined

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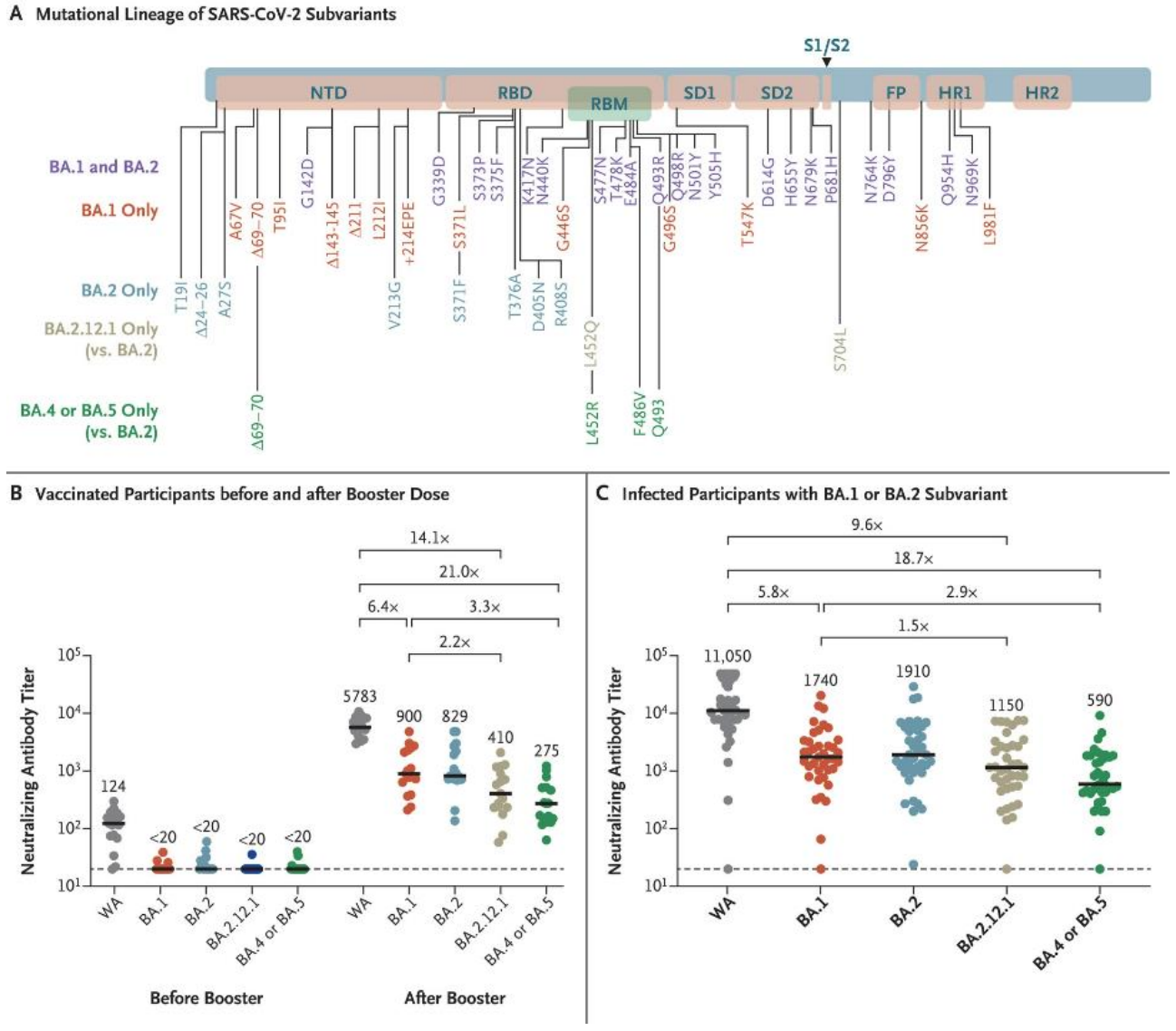
Neutralization Escape by SARS-CoV-2 Omicron Subvariants BA.2.12.1, BA.4, and BA.5

- BA.2.12.1, BA.4, and BA.5 subvariants substantially escape neutralizing antibodies induced by both vaccination and infection
- In those with previous infection – most of whom also had been vaccinated – the neutralizing antibody levels were lower by a factor of 6.4 against BA.1; by a factor of 5.8 against BA.2; by a factor of 9.6 against BA.2.12.1 and by a factor of 18.7 against BA.4 or BA.5.



N Engl J Med 2022; 387:86-88
DOI: 10.1056/NEJMc2206576

Outcomes of laboratory-confirmed SARS-CoV-2 infection during resurgence driven by Omicron lineages BA.4 and BA.5 compared with previous waves in South Africa

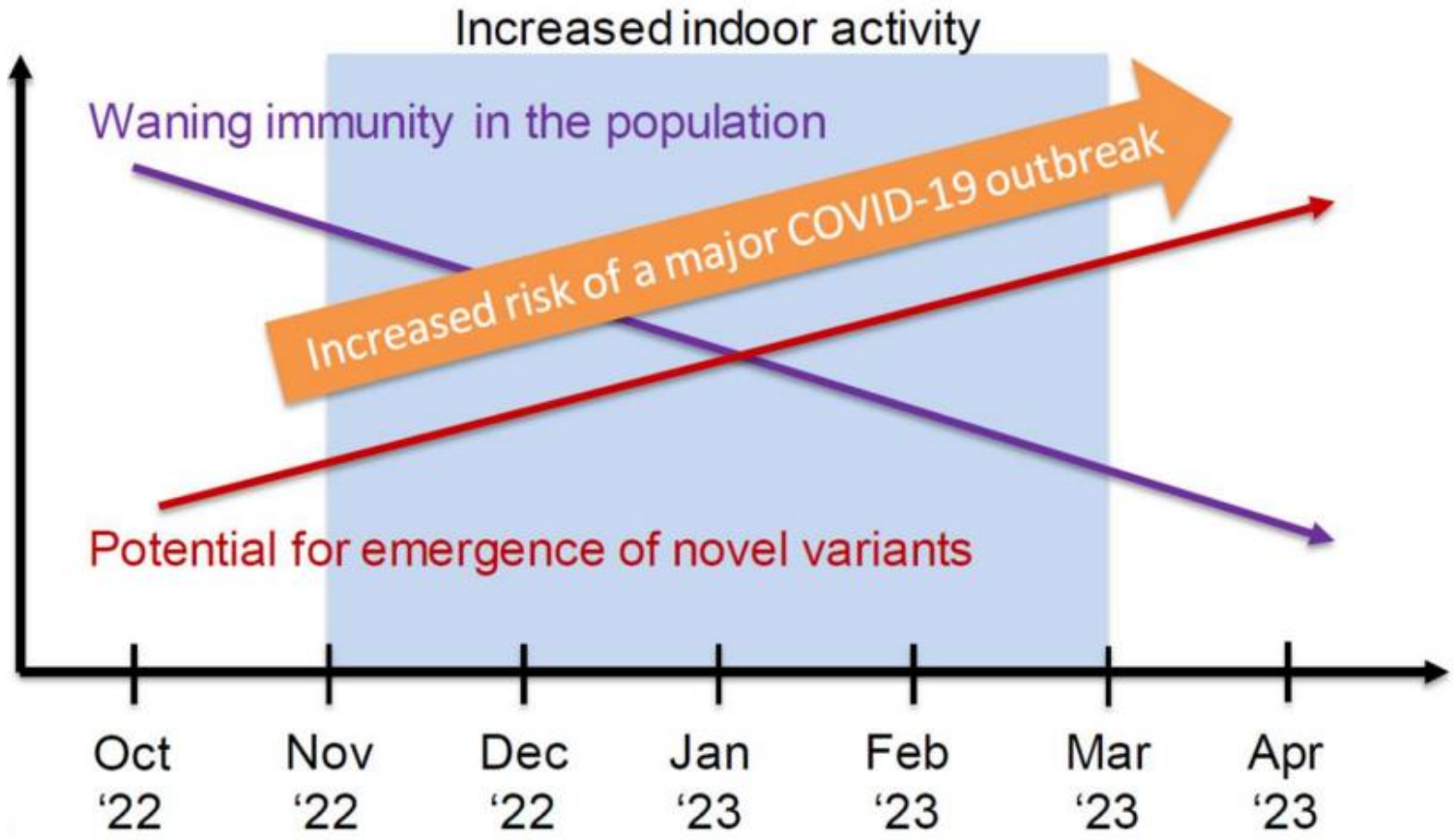
- Among 3,793 patients from the BA.4/BA.5 wave and 190,836 patients from previous waves the risk of severe hospitalization/death was similar in the BA.4/BA.5 and BA.1 waves (adjusted hazard ratio [aHR] 1.12).
- Both Omicron waves had lower risk of severe outcomes than previous waves. Prior infection (aHR 0.29) and vaccination (aHR 0.17 for boosted vs. no vaccine) were protective.
- Disease severity was similar amongst diagnosed COVID-19 cases in the BA.4/BA.5 and BA.1 periods in the context of growing immunity against SARS-CoV-2 due to prior infection and vaccination, both of which were strongly protective.

https://doi.org/10.1101/2022.06.28.22276983

FDA Recommends Inclusion of Omicron BA.4/5 Component for COVID-19 Vaccine Booster Doses

- Following a thorough discussion on June 28, 2022, an overwhelming majority of the advisory committee voted in favor of including a SARS-CoV-2 omicron component in COVID-19 vaccines that would be used for boosters in the U.S. beginning in fall 2022
- Manufacturers will also be asked to begin clinical trials with modified vaccines containing an omicron BA.4/5 component, as these data will be of use as the pandemic further evolves
- Dr. Hotez (Baylor): The only justification for including Omicron components in a COVID-19 vaccine would be as part of an effort to make a universal vaccine that would protect against whatever SARS-CoV-2 variant pops up, “We need an overarching coronavirus vaccination strategy for the country,” Hotez said. “What we’re doing is we’re allowing the pharma companies to push their own agenda.”

Omicron Vaccines?



- Omicron specific vaccines elicit stronger immune response by roughly a factor of 2
- New vaccine may only be as good as our ability to predict what variant(s) will be circulating

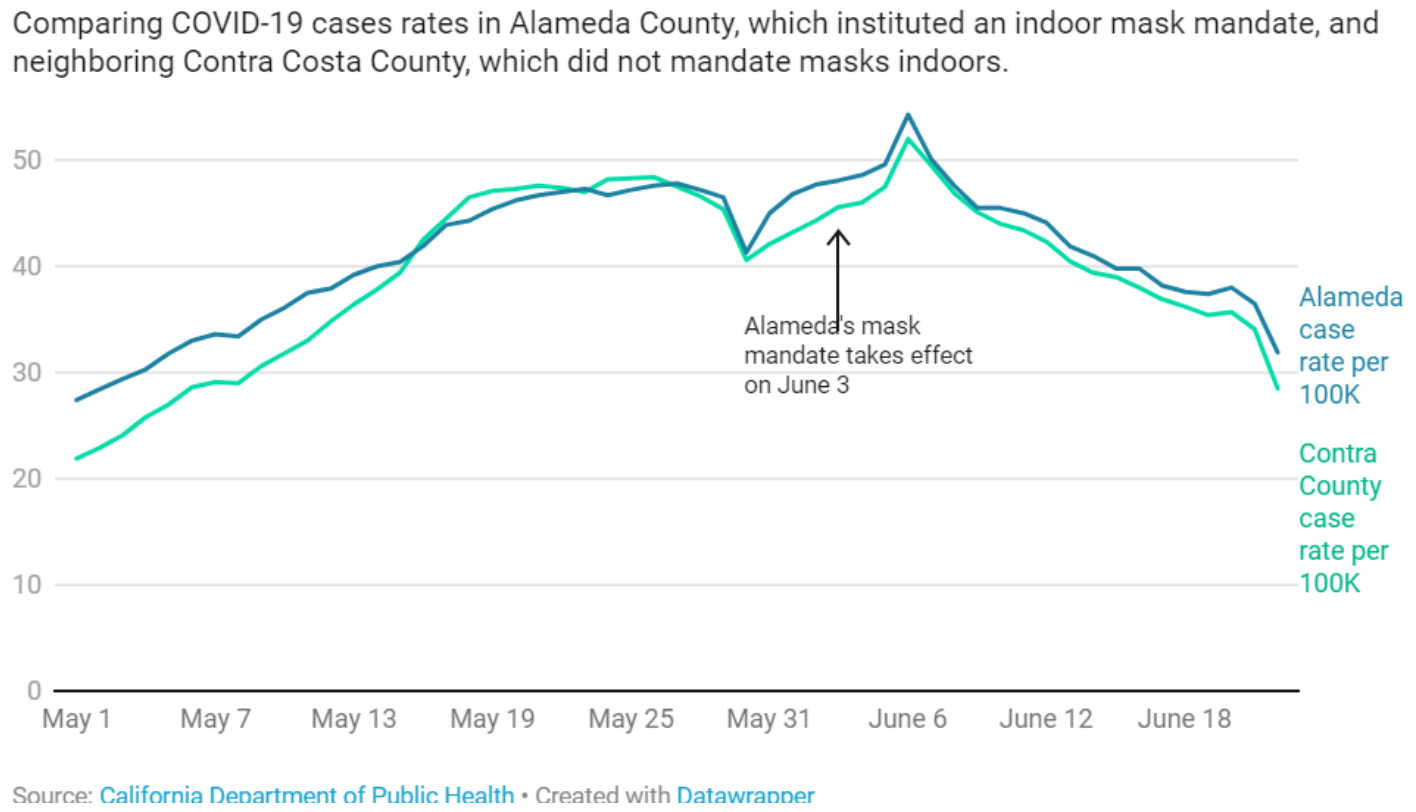

YOU CAN GET COVID-19
OVER & OVER AGAIN

And it continues… BA 2.75

- “It’s still really early on for us to draw too many conclusions,” said Matthew Binnicker, director of clinical virology at the Mayo Clinic in Rochester, Minn. “But it does look like, especially in India, the rates of transmission are showing kind of that exponential increase.” Whether it will outcompete BA.5, Binnicker said, is yet to be determined.
- The fact that it has already been detected even in many parts of the world with lower levels of viral surveillance “is an early indication it is spreading,” said Shishi Luo, head of infectious diseases for Helix.

Mask Mandates Return?

- As cases with BA 5 surge, places such as LA county are considering reinstating mask mandates for indoor public places
- Initial Omicron surge occurred in January when mask mandates were still commonplace in many parts of US, so how effective are mask mandates in the current era?
- Masking works even if mandates do not! It should still be considered if patient is immunocompromised
- Should still be testing and isolating if positive. And should quarantine if household contact has COVID
- Mask needs to N95 or kn95 to be effective.



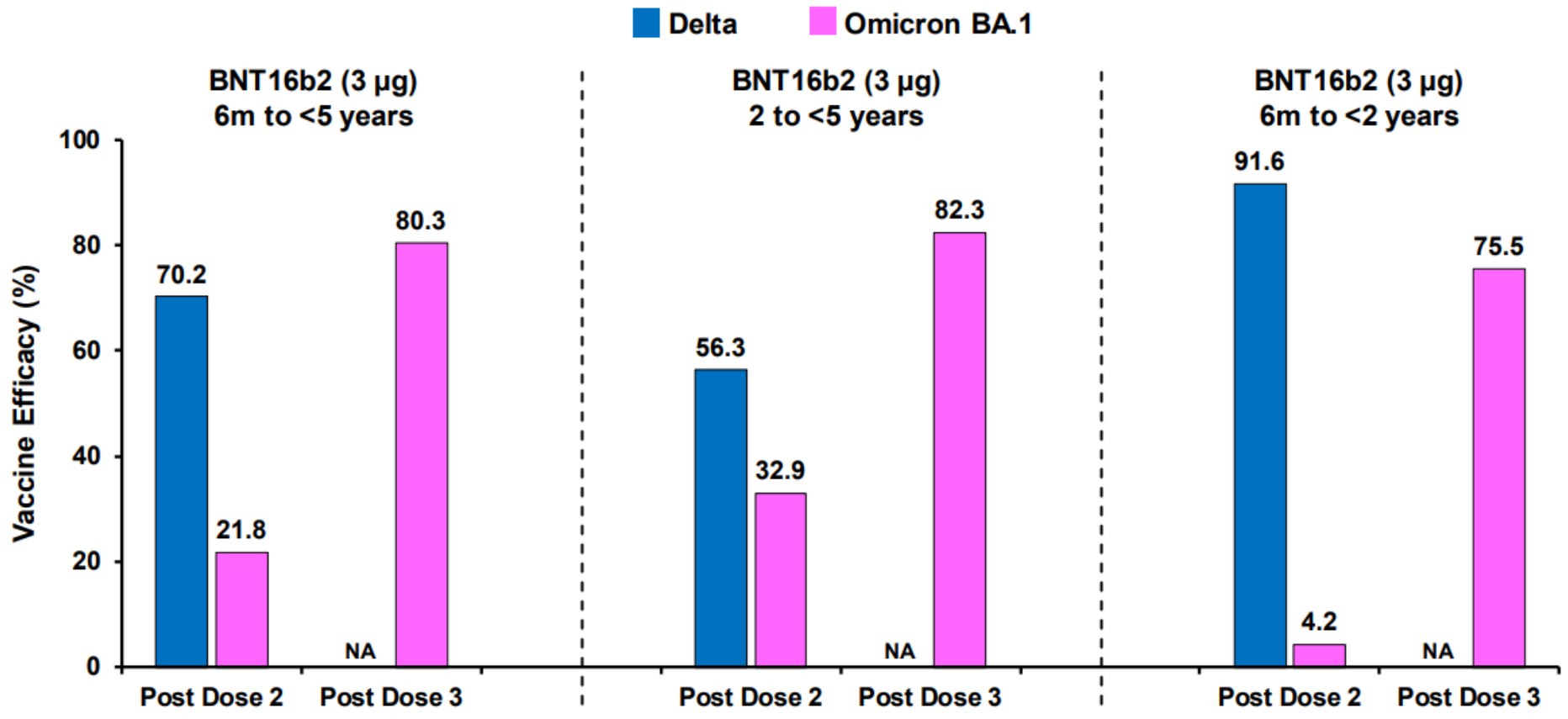
https://www.sfgate.com/coronavirus/article/bay-area-mask-mandate-results-17271294.php

Pfizer-BioNTech COVID-19 Vaccine Demonstrates Strong Immune Response, Efficacy and Favorable Safety in Children 6 Months to 5 Years of Age Following Third Dose

- Phase 2/3 trial evaluating a third 3-µg dose of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months to under 5 years of age. Following a third dose in this age group, the vaccine was found to elicit a strong immune response, with a favorable safety profile similar to placebo.
- Vaccine efficacy was 80.3% in children 6 months to under 5 years of age. This descriptive analysis was based on 10 symptomatic COVID-19 cases identified from seven days after the third dose and accrued as of April 29, 2022. The trial protocol specifies a formal analysis will be performed when at least 21 cases have accrued from seven days after the third dose.
- Final vaccine efficacy data will be shared once available.
- FDA has agreed that the vaccine is effective in this age group

https://www.fda.gov/media/159195/download

Pfizer was Effective Against Omicron



NA - Not applicable as Delta cases post Dose 3 did not occur during this time period.

CC-34

https://www.fda.gov/media/159258/download

Summary of Moderna COVID-19 Vaccine

Study 204: Infants, Toddlers and Young Children (6 Months - 5 Years)

Safety
(Primary Objective)

- mRNA-1273 was generally well-tolerated in this age group
  - Local and systemic reactions lower than older children and adults
  - Fever in ~25% of participants, mostly grade 1-2, short duration
- 1 related SAE of fever/seizure within 28 days

Immunogenicity
(Primary Objective)

- Pre-specified immunogenicity objectives met
- Vaccine immunogenic, GMCs and seroresponse rates non-inferior to young adults
  - *Children (2-5 years):* GMC ratio 1.01 & difference in seroresponse rates -0.4
  - *Infants/Toddlers (6-23 months):* GMC ratio 1.28 & difference in seroresponse rates 0.7
- Vaccine effectiveness successfully inferred based on immunogenicity

Efficacy
(Secondary Objective)

- Demonstrated efficacy against COVID-19, 14 days after dose 2, during Omicron period
  - *Children (2-5 years):* 36.8% (CDC definition) & 46.4% (Study 301 definition)
  - *Infants/Toddlers (6-23 months):* 50.6% (CDC definition) & 31.5% (Study 301 definition)
- Consistent with adult effectiveness against Omicron
- Boosters are under evaluation

https://www.fda.gov/media/159257/download

Are the Vaccines Safe?

- Yes. During the clinical trials, side effects were minimal:
  - For 6-23 month olds, irritability (65% Moderna vs. 44% Pfizer) and drowsiness (40% Moderna vs. 20% Pfizer) were most common.
  - For 2-5 year olds, pain at injection site were most common (60-70% Moderna vs. 27% Pfizer), followed by fatigue.
- For Moderna, 1 in 4 experienced a fever. Side effects were more common after Dose 2.
- For Pfizer, 1 in 20 experienced a fever, and side effects for Dose 3 were similar to Dose 2.
  - The higher rate of Moderna side effects is likely due to the higher dosage of RNA.
- No myocarditis cases were reported in either clinical trial.

Does my child *actually* need the vaccine?

- As of June 7, 2022, COVID-19 has caused >13.1 million cases among children and adolescents ages 0–17 years
- Omicron surge led to the highest numbers of COVID-19 cases, emergency department visits, and hospitalization rates seen during the pandemic
- Children and adolescents are at risk of severe illness from COVID-19 – More than half of hospitalized children ages 6 months–4 years had no underlying conditions
- During Omicron predominance, COVID-19 associated hospitalizations among children ages 6 months–4 years have similar or increased severity compared to older children and adolescents
- Burden of COVID-19 hospitalization is similar to or exceeds that of other pediatric vaccine preventable diseases
- COVID-19 pandemic continues to have significant impact on families and increases disparities

The case for vaccinating children < 5 years

- Severe COVID-19 occurs in children <5 years of age
  - As of May 2022, 45,000 hospitalizations (24% require ICU) and 475 deaths
  - Roughly 50% of these hospitalizations were likely due to Omicron
  - Burden comparable to influenza –for which children are routinely immunized
- Severe COVID-19 outcomes are unpredictable and can occur in healthy children
  - 64% of hospitalizations in children <5 years occur in those without comorbidities
- COVID-19 can cause additional long-term sequelae in children
  - 3–6% of children report continued symptoms for >12 weeks
- Pandemic adversely impacts developmental and psychosocial well-being

What Conversations Should Be Happening

- IF Unvaccinated:
  - COVID is still a SERIOUS problem
  - The vaccines have been proven safe and effective at preventing severe illness
- IF lacking a 3rd or 4th dose:
  - Current variants require another dose
  - Immunity wanes, if older or immunucompromised a 4th dose is needed
- Children:
  - COVID is still a problem and previous illness may or may not protect
  - Helps to protect other
- IN general:
  - COVID is here to stay, protect yourself!

Questions?

Thank you!

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

Resources & recording of the session

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

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