COVID-19 Series for Free & Charitable Clinics

June 16, 2022

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AT THE FOREFRONT UChicago Medicine

Vaccinate with Confidence

A National Strategy to Reinforce Confidence in COVID-19 Vaccines

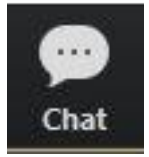
CDC's Strategy: **Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

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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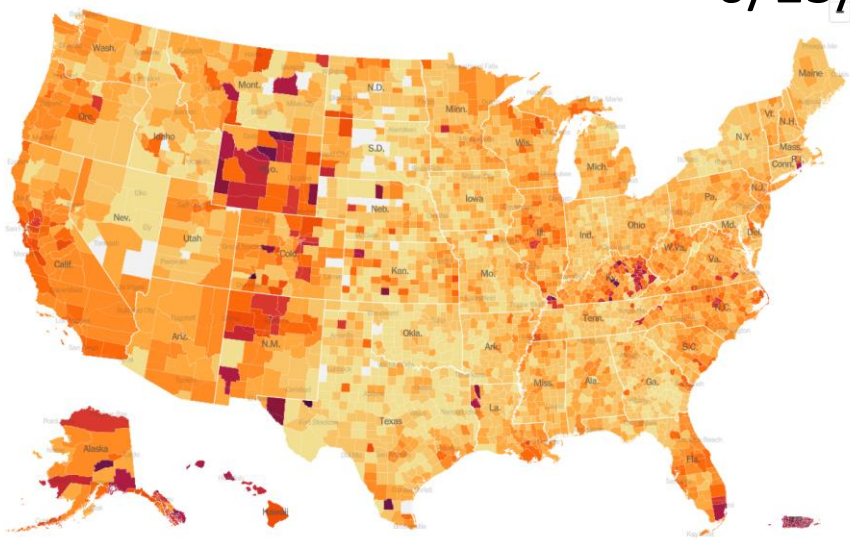
Disclosures

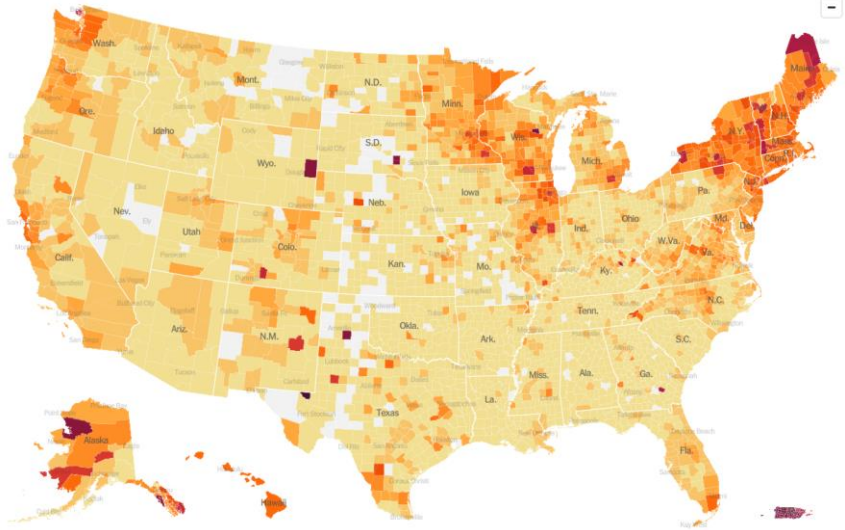
- We have no relevant financial interests to disclose.

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

6/15/22

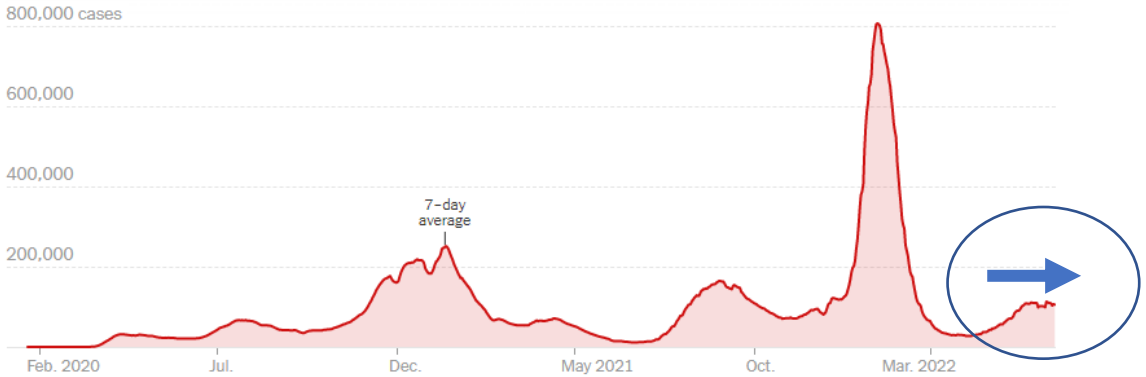


5/11/22

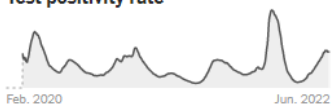


New reported cases

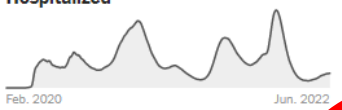
All time | Last 90 days



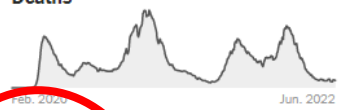
Test positivity rate



Hospitalized



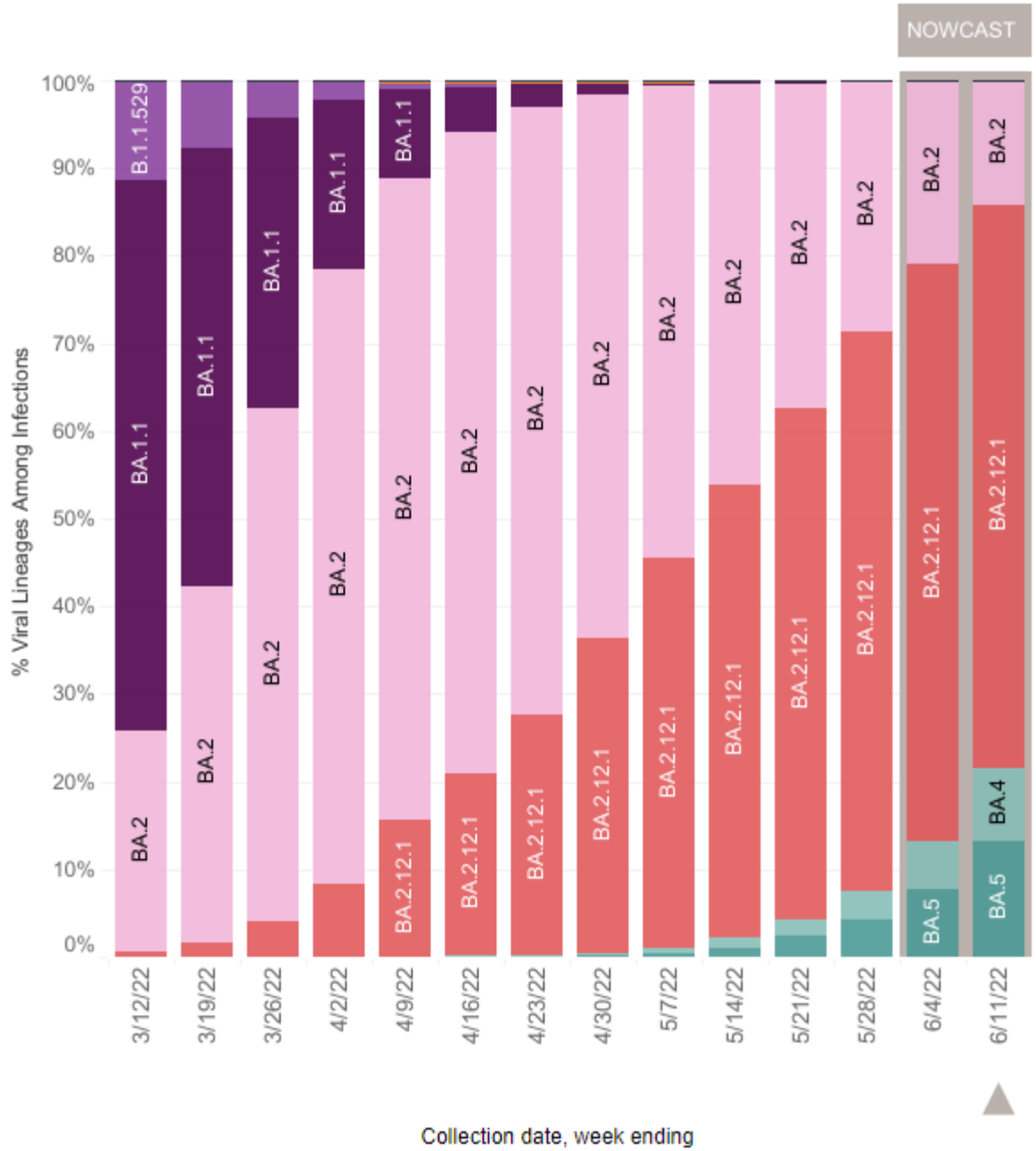
Deaths



	DAILY AVG. ON JUN. 14	14-DAY CHANGE	TOTAL REPORTED
Cases	105,605	+7%	85,703,699
Test positivity	14%	—	—
Hospitalized	29,728	+8%	—
In I.C.U.s	3,263	+12%	—
Deaths	322	+8%	1,008,554

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

United States: 3/6/2022 – 6/11/2022



United States: 6/5/2022 – 6/11/2022 NOWCAST

USA

WHO label	Lineage #	US Class	%Total	95%PI
Omicron	BA.2.12.1	VOC	64.2%	59.9-68.3%
	BA.2	VOC	14.2%	12.7-15.9%
	BA.5	VOC	13.3%	10.0-17.4%
	BA.4	VOC	8.3%	6.3-10.7%
	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%	0.0-0.1%

* 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
# 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 and its sublineages, BA.2 sublineages are aggregated with BA.2. BA.5.1 is aggregated with BA.5.

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
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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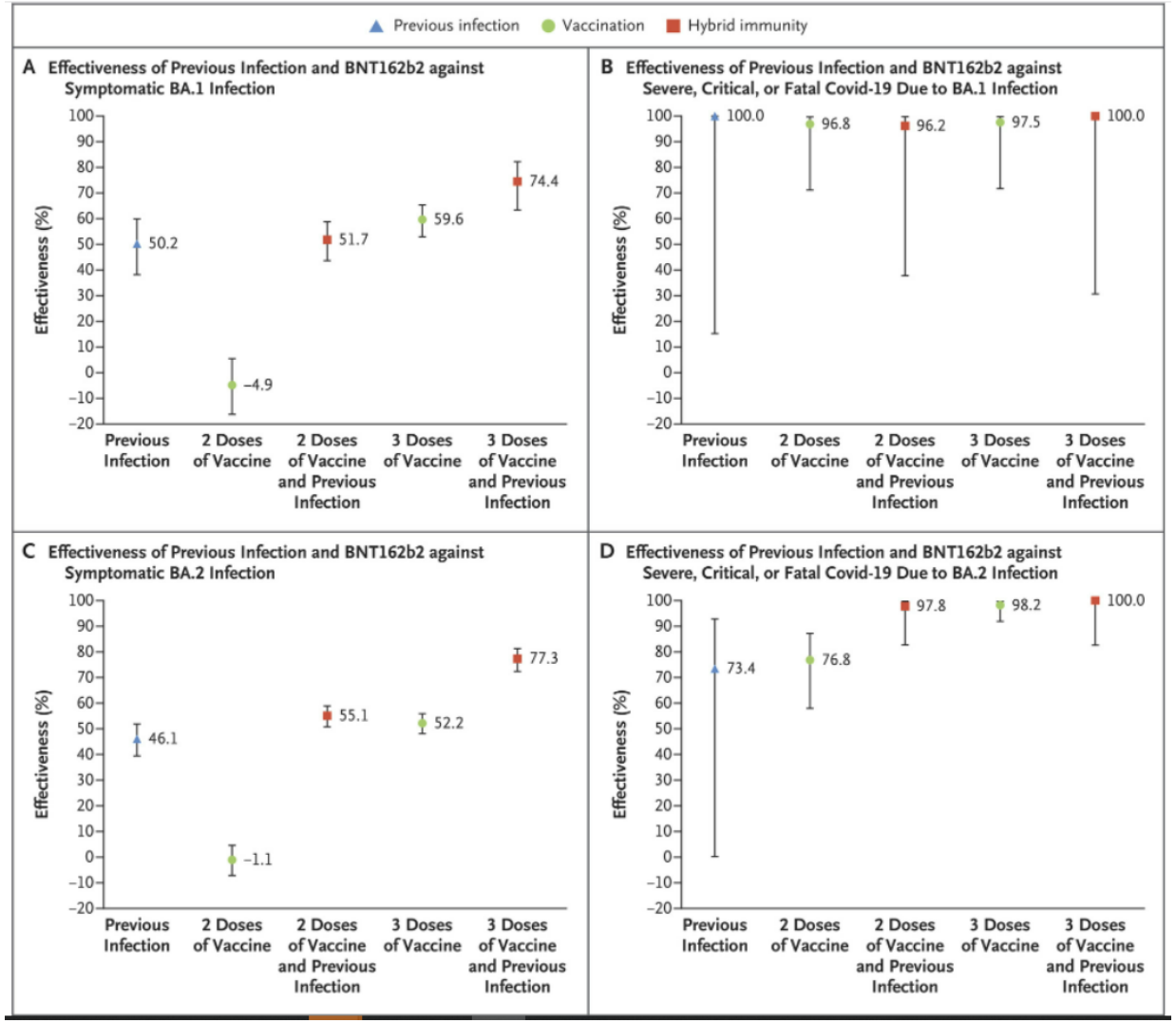
Vaccines Hold Up

- Case–control study in Qatar from December 23, 2021, through February 21, 2022
- Previous infection alone, BNT162b2 vaccination alone, and hybrid immunity all showed strong effectiveness (>70%) against severe, critical, or fatal Covid-19 due to BA.2 infection
- No notable differences were observed in the effectiveness against BA.1 and BA.2 of previous infection, vaccination, and hybrid immunity.
- Protection from previous infection with variants other than omicron against reinfection was moderate and durable, but protection of primary-series vaccination against infection was negligible by 6 months after the second dose.
- Recent booster vaccination had moderate effectiveness, whereas hybrid immunity from previous infection and recent booster vaccination conferred the strongest protection against infection, at approximately 80%.
- All five forms of immunity were associated with strong and durable protection against Covid-19–related hospitalization and death



June 15, 2022
DOI: 10.1056/NEJMoa2203965

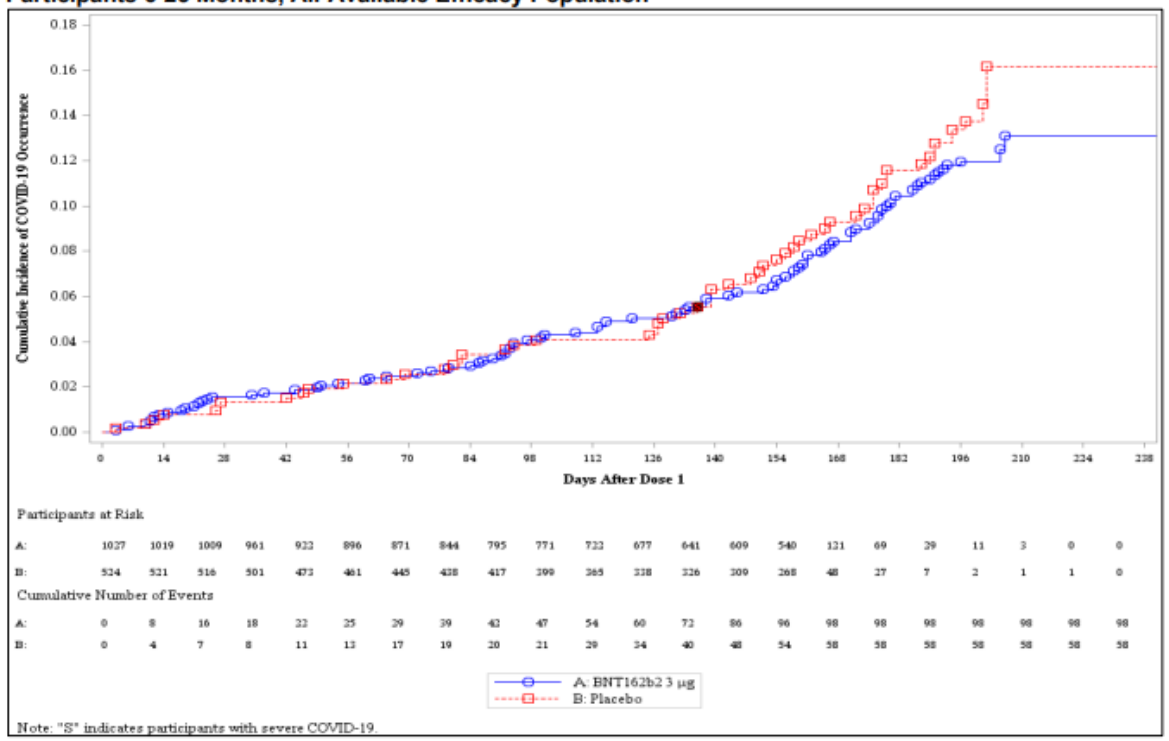
Pfizer-BioNTech COVID-19 Vaccine Demonstrates Strong Immune Response, Efficacy and Favorable Safety in Children 6 Months to 5 Years of Age Following Third Dose

- 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

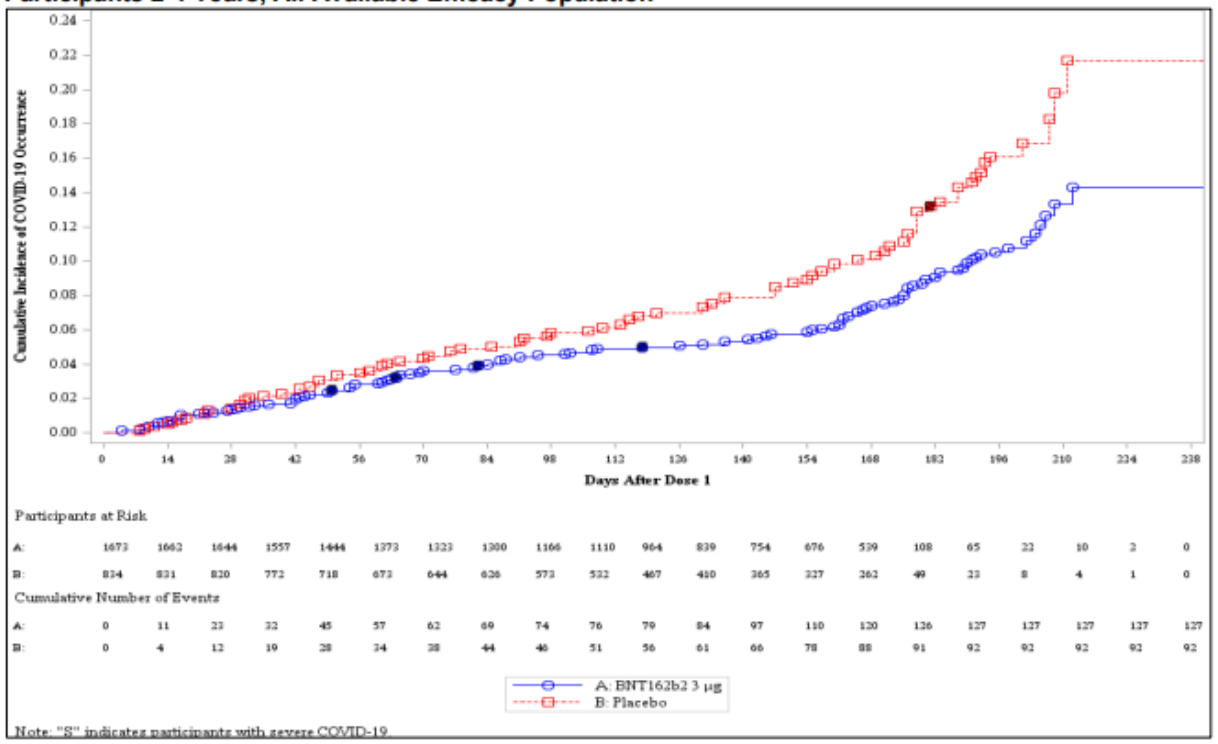
It takes time to do a study like this…

Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Participants 6-23 Months, All-Available Efficacy Population



Source: Source: EUA 27034.554 Efficacy 508 tables.

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Participants 2-4 Years, All-Available Efficacy Population



Source: Source: EUA 27034.554 Efficacy 508 tables.

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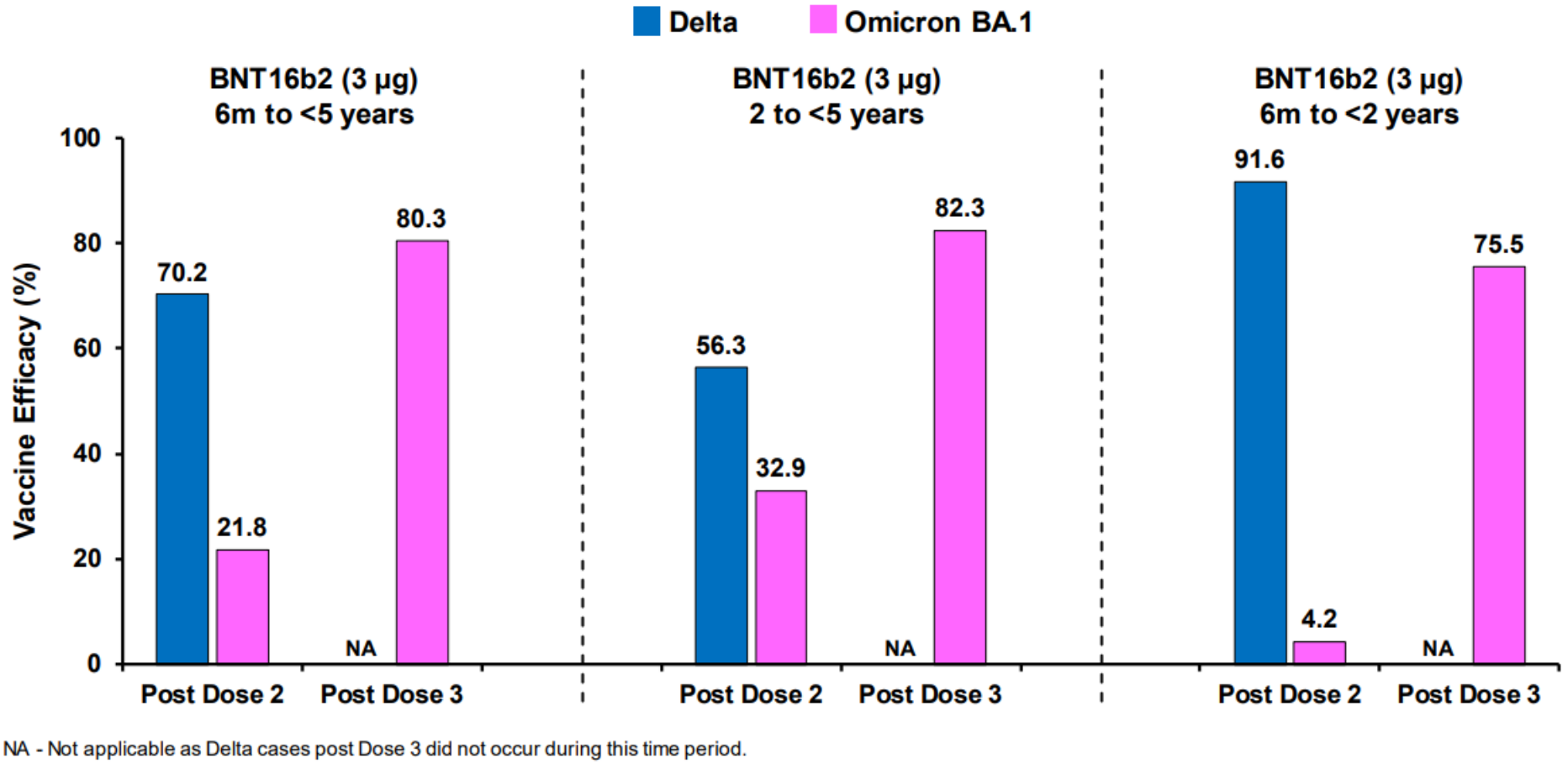
Pfizer was Effective Against Omicron



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

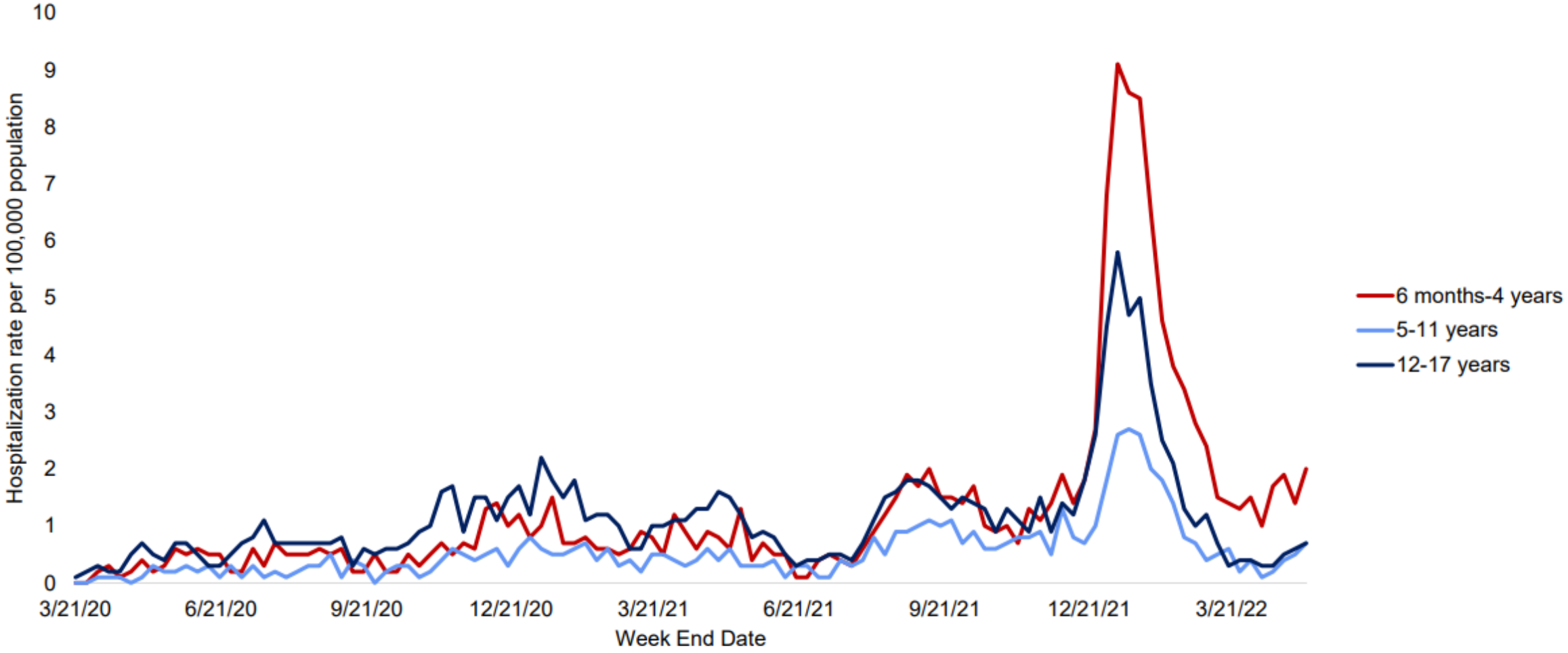
https://www.fda.gov/media/159257/download

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

COVID-19-associated hospitalizations among children and adolescents 6 months–17 years, COVID-NET

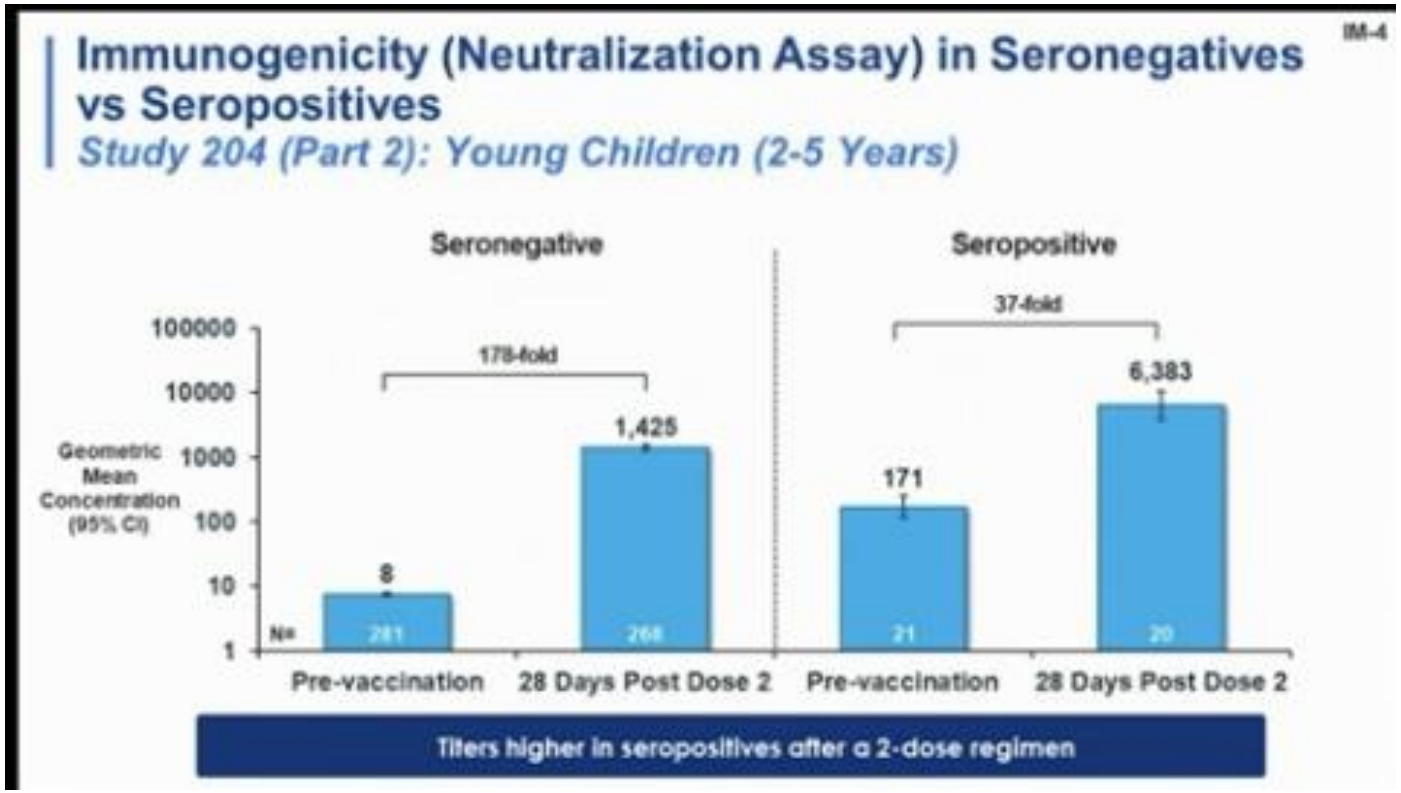
March 2020 – March 2022



Source: COVID-NET, https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. Accessed May 21, 2022.

What if my child was recently infected with COVID-19?

- Recent evidence has shown 32% of children failed to make anti-SARS CoV-2 antibodies following infection and T-cell response were also variable*



*DOI: https://doi.org/10.1016/j.immuni.2022.06.003

Variability between Moderna and Pfizer

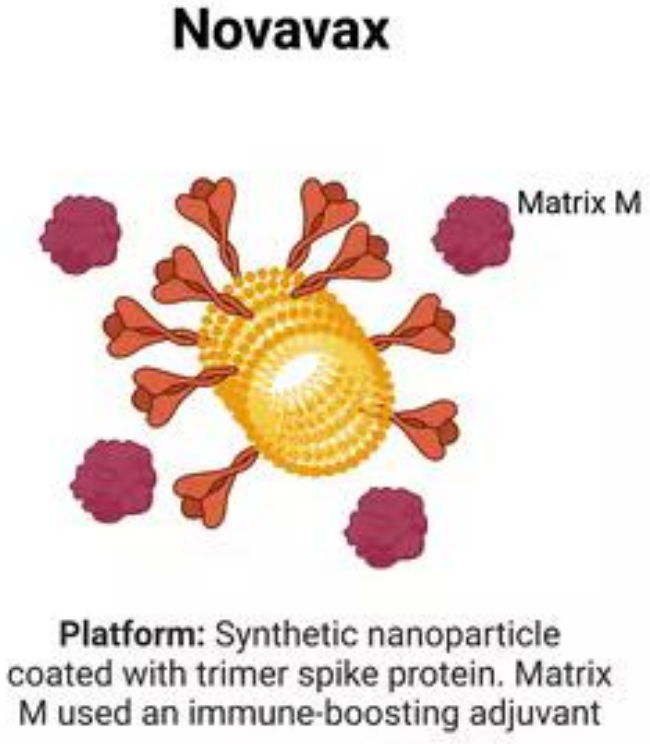
	Moderna	**Pfizer**
Ages	6 month-5 years	6 month – 4 years
# of kids in clinical trial	6,607 total 4,107 for 2-5 year old 2,500 for 6-23 months	4,526 total 2,750 for 2-4 year olds 1,776 for 6-23 months
Follow-up	2 months after dose 2	1.4 months after dose 3
Doses	2	3
Dosage of RNA	25 mcg	3 mcg

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.

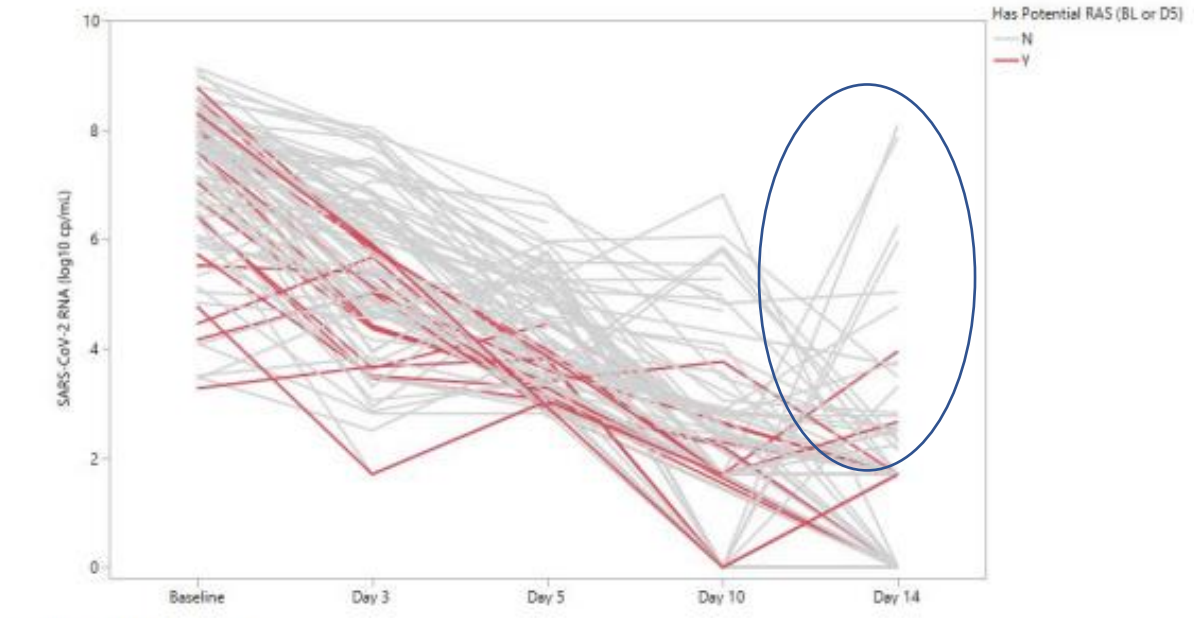
What about Novavax?

- The FDA's vaccine advisory committee recommended authorization of Novavax's protein subunit COVID-19 vaccine on June 7.
- Protein subunit vaccines utilize a more traditional development process, similar to existing vaccines for pertussis (whooping cough) and hepatitis B.
- The vaccine is 90.4 percent effective against laboratory-confirmed, symptomatic infection, and 100 percent effective against moderate and severe disease.
- Even though the FDA vaccine advisory committee voted to recommend emergency use authorization (EUA), the FDA will need additional time to review manufacturing changes.
- There is no confirmed release date for the Novavax COVID-19 vaccine.



Relapses After Paxlovid?

- Sequencing of SARS-CoV-2 from these cases did not demonstrate resistance mutations either at baseline or at relapse that correlated with resistance. Currently there are no clear signals of baseline or treatment-emergent NIR resistance from the preliminary analyses of clinical trial EPIC-HR.
- What to do? Treat longer? New medication? Continue to isolate?
- Seems to be uncommon, but need to understand which patients may relapse



Source: FDA analysis.

Rebound Phenomenon after Nirmatrelvir/Ritonavir Treatment of Coronavirus Disease-2019 in High-Risk Persons

- In a cohort of 483 high-risk patients treated with nirmatrelvir/ritonavir for coronavirus disease-2019:
  - 2 patients (0.4%) required hospitalization by day 30.
  - Four patients (0.8%) experienced rebound of symptoms, which were generally mild, at median of 9 days after treatment
  - All resolved without additional COVID-19-directed therapy

https://doi.org/10.1093/cid/ciac481

Paxlovid for Non-High Risk Patients?

- Pfizer revealed that a much-watched study of Paxlovid in patients who have COVID but don't have risk factors for severe disease failed to show a benefit in speeding alleviation of COVID symptoms, but did seem to prevent doctor's visits and hospitalizations.
- Additionally, because of the small number of hospitalizations overall in the study, it failed to produce a statistically significant finding on whether patients who had previously been vaccinated against COVID were hospitalized less often if they received Paxlovid.
- The results are likely to spur debates on how careful doctors should be in prescribing Paxlovid. Pfizer's profound early results came from a group of high-risk, unvaccinated patients. But the Food and Drug Administration authorized it for anyone with at least one risk factor such as diabetes or high blood pressure; anecdotally, doctors report that the drug is largely being used in high-risk vaccinated patients, especially amid a big push by the U.S. government to make sure the drug reaches all people indicated to get it.

https://www.statnews.com/2022/06/14/pfizers-paxlovid-study-fails-to-answer-key-questions-over-benefit-for-broader-populations/

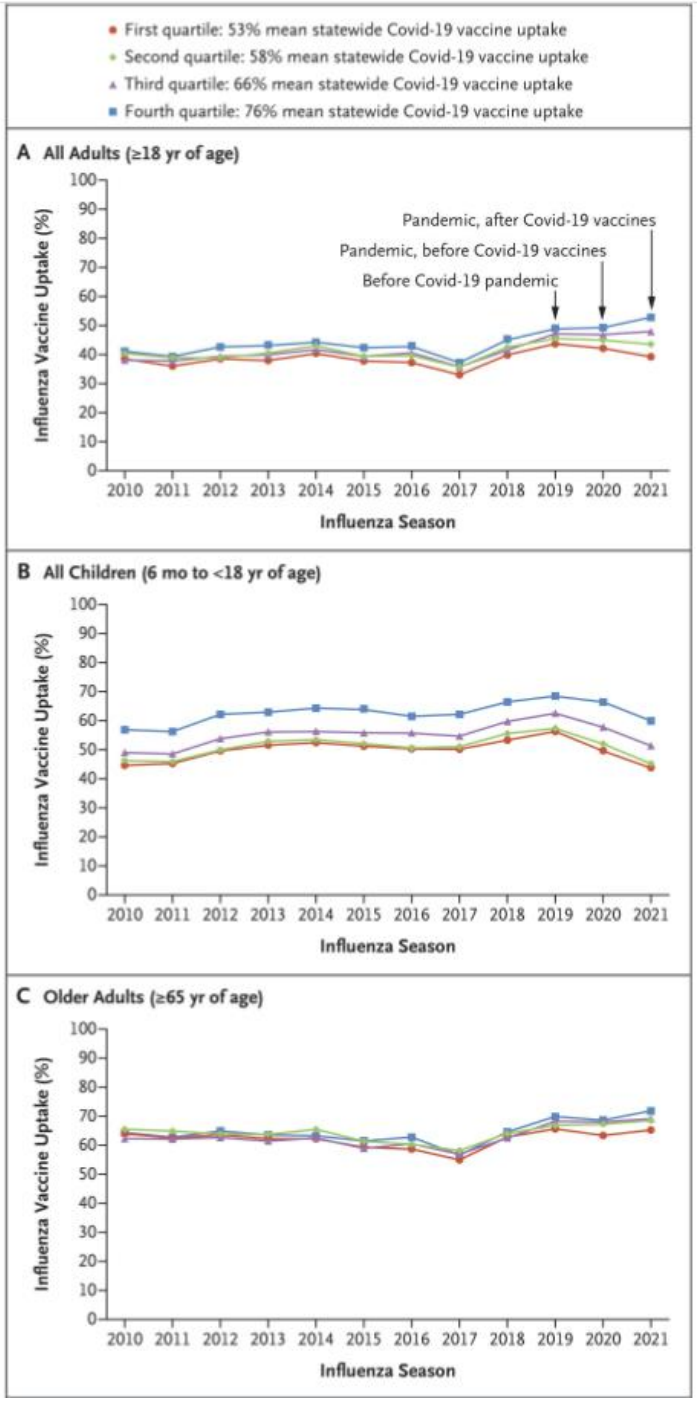
Is COVID-19 Becoming Endemic?

- en·dem·ic *adjective*
  1. (of a disease or condition) regularly found among particular people or in a certain area.
- **Endemicity ≠ Complacency**
- An endemic infection is one in which overall rates are static — not rising, not falling. More precisely, it means that the proportion of people who can get sick balances out the 'basic reproduction number' of the virus, the number of individuals that an infected individual would infect, assuming a population in which everyone could get sick. Yes, common colds are endemic. So are Lassa fever, malaria and polio.
- Does not suggest guaranteed stability: there can still be disruptive waves from endemic infections, as seen with the US measles outbreak in 2019. Health policies and individual behavior will determine what form — out of many possibilities — endemic COVID-19 takes.
- Thinking that endemicity is both mild and inevitable is more than wrong, it is dangerous: it sets humanity up for many more years of disease, including unpredictable waves of outbreaks

doi: https://doi.org/10.1038/d41586-022-00155-x

Association between Covid-19 Vaccination and Influenza Vaccination Rates

- The polarizing nature of vaccination against coronavirus disease 2019 (Covid-19) within the United States threatens public health and has contributed to variable statewide vaccine uptake that ranged from 50 to 80% as of January 2022. Given the divided national landscape and anecdotal evidence from our own patients, authors hypothesized that low Covid-19 vaccination rates would be associated with decreases in influenza vaccination rates.
- Areas that had more vaccine skepticism may have worsened



Questions?

Thank you!

Next Session: Thursday, July 14th ,12-1:15pm 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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