COVID-19 Series for Free & Charitable Clinics

September 8, 2022









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







Disclosures

• We have no relevant financial interests to disclose.

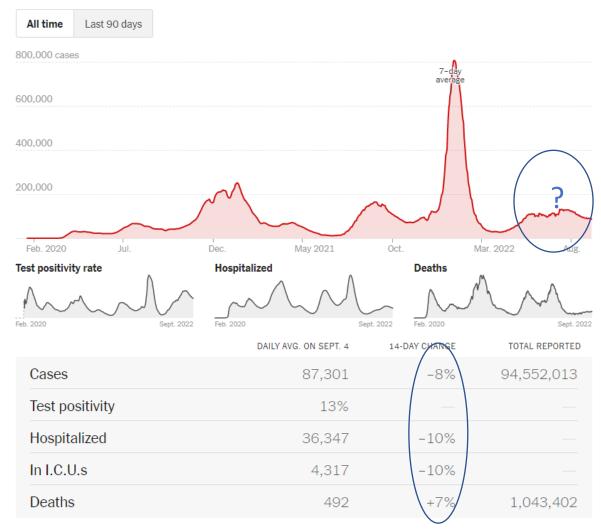


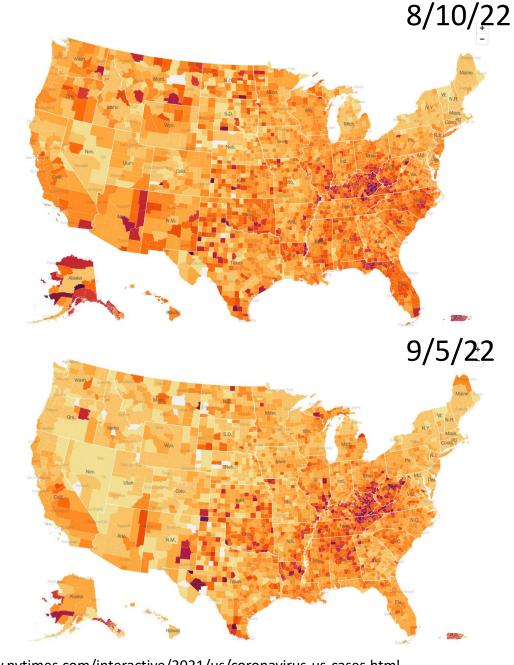




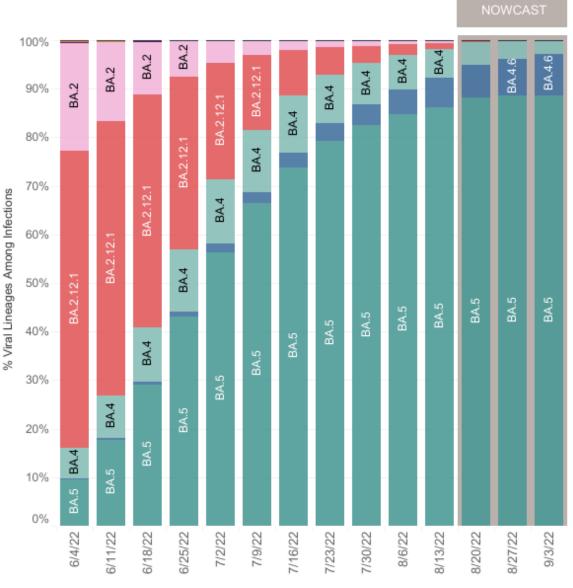
Coronavirus in the U.S.: Latest Map and Case Count

New reported cases





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



USA

WHO label	Lineage #	US Class	%Total	95%PI	
Omicron	BA.5	VOC	88.6%	87.0-90.0%	
	BA.4.6	VOC	8.4%	7.1-10.0%	
	BA.4	VOC	2.8%	2.6-3.0%	
	BA.2.12.1	VOC	0.1%	0.1-0.2%	
	BA.2	VOC	0.0%	0.0-0.0%	
	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%	

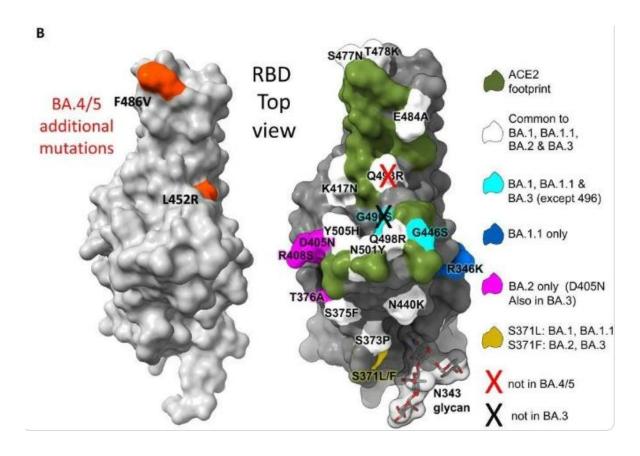
^{*} Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.</p>

^{**} 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. Except BA.4.6, sublineages of BA.4 are aggregated to BA.4. Sublineages of BA.5 are aggregated to BA.5.

Further antibody escape by Omicron BA.4 and BA.5 from vaccine and BA.1 serum

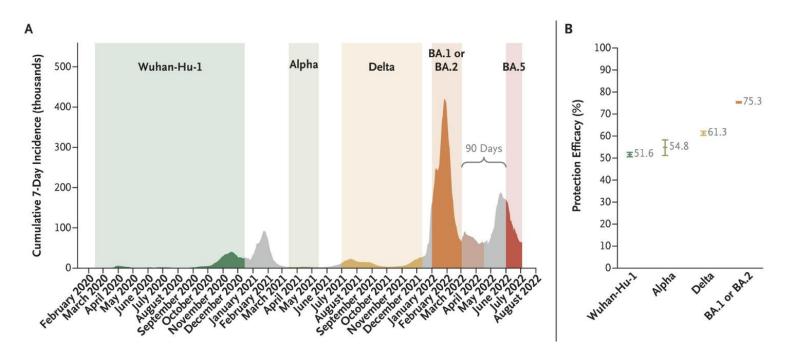
- BA.4/5 shows reduced neutralization by serum from triple AstraZeneca or Pfizer vaccinated individuals compared to BA.1 and BA.2.
- Using serum from BA.1 vaccine breakthrough infections there are likewise, significant reductions in the neutralization of BA.4/5, raising the possibility of repeat Omicron infections.



doi: https://doi.org/10.1101/2022.05.21.492554

Risk of BA.5 Infection following Previous Infection

 Retrospective study of Portugal showed that infection with BA.1/BA.2 of a population mostly vaccinated provided significant protection against BA.5 reinfection



Here Come the Next Iteration of COVID Vaccines!

- On August 31, FDA authorized Bivalent COVID-19 vaccines from Pfizer/BioNTech and Moderna
- On September 1, CDC recommended the same
- Currently only authorized as a "booster" for those >12 years, if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose



- What sort of data have the companies collected?
 - Human data are only available for the companies' boosters targeted to BA.1. At a June meeting of FDA's vaccine advisory committee, both the Pfizer-BioNTech collaboration and Moderna presented data showing that the shots had side effects similar to those of the original vaccines—including soreness at the injection site and fatigue—and induced strong antibody responses to both the original strain and Omicron BA.1. The companies also showed that the BA.1 vaccines prompted significant antibody responses to BA.4 and BA.5, although lower than that to BA.1.
 - For the BA.4/BA.5 boosters, the companies have submitted animal data. They have not released those data publicly, although at the June FDA meeting, Pfizer presented preliminary findings in eight mice given BA.4/BA.5 vaccines as their third dose. Compared with the mice that received the original vaccine as a booster, the animals showed an increased response to all Omicron variants tested: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5.

What do the new boosters contain?

• The new vaccines are bivalent. Half of the mRNA codes for the spike protein of the ancestral virus strain that emerged in Wuhan, China, in late 2019, which is also in the original shots; the other half codes for the spike protein in BA.4 and BA.5 (which have identical spikes.) Because they contain a lower dose of mRNA, the shots are meant to be used as boosters only, and not in people who were never vaccinated.

- How can authorities consider authorizing vaccines without data from human trials?
 - Similar to Influenza vaccine approval
 - Don't have to undergo new clinical trials unless the manufacturers significantly change the way they make the vaccine
 - Potential downside: Authorizing updated vaccines without clinical data could lower public acceptance

- Why do the new vaccines still contain mRNA targeting the ancestral strain, which is long gone?
 - Not clear.
 - Some studies showed the monovalent Omicron was more effective at producing neutralizing antibodies – even in Pfizer's own data!
 - However, the next variant to emerge might be more closely related to the ancestral strain than to Omicron, so the bivalent formula could be a useful hedge

- Will the strain-specific mRNA lead to better protection?
 - THE Question!
 - Depends in part on how much BA.4 and BA.5 are still circulating by the time the shots are delivered and how closely the next dominant strain matches them. It also depends on how many people have immunity from a recent infection
 - Recent preprint, meta-analysis by Cromer and colleagues* found that the biggest
 effect came from administering any booster: On average, an additional dose of a
 vaccine coding for the ancestral virus' spike protein resulted in an 11-fold increase in
 neutralizing antibodies against all variants. But strain-specific vaccines improved
 things slightly. Recipients of updated vaccines had, on average, antibody levels 1.5
 times higher than those who received an ancestral strain vaccine. Even if the vaccine
 didn't exactly match the viral strain, there was still some benefit

• If the benefits are limited, do we really need the new boosters?

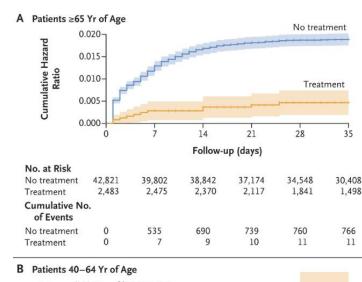
- Most say "yes"
- Strain-adapted boosters had some benefit at the population level as well, according to Cromer's models, although much depends on the existing levels of immunity in a population. If, for example, a population already has 86% protection against severe disease, ancestral-strain boosters could increase that to 98%, and updated boosters to 98.8%. That might not sound like much, Cromer admits, "but if you have a large population and limited hospital beds it can make a difference."
- Some disagree: Paul Offit at CHOP, believes the current vaccines are already successful at limiting severe disease and the new vaccines will do little to reduce new infections because of the short incubation period of COVID-19.

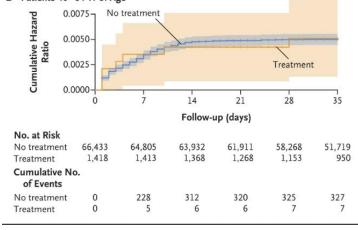
Where to Get the New Booster

- The new shots are free of charge to receive, for now. Here's where you can get them if you're eligible:
 - Walgreens began offering both Pfizer and Moderna's new boosters on Friday, 9/2. The shots haven't reached all of the chain's locations yet, but new appointments are being added daily. You can view and schedule appointments on the Walgreens website, on the pharmacy's app or by calling 1-800-WALGREENS.
 - **CVS** also began offering both updated boosters on Friday, 9/2. Its online system allows you to schedule multiple patients at once, which could make it easier for your family to get vaccinated together. You can schedule those appointments on the CVS website or on the pharmacy's app.
 - Multiple states including Massachusetts, New Jersey and Colorado have websites to help you find other clinics with new boosters in stock. Check your state's health department website to see if it's offering similar resources.
 - <u>Vaccines.gov</u> currently has sites offering updated boosters.
- Biden administration has secured 171 million doses of the new boosters, including 105 million from Pfizer and 66 million from Moderna should meet demand.

Nirmatrelvir Use and Severe Covid-19 Outcomes during the Omicron Surge

- Israeli study of 109,254 patients met the eligibility criteria, of whom 3902 (4%) received nirmatrelvir
- Among patients 65 years of age or older, the rate of hospitalization was 14.7 cases per 100,000 person-days among treated patients as compared with 58.9 cases per 100,000 person-days among untreated patients (adjusted hazard ratio, 0.27; 95% confidence interval [CI], 0.15 to 0.49).
- The adjusted hazard ratio for death due to Covid-19 was 0.21 (95% CI, 0.05 to 0.82).
- Among patients 40 to 64 years of age, the rate of hospitalization due to Covid-19 was 15.2 cases per 100,000 person-days among treated patients and 15.8 cases per 100,000 person-days among untreated patients (adjusted hazard ratio, 0.74; 95% CI, 0.35 to 1.58). The adjusted hazard ratio for death due to Covid-19 was 1.32 (95% CI, 0.16 to 10.75).
- During the omicron variant surge, among adults 65 years of age or older, the
 rates of severe Covid-19 outcomes were significantly lower among those who
 received nirmatrelvir than among those who did not receive nirmatrelvir.
 However, no evidence of benefit was found in younger adults.





Updated CDC Guidance on Isolation

https://www.cdc.gov/media/releases/2022/p0811-covid-guidance.html

- Continuing to promote the importance of being up to date with vaccination
- Updating its guidance for people who are not up to date on COVID-19 vaccines on what to do if exposed to someone with COVID-19. This is consistent with the existing guidance for people who are up to date on COVID-19 vaccines.
- Recommending that instead of quarantining if you were exposed to COVID-19, you wear a high-quality mask for 10 days and get tested on day 5.
- Reiterating that regardless of vaccination status, you should isolate from others when you have COVID-19.
 - You should also isolate if you are sick and suspect that you have COVID-19 but do not yet have test results.
 - If your results are positive, follow CDC's full isolation recommendations.
 - · If your results are negative, you can end your isolation.
- Recommending that if you test positive for COVID-19, you stay home for at least 5 days and isolate from others in your home. You are likely most infectious during
 these first 5 days. Wear a high-quality mask when you must be around others at home and in public.
 - If after 5 days, fever-free for 24 hours without the use of medication, and your symptoms are improving, or you never had symptoms, you may end isolation after day 5.
 - Regardless of when you end isolation, avoid being around people who are more likely to get very sick from COVID-19 until at least day 11.
 - You should wear a high-quality mask through day 10.
- Recommending that if you had <u>moderate illness</u> (if you experienced shortness of breath or had difficulty breathing) or <u>severe illness</u> (you were hospitalized) due to COVID-19 or you have a weakened immune system, you need to isolate through day 10.
- Recommending that if you had severe illness or have a weakened immune system, consult your doctor before ending isolation. Ending isolation without a viral test may not be an option for you. If you are unsure if your symptoms are moderate or severe or if you have a weakened immune system, talk to a healthcare provider for further guidance.
- Clarifying that after you have ended isolation, if your COVID-19 symptoms worsen, restart your isolation at day 0. Talk to a healthcare provider if you have questions about your symptoms or when to end isolation.
- Recommending screening testing of asymptomatic people without known exposures will no longer be recommended in most community settings.
- Emphasizing that physical distance is just one component of how to protect yourself and others. It is important to consider the risk in a particular setting, including local COVID-19 Community Levels and the important role of ventilation, when assessing the need to maintain physical distance.

Questions?

Thank you!

Next Session: Thursday, October 13th ,12-1 pm CST

Resources & recording of the session

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

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