COVID-19 Series for Free & Charitable Clinics

February 16, 2023









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 6 State Associations: to consult directly with clinic personnel in highly vulnerable areas with low vaccination rates.

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.



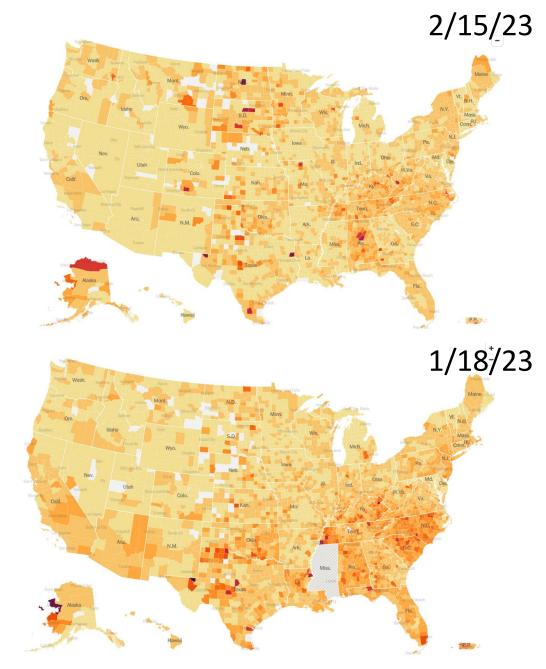




Coronavirus in the U.S.: Latest Map and Case Count

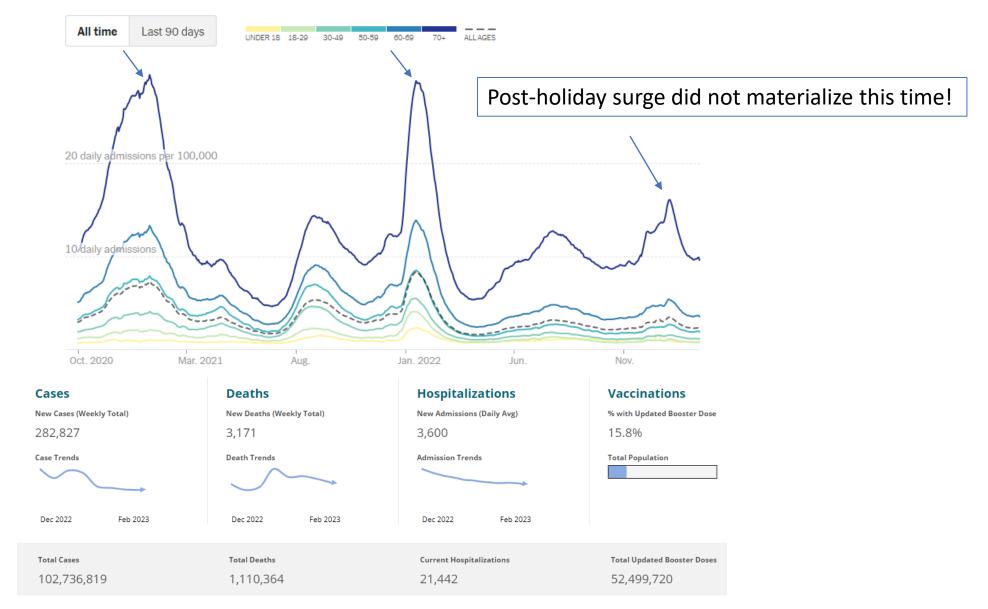
New reported cases

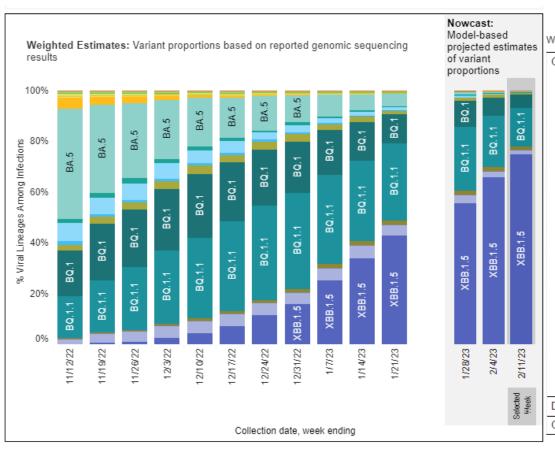




https://www.nytimes.com/interactive/2021/us/coronavirus-us-cases.html

Daily new hospital admissions by age



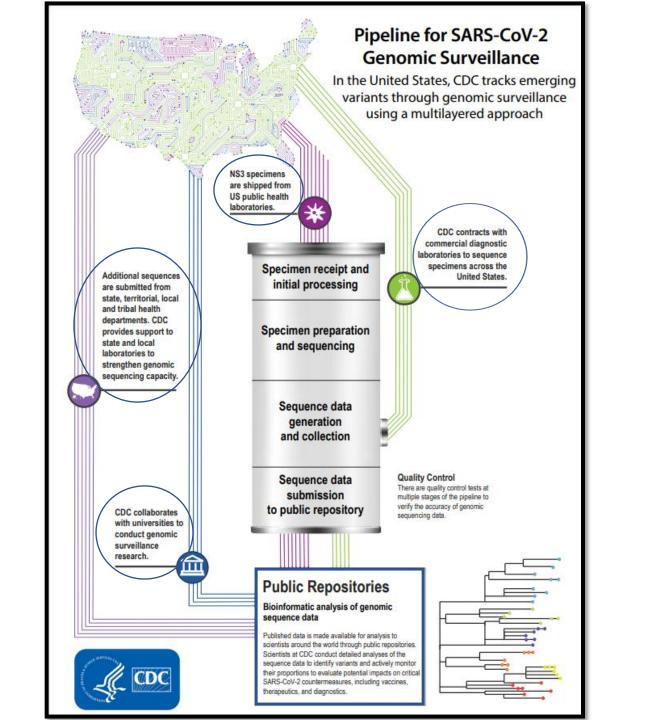


USA WHO label Lineage # US Class %Total 95%PI Omicron XBB.1.5 VOC 74.7% 67.0-81.2% 11.4-20.2% BQ.1.1 VOC 15.3% VOC 5.1% 3.7-6.8% BQ.1 XBB VOC 1.9% 1.4-2.5% CH.1.1 VOC 1.3% 0.9-1.9% BN.1 VOC 0.8% 0.5-1.1% BA.5 VOC 0.3% 0.2-0.5% BF.7 VOC 0.3% 0.2-0.4% BA.5.2.6 VOC 0.1% 0.1-0.2% BA.2 VOC 0.1% 0.0-0.1% BF.11 VOC 0.0% 0.0-0.1% BA.2.75 VOC 0.0% 0.0-0.0% 0.0-0.0% BA.2.75.2 VOC 0.0% BA.4.6 VOC 0.0% 0.0-0.0% B.1.1.529 VOC 0.0% 0.0-0.0% BA.2.12.1 VOC 0.0% 0.0-0.0% VOC 0.0% 0.0-0.0% BA.4 BA.1.1 VOC 0.0% 0.0-0.0% B.1.617.2 VBM 0.0% 0.0-0.0% Delta Other Other* 0.1% 0.0-0.1%

Wastewater Surveillance

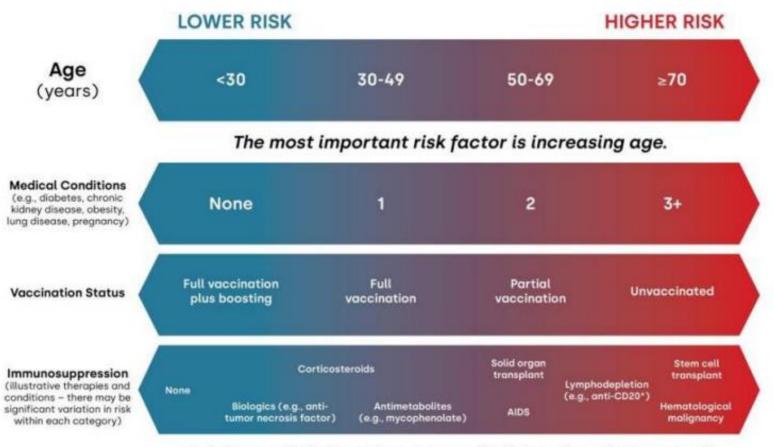
Relative Lineage Abundance, United States

Lineage #	% Sites
BA.2	9
BA.5	8
BQ.1	7
BQ.1.1	8
Other	16
XBB	10
XBB.1.5	43



COVID-19 Risk Continuum

COVID-19 Risk Continuum



Sociodemographic factors and non-pharmaceutical interventions affect exposure risk



If you have a weakened immune system or live with someone who does, create a COVID-19 action plan

Prevention Measures:

Get an updated COVID-19 vaccine



Improve ventilation and spend time outdoors



Learn about testing locations and treatment options **before** getting exposed or sick



Get tested if you've been exposed or have symptoms*



Wash your hands often



Wear a well-fitting mask and maintain distance in crowded spaces





*Talk to your doctor about treatment options if you test positive



	Current COVID-19 Variants of Concern	Fold Reduction in Susceptibility	
Omicron Variant (PANGO lineage)	Key Substitutions Tested	Bebtelovimab	Tixagevimab- cilgavimab
BA.1.1	BA.1 + R346K	No change	176
BA.2	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, S477N, T478K, E484A, Q493R, Q498R, N501Y, Y505H No change		5.4
BA.2.12.1	BA.2 + L452Q No c		5*
BA.2.75	BA.2 + D339H, G446S, N460K, R493Q (reversion)	No change	2.4-15*
BA.4	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H		33-65*
BA.5	G339D, S371F, S373P, S375F, T376A, D405N, R408S, K417N, N440K, L452R, S477N, T478K, E484A, F486V, Q498R, N501Y, Y505H		2.8-16
BA.4.6	BA.4 + R346T	No change	>1000*
BF.7	BA.4 + R346T		>5000*
BQ.1	BA.5 + K444T, N460K		>2000*
BQ.1.1	BA.5 + R346T, K444T, N460K	>672*	>2000*
XBB	BA.2 + R346T, L368I, V445P, G446S, N460K, F486S, F490S	Not promising	>1400*
XBB.1.5	XBB (F486P replaces F486S)	Not promising	>5000*

Source: FDA healthcare provider fact sheets. Last updated January 26, 2023 No change: < 5-fold reduction in susceptibility

^{*} Performed in pseudotyped virus-like particles rather than authentic SARS-CoV-2 virus



Proportion of Variants Susceptible: Bebtelovimab



Resistant variants: 80.1 + 80.1.1 + XB8 + XB8.1.3

Proportion of Variants Susceptible: Tixagevimab-Cilgavimab



Resistant variants: BQ.1 + BQ.1.1 + BF.7 + BA.4.6 + BA.2.75.2 + BA.5.2.6 + XBB + XBB.1.5

Last updated January 26, 2023



Small molecule antivirals anticipated to be active against new variants

	1) Nirmatrelvir/r	2) Remdesivir	3) Molnupiravir
Efficacy (hospitaliza- tion/death in unvaccinated, high risk)	•Relative risk reduction: 88% (EPIC-HR) •Absolute risk: 6.3%→0.8% •NNT: 18	 •Relative risk reduction: 87% (PINETREE) •Absolute risk: 5.3%→0.7% •NNT: 22 	 •Relative risk reduction: 30% (MOVe-OUT) •Absolute risk: 9.7%→6.8% •NNT: 35
Pros	Highly efficaciousOral regimenRitonavir studied (safe) in pregnancy	Highly efficaciousStudied in pregnancyFew/no drug interactions	 Oral regimen Not anticipated to have drug interactions
Cons	•Drug drug interactions	•Requires IV infusion on 3 consecutive days	 Lower efficacy Concern: mutagenicity Not recommended in pregnancy/children

RESEARCH SUMMARY

Early Treatment with Pegylated Interferon Lambda for Covid-19

Reis G et al. DOI: 10.1056/NEJMoa2209760

CLINICAL PROBLEM

Convenient, widely available, and effective therapies to treat Covid-19 in outpatients are needed. SARS-CoV-2 infection induces weak expression of naturally produced type III interferons — an early line of defense against respiratory viruses — in infected cells. Whether an exogenous source of interferons, such as pegylated interferon lambda, can treat early SARS-CoV-2 infection is unknown.

CLINICAL TRIAL

Design: A phase 3, adaptive platform, randomized, placebo-controlled trial assessed the efficacy and safety of pegylated interferon lambda in adult outpatients in Brazil and Canada who were at high risk for severe illness soon after they received a diagnosis of Covid-19.

Intervention: 1949 adults presenting within 7 days after symptom onset with a positive rapid test for SARS-CoV-2 and with at least one high-risk criterion (e.g., age ≥ 50 years, diabetes mellitus, and hypertension leading to the use of medication) were assigned to receive a single subcutaneous injection of pegylated interferon lambda (180 μg) or placebo. Most patients had received at least one dose of Covid-19 vaccine. The primary outcome was a composite of Covid-19–related hospitalization (or referral to a tertiary hospital) or admission to an emergency department (ED) (observation for >6 hours) within 28 days after randomization.

RESULTS

Efficacy: The risk of Covid-19-related hospitalization or an ED visit was approximately 50% lower in the interferon group than in the placebo group. Results were consistent regardless of vaccination status.

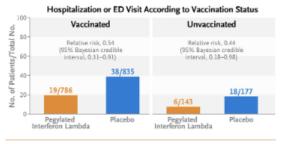
Safety: The incidence of adverse events was similar in the two groups.

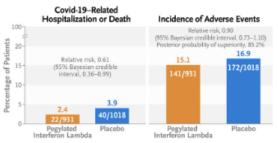
REMAINING QUESTIONS

 Since the completion of the trial, a polymorphism in the innate antiviral response gene OASI has been linked to clearance of SARS-CoV-2, and a common haplotype could indicate a greater likelihood of response to pegylated interferon lambda and other interferons.



Hospitalization or ED Visit within 28 Days 100 Relative risk, 0.49 (95% Bayesian credible interval, 0.30-0.76) Posterior probability of superiority, >99.9% 5.6 2.7 25/931 Pegylated Interferon Lambda Placebo





CONCLUSIONS

Among high-risk, symptomatic, largely vaccinated outpatients with a recent diagnosis of Covid-19, those who received a single subcutaneous injection of pegylated interferon lambda had a lower risk of Covid-19–related hospitalization or an ED visit within 28 days than those who received placebo.

The best treatment for COVID-19 could be the one you can't get

- 1. Efficacy shown even in vaccinated people
- 2. Worked across all variants
- 3. Dropped viral loads faster
- 4. Side effects comparable to placebo
- 5. "One and done" treatment
- 6.No drug interactions
- 7. Might work against other viral infections too!

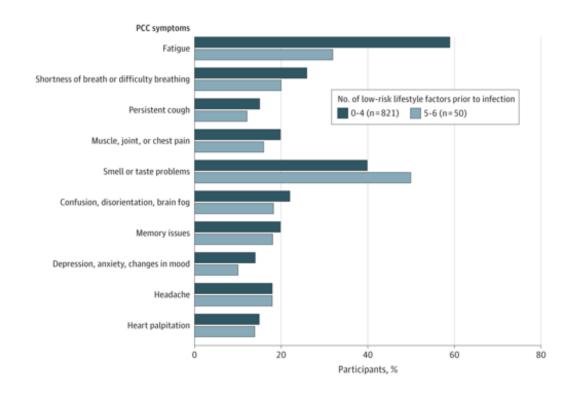
https://www.bostonglobe.com/2023/02/10/opinion/best-treatment-covid-19-could-be-one-you-cant-get/

Masks Don't Work?

- Recent publication of updated Cochrane Review suggests wearing masks in the community cast doubt on masking's ability to reduce the spread of viral infections
- Meta analysis performed on 78 RCTs (11 new ones since 2020)
- The studies were heterogenous some in non-epidemic settings, some with H1N1 in 2009
 - Apples and oranges were analyzed together -- If apples work but oranges don't, combining all studies in a single average figure may lead to the conclusion that apples do not work.
- Adherence to mask wearing was questionable in many studies analyzed
- Paper's conclusion: There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes.

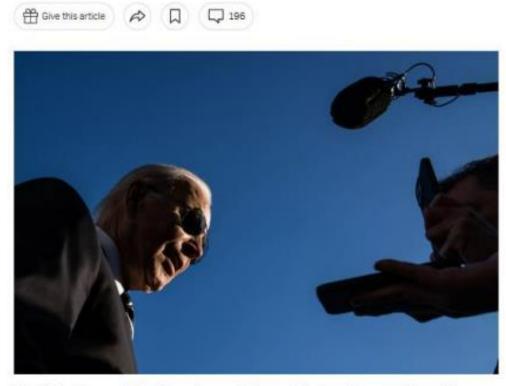
The Best Defense Against Long COVID?

- The findings of this prospective cohort study indicate that adherence to a healthy lifestyle was associated with substantially reduced risk of developing PCC among individuals subsequently infected with SARS-CoV-2. If the associations we found were causal, among healthy lifestyle factors, maintaining a healthy weight and having adequate sleep duration may confer the greatest benefit for prevention of PCC.
- A total of 1981 women with a positive SARS-CoV-2 test over 19 months of follow-up were documented. Among those participants, mean age was 64.7 years (SD, 4.6; range, 55-75); 97.4% (n = 1929) were White; and 42.8% (n = 848) were active health care workers. Among these, 871 (44.0%) developed PCC. Healthy lifestyle was associated with lower risk of PCC in a dose-dependent manner.



U.S. Plans to End Public Health Emergency for Covid in May

The end of the emergency, planned for May 11, will bring about a complex set of policy changes and signals a new chapter in the government's pandemic response.



The White House said that the nation needed an orderly transition out of the public health emergency, which has been in effect for all of President Biden's time in office. Haiyun Jiang/The New York Times

End of Public Health Emergency

What it means for free and charitable clinics

Ending of Public Health Emergency

- On May 11, 2023, the Biden Administration will end the public health emergency declarations
- The administration does not have additional funding for COVID-19 testing, vaccination, or treatment unless authorized by Congress

COVID-19 Testing

 Most significant immediate change will be increased cost and decreased access to testing

- At-home and in-office tests will no longer be free for most people
 - For those on Medicaid, tests are covered at no cost through Sept 2024
 - Subject to cost-sharing for those with insurance
 - Free tests to uninsured will not be federally funded

COVID-19 Treatment

- Any doses of treatment (ie Paxlovid) purchased by the federal government are still free until federal supply is depleted
- Medicaid will cover COVID-19 treatment through Sept 30, 2024

COVID-19 Vaccines

- No significant changes at this time
 - Availability of vaccines is determined by supply of federally purchased vaccines and not the public health emergency
 - Providers of federally purchased vaccine CANNOT charge patients
- When federal supply runs out
 - Patients with Medicaid, Medicare, and private insurance will have access to free vaccines
 - Access for uninsured remains questionable
- FDA emergency use authorizations are not tied to the public health emergency

Other Changes

Telemedicine

- Prescriptions for controlled substances require an in-person visit again
- Some states with temporary waivers for out-of-state providers to provide telehealth will expire
- Telemedicine will be restricted to HIPPA compliant technology and products

Data availability

- DHHS will no longer have the authority to require labs to report COVID-19 testing results
- Decrease ability to calculate percent positivity

Other Changes

- Millions of people who gained access to Medicaid may loose it
 - Families First Coronavirus Response Act: Required state Medicaid programs to keep people continuously enrolled until PHE ends to receive enhanced federal funding
 - Since February 2020, Medicaid enrollment increased by 19.8 million (27.9%)
 - States can begin disenrollment in April
 - 5-14 million expected to loose Medicaid as a result

Planning for FCCs

- Encourage patients to take advantage of options for free at-home tests now, request and stock up
- Explore options for affordable in-office testing
- Encourage vaccination while vaccination is free
- Education and outreach
 - Re-enrollment efforts for individuals still eligible for Medicaid
 - Resources for individuals no longer eligible for Medicaid
- Consider data resources available and adjusting safety plans to account for limited percent positivity data

Questions?

Thank you!

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

Resources & recording of the session

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

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