Monthly Healthcare Provider & Public Health Partner Webinar

Discuss Emerging Public Health Topics

March 9, 2023



Next Webinar is **April 13**th

- We will continue to have these webinars on a monthly cadence (2nd Thursday of each month from 12-1pm)
- These "Public Health Grand Rounds" webinars will transition to broader topics
- Dr. Talbot will provide an update on:
 - H5N1 Avian Influenza
 - Emerging infectious diseases diagnostics



Topics for Today's Discussion

- Epidemiology update
- U.S. Public Health Emergency Ending May 11, 2023
- COVID-19 treatment
- Future of COVID-19 vaccination in the U.S.
- COVID-19 vaccine effectiveness (VE) data/studies
- Mpox vaccination (JYNNEOS) and treatment

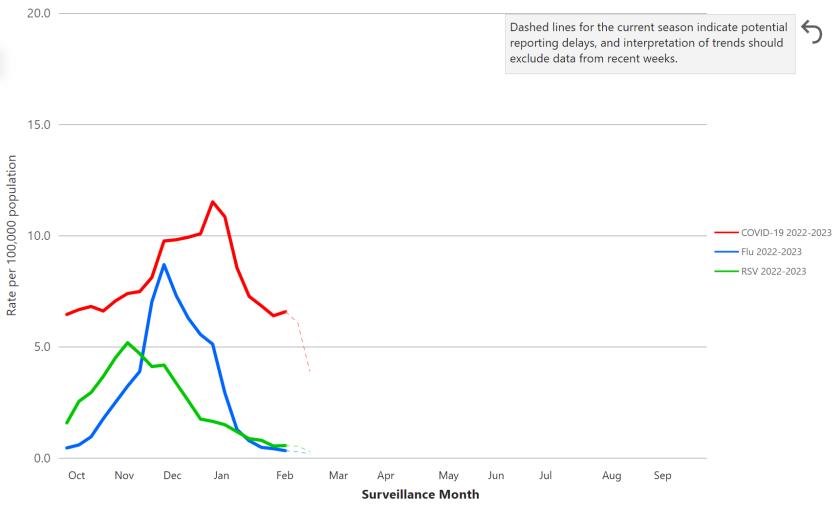


Epidemiology Update

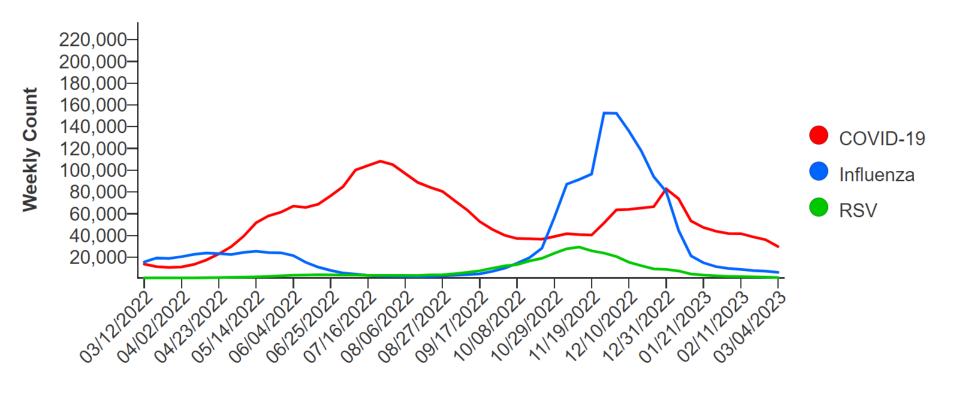


RESP-NET: National Hospitalizations for COVID-19, Influenza, & RSV

Weekly Rates of Respiratory Virus-Associated Hospitalizations by Season



National Emergency Department Visits for COVID-19, Influenza, & RSV



End Date of MMWR Week

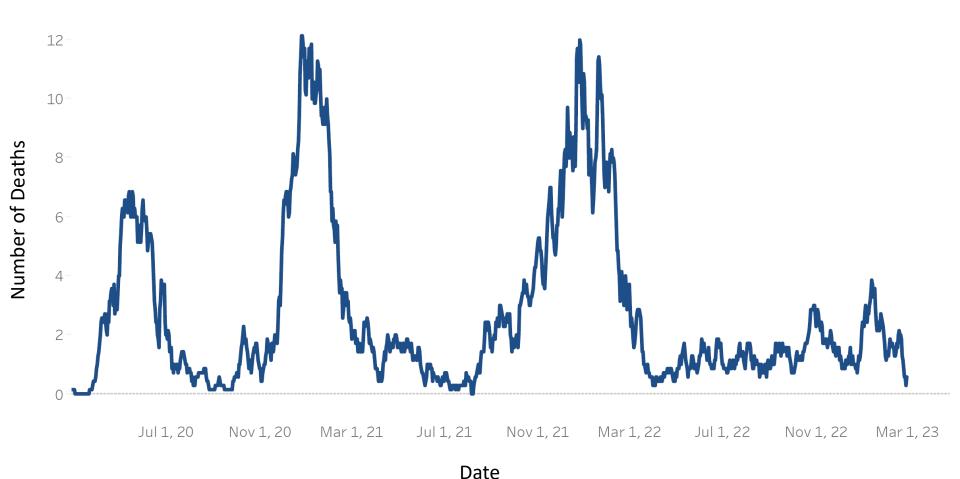


Number of People Hospitalized & Treated for COVID-19 Each Day in NH





Average Number of COVID-19 Deaths Each Day in NH (Based on Date of Death)



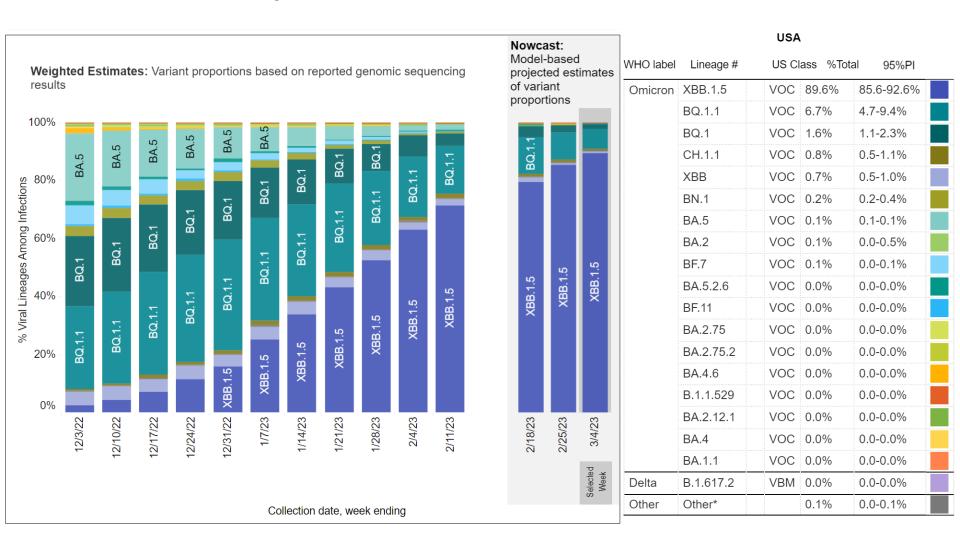
U.S. Public Health Emergency Ends May 11, 2023



COVID-19 Treatment



Variant Proportions in the U.S.

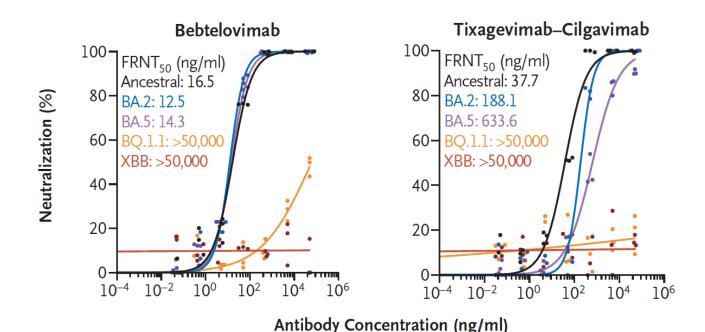


Efficacy of Antiviral Agents against Omicron Subvariants BQ.1.1 and XBB

Ancestral strain: SARS-CoV-2/UT-NC002-1T/Human/2020/Tokyo
 Omicron BQ.1.1: hCoV-19/Japan/TY41-796/2022
 Omicron XBB: hCoV-19/Japan/TY41-795/2022

Omicron BA.5: hCoV-19/Japan/TY41-702/2022

A Neutralizing Activity of Monoclonal Antibodies

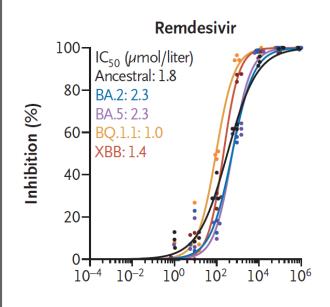


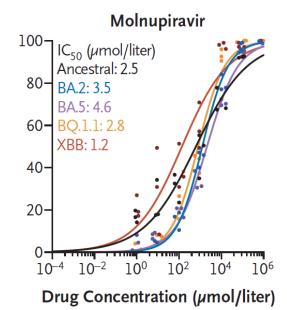


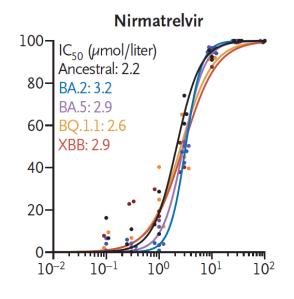
Efficacy of Antiviral Agents against Omicron Subvariants BQ.1.1 and XBB

Ancestral strain: SARS-CoV-2/UT-NC002-1T/Human/2020/Tokyo
 Omicron BA.2: hCoV-19/Japan/UT-NCD1288-2N/2022
 Omicron BA.5: hCoV-19/Japan/TY41-702/2022

B Inhibitory Activity of Antiviral Drugs







Outpatient Management of Non-Hospitalized Adults with COVID-19

Last Updated: December 28, 2022

Patient Disposition	Panel's Recommendations					
All Patients	 All patients should be offered symptom management (AIII). The Panel recommends against the use of dexamethasone^a or other system corticosteroids in the absence of another indication (AIIb). 					
Patients Who Are at High Risk of Progressing to Severe COVID-19 ^b	Preferred therapies. Listed in order of preference: • Ritonavir-boosted nirmatrelvir (Paxlovid) ^{c,d} (Alla) • Remdesivir ^{d,e} (Blla)					
	Alternative therapy. For use when the preferred therapies are not available, feasible to use, or clinically appropriate: • Molnupiravir ^{d,f,g} (Clla)					



Outpatient Management of Non-Hospitalized Children with COVID-19

Last Updated: December 28, 2022

Risk of Severe	Panel's Recommendations						
COVID-19	Aged 12–17 years	Aged <12 years					
Symptomatic, Regardless of Risk Factors	• Provide supportive care (AIII).	Provide supportive care (AIII).					
High Risk ^{a,b}	 Use 1 of the following options (listed in order of preference):^c Ritonavir-boosted nirmatrelvir (Paxlovid) within 5 days of symptom onset (BIII) Remdesivir within 7 days of symptom onset (CIII) 	 Ritonavir-boosted nirmatrelvir is not authorized by the FDA for use in children aged <12 years. There is insufficient evidence to recommend either for or against the routine use of remdesivir. Consider treatment based on age and other risk factors. 					
Intermediate Risk ^{b,d}	There is insufficient evidence to recommend either for or against the use of any antiviral therapy. Consider treatment based on age and other risk factors.	There is insufficient evidence to recommend either for or against the routine use of remdesivir.					
Low Risk ^{b,e}	Manage with supportive care alone (BIII).	Manage with supportive care alone (BIII).					





Free telehealth for COVID-19 treatment with Paxlovid

Telehealth is a quick and easy way to see if Paxlovid, a COVID-19 treatment pill, is right for you.

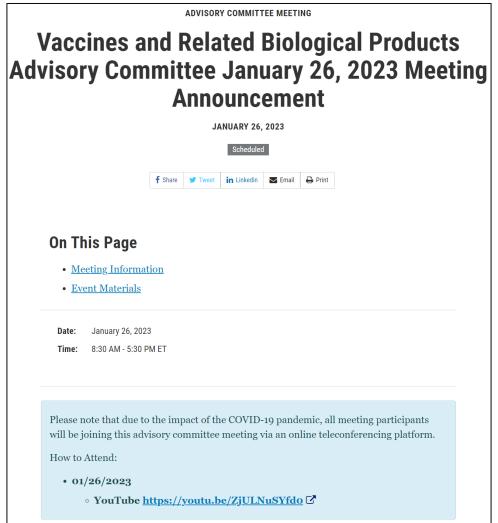




Future of COVID-19 Vaccination



FDA's Jan 26th VRBPAC Meeting Discussed the Future of COVID-19 Vaccination





Summary of FDA VRBPAC Discussion

- COVID-19 vaccination should change so that vaccines used for primary series and booster vaccination contain the same virus strain composition (note: this has NOT yet occurred)
- Original monovalent vaccines are still effective at protecting against severe disease, but emerging evidence is showing that vaccines with updated strain compositions are more effective
- Therefore, vaccines should be updated yearly to include most current circulating strain(s)
- ACIP met February 24th to discuss potential future COVID-19 vaccine recommendations



ACIP February 24th Meeting Discussion

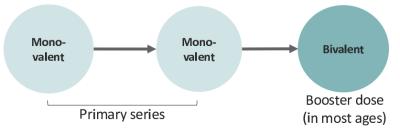
Question for consideration

Does ACIP support harmonizing the vaccine strain composition for mRNA COVID-19 vaccines across both primary series and booster doses: Changing the primary series from monovalent (Original) to bivalent (Original plus Omicron BA.4/5) for all ages?

Current recommendations

(Simplified representation)

People ages 6 months and older*

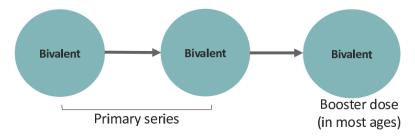


^{*}Ages and vaccines as authorized by FDA and recommended by ACIP/CDC

For children ages 6 months-4 years of age who start a Pfizer-BioNTech primary series, the third dose in a 3-dose primary series is a bivalent dose

Future proposed recommendations

People ages 6 months and older*



^{*}Ages and vaccines as authorized by FDA and recommended by ACIP/CDC

For children ages 6 months-4 years of age who start a Pfizer-BioNTech primary series, 3-dose primary series still needed 45



Number of mRNA COVID-19 vaccine products currently

Moderna: 5 products

Pfizer-BioNTech: 6 products





11 TOTAL Products!



Possible number of mRNA COVID-19 vaccine products with a bivalent primary series

Moderna: 2 products

Pfizer-BioNTech: 3 products











Could be reduced to 5 total products



Would eliminates look-alike vials for Moderna and Pfizer-BioNTech



Considerations for future planning

COVID-19 vaccines

- COVID-19 vaccines continue to be the most effective tool we have to prevent serious illness, hospitalization and death from COVID-19
- Goal of COVID-19 vaccine program continues to be prevention of severe disease
 - Prevention of post-COVID conditions, increased confidence in social interactions important as well
- Benefits of additional COVID-19 vaccine booster doses vary by age, time since last dose, and COVID-19 incidence
- A simplified, annual recommendation could help reduce vaccine and message fatigue
- A COVID-19 vaccine framework that is similar to a well understood influenza vaccine framework could be easy for COVID-19 vaccine providers to implement, and for the public to understand



Summary of Likely Future COVID-19 Vaccination Strategy

- Same vaccine formulation/composition for both primary series and booster dosing (lead to a fewer number of mRNA vaccine products)
- Simplified vaccine recommendations with yearly boosting for at least certain higher-risk populations (if not a broader booster recommendation for everybody)
- Details of future vaccine recommendations still need to be developed, but healthcare providers should plan for COVID-19 boosting again in the Fall (timing and exact recommendations are unclear)



COVID-19 Vaccine Effectiveness (VE) Data/Studies



NH COVID-19 Vaccination by Age Group

Age Group	Completed COVID-19 Vaccine Primary Series No. (% of population)	Received COVID-19 Bivalent Omicron Booster No. (% of population)
6 months – 4 years	4,374 (7%)	1,019 (2%)
5 – 11 years	30,970 (32%)	6,072 (6%)
12 – 17 years	54,889 (58%)	10,823 (12%)
18-64 years	631,990 (74%)	156,784 (18%)
65+ years	256,698 (>99%)	146,188 (58%)



Systematic Review & Meta-Analysis: 2-Dose mRNA Vaccine Efficacy in Children 5-11 Years

A SARS-CoV-2 infections with or without symptoms

Study or subgroup	log OR	SE	IV, random OR (95% CI)		Favors vaccinated	Favors unvaccinated	Weight, %
Amir et al, ³⁶ 2022	-0.84	0.12	0.43 (0.34-0.54)	_	-		16.7
Cohen-Stavi et al, ³² 2022	-0.73	0.03	0.48 (0.45-0.51)		-		18.2
Creech et al, ¹⁹ 2022	-1.35	0.24	0.26 (0.16-0.42)				12.7
Fowlkes et al, ¹³ 2022	-0.37	0.14	0.69 (0.52-0.91)			_	16.0
Sacco et al, ³⁵ 2022	-0.34	0.007	0.71 (0.70-0.72)		-		18.4
Tan et al, ³⁴ 2022	-1.05	0.04	0.35 (0.32-0.38)		-		18.1
Total (95% CI)			0.47 (0.35-0.64))			100.0
Heterogeneity: $\tau^2 = 0.13$; $\chi^2 = 443.99$; $df = 5$ ($P < .001$); $I^2 = 99\%$ Test for overall effect: $z = 4.84$ ($P < .001$)			0.01	0.1 IV, random	1 10 OR (95% CI)	100	

B Symptomatic SARS-CoV-2 infections

Study or subgroup	log OR	SE	IV, random OR (95% CI)	Favors vaccinated	Favors unvaccinated	Weight, %
Cohen-Stavi et al, ³² 2022	-0.65	0.05	0.52 (0.47-0.57)			28.8
Creech et al, ¹⁹ 2022	-2.12	0.50	0.12 (0.05-0.32)			6.1
Fleming-Dutra et al, 31 2022	-0.34	0.03	0.71 (0.66-0.76)			29.2
Fowlkes et al, ¹³ 2022	-0.09	0.31	0.91 (0.50-1.66)			12.2
Klein et al, ²⁰ 2022	-0.62	0.17	0.54 (0.39-0.75)	-		20.8
Walter et al, 15 2022	-2.41	0.77	0.09 (0.02-0.41)	- 		2.9
Total (95% CI) 0.53 (0.41-0.70)			♦		100.0	
Heterogeneity: $\tau^2 = 0.06$; $\chi^2 = 48.26$; $df = 5$ ($P < .001$); $I^2 = 90\%$ Test for overall effect: $z = 4.52$ ($P < .001$)			0.01 0.1 IV, random	1 10 OR (95% CI)	100	



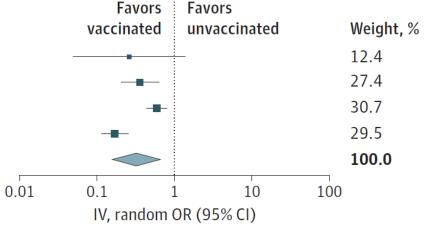
Systematic Review & Meta-Analysis: 2-Dose mRNA Vaccine Efficacy in Children 5-11 Years

Hospitalizations due to COVID-19-related illnesses

Study or subgroup	log OR	SE	IV, random OR (95% CI)
Klein et al, ²⁰ 2022	-1.35	0.84	0.26 (0.05-1.35)
Price et al, ¹⁴ 2022	-1.02	0.28	0.36 (0.21-0.62)
Sacco et al, ³⁵ 2022	-0.53	0.14	0.59 (0.45-0.78)
Tan et al, ³⁴ 2022	-1.77	0.20	0.17 (0.12-0.25)
Total (95% CI)			0.32 (0.15-0.68)
	2 26 50 16	2 / 5 0	01) 1) 000/

Heterogeneity: $\tau^2 = 0.44$; $\chi^2 = 26.50$; df = 3 (P < .001); $I^2 = 89\%$

Test for overall effect: z = 3.00 (P = .003)



Multisystem inflammatory syndrome in children

			IV, random		Favor	s F	avors
Study or subgroup	log OR	SE	OR (95% CI)	_	vaccinate	d u	invaccinated
Block et al, ³⁸ 2022	-3.22	0.41	0.04 (0.02-0.09)				
Zambrano et al, ¹² 2022	-2.41	0.91	0.09 (0.02-0.54)		-		
Total (95% CI)			0.05 (0.02-0.10)	<			
Heterogeneity: $\tau^2 = 0$; $\chi^2 = 0$	Heterogeneity: $\tau^2 = 0$; $\chi^2 = 0.65$; $df = 1$ ($P = .42$); $I^2 = 0$ %					1	10
Test for overall effect: $z = 8$.17 (P<.001	.)			IV. rando	m OR	(95% CI)



100

Weight, %

83.0 17.0

100.0

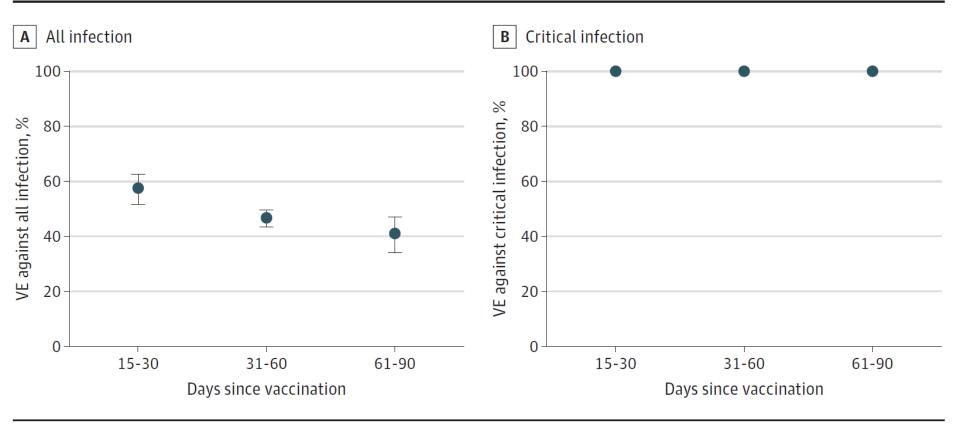
RESEARCH LETTER

BNT162b2 Vaccine Effectiveness Against the SARS-CoV-2 Omicron Variant in Children Aged 5 to 11 Years

- Cohort study in South Korea
- Study during Omicron surge: March 31, 2022 August 6, 2022
- Studied Pfizer-BioNTech VE in Children 5-11 years
- Required testing when developed fever or respiratory symptoms or had contact with an infected person



Figure. Adjusted Vaccine Effectiveness (VE) Against All SARS-CoV-2 Infection and Critical Infection



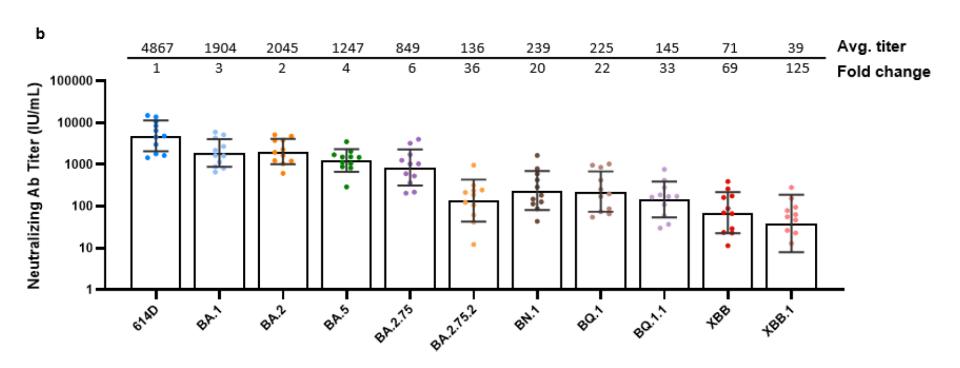


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Neutralizing Ab Titers After Bivalent Booster Vaccination by Variant

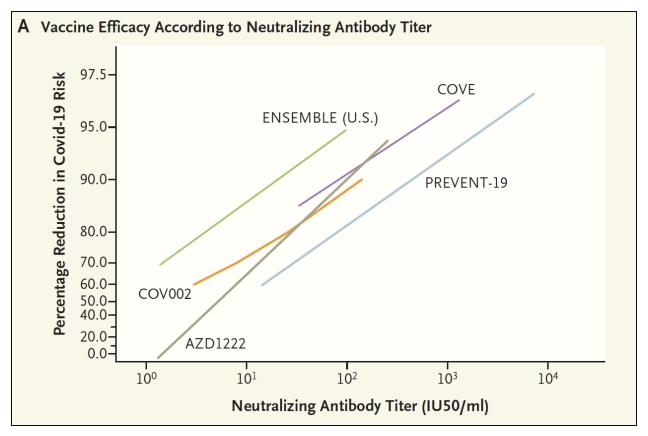




Perspective



A Covid-19 Milestone Attained — A Correlate of Protection for Vaccines



 Neutralizing antibody levels are correlated with vaccine effectiveness at preventing <u>symptomatic COVID-19</u> (no specific threshold identified)

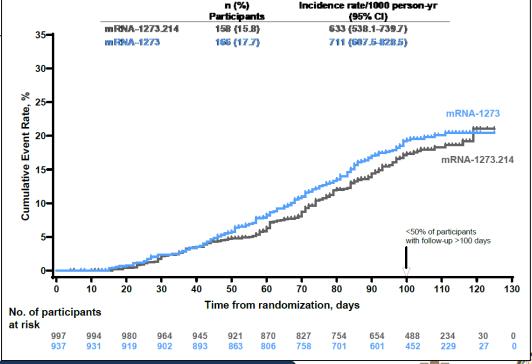
Moderna UK RCT Comparing Bivalent BA.1 vs. Original Monovalent Vaccine Booster

Conclusion

The bivalent omicron BA.1 containing booster elicited superior neutralizing antibody responses against omicron BA.1 with acceptable safety results consistent with the BA.1 monovalent vaccine. Incidence rates for Covid-19 were numerically lower in participants who received

mRNA-1273.214 compared to the original booster vaccine mRNA-1273, driven by the BA.2 and

BA.4 sublineages.



Relative VE of a Bivalent Booster Against BA.5 and XBB Symptomatic Infection (compared to persons who received 2-4 monovalent doses)

		SARS-CoV-2	SARS-CoV-2–positive test results by S-gene target status					
		negative test results		TF <mark>.5-related</mark>)		TP <mark>B.1.5-related</mark>)		
Age group, yrs/mRNA dosage pattern [†]	Total no of tests	No. (row %)	No. (row %)	VE (95% CI)	No. (row %)	VE (95% CI)		
18-49								
Received 2–3 monovalent doses only (Ref)§	13,921	7,043 (51)	5,326 (38)	_	1,552 (11)	_		
Overall (≥2 weeks since bivalent booster dose)	4,199	2,864 (68)	1,027 (24)	52 (48-56)	308 (7)	49 (41-55)		
0–1 month since bivalent booster	1,056	716 (68)	262 (25)	51 (43-58)	78 (7)	50 (36-61)		
2–3 months since bivalent booster	3,143	2,148 (68)	765 (24)	52 (48–56)	230 (7)	48 (39–55)		
50-64								
Received 2–4 monovalent doses only (Ref)	4,603	2,036 (44)	1,983 (43)	_	584 (13)	_		
Overall (≥2 weeks since bivalent booster dose)	2,038	1,182 (58)	656 (32)	43 (36-49)	200 (10)	40 (28-50)		
0–1 month since bivalent booster	538	336 (62)	149 (28)	54 (43-63)	53 (10)	45 (25-60)		
2–3 months since bivalent booster	1,500	846 (56)	507 (34)	39 (30–46)	147 (10)	38 (24–50)		
≥65								
Received 2–4 monovalent doses only (Ref)	2,393	1,159 (48)	972 (41)	_	262 (11)	_		
Overall (≥2 weeks since bivalent booster dose)	2,021	1,243 (62)	632 (31)	37 (28-44)	146 (7)	43 (29-55)		
0–1 month since bivalent booster	381	260 (68)	94 (25)	55 (42-65)	27 (7)	50 (24-68)		
2–3 months since bivalent booster	1,640	983 (60)	538 (33)	32 (21–40)	119 (7)	42 (26–54)		

Abbreviations: Ref = referent group; SGTF = S-gene target failure; SGTP = S-gene target presence; VE = vaccine effectiveness.



CORRESPONDENCE

Effectiveness of Bivalent Boosters against Severe Omicron Infection

Table 1. Estimates of Effectiveness of One Monovalent or Bivalent Booster Dose against Severe Omicron Infection.*								
Group	Vaccine Effective	eness against Hospita	zation (95% CI) Vaccine Effectiveness against Hospitaliza		on or Death (95% CI)			
	Monovalent Booster	Bivalent Booster	Difference	Monovalent Booster	Bivalent Booster	Difference		
	percent		percentage points	percent		percentage points		
All participants	25.2 (-0.2 to 44.2)	58.7 (43.7 to 69.8)	33.5 (2.9 to 62.1)	24.9 (1.4 to 42.8)	61.8 (48.2 to 71.8)	36.9 (12.6 to 64.3)		

- Study compares relative VE of a monovalent booster vs. relative VE of a bivalent booster
- "Relative VE" estimates are showing added protection of a booster (monovalent or bivalent) compared to persons with a primary series who are NOT recently boosted

Summary: Future of COVID-19 Vaccines

- COVID-19 vaccines (including original monovalent vaccines) remain very effective at preventing severe disease
- Protection wanes over time and because of emerging variants
- Bivalent vaccine boosters are more effective than original monovalent vaccine boosters at protecting against COVID-19 and severe disease
- Over the coming months, FDA and CDC will likely move to unify vaccine composition and simplify clinical recommendations with some guidance likely for annual boosting, particularly for persons at increased risk for severe disease



Mpox Vaccination and Treatment



NH MONKEYPOX VACCINE CLINIC SITES

ConvenientMD Urgent Care TAKING WALK-INS

BEDFORD	603-472-6700	MANCHESTER	603-384-3900
BELMONT	603-737-0550	MERRIMACK	603-471-6069
CONCORD	603-226-9000	NASHUA	603-578-3347
DOVER	603-742-7900	PORTSMOUTH	603-942-7900
KEENE	603-352-3406	STRATHAM	603-772-3600
LITTLETON	603-761-3660	WINDHAM	603-890-6330
LONDONDERRY	603-413-6800		

Coos Family Health

BERLIN 603-752-2040

Dartmouth Hitchcock
LEBANON 603-650-1818

Keady Family Practice
CLAREMONT 603-863-7777

4 White Mountain Community Health

CONWAY 603-447-8900

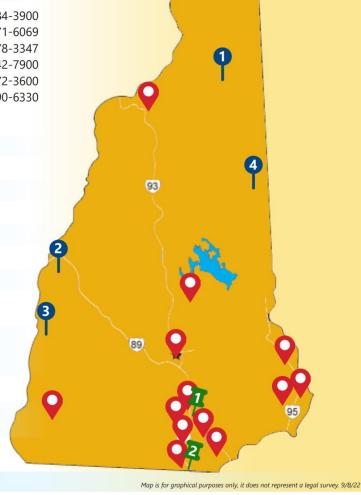
Manchester Health Department_ - Serving persons in the Greater Manchester Area (Auburn, Bedford, Candia, Deerfield, Goffstown, Hooksett, Manchester and New Boston) with/without insurance.

MANCHESTER 603-624-6466

Nashua Health Department - Clients who are under/ uninsured in the Greater Nashua Region

NASHUA 603-589-4500 option 2

Please select highlighted locations for website link.



ACIP Mpox Vaccination Discussion

Tentative timeline for ACIP discussions and votes*

Current US mpox vaccination strategy remains active: Populations at high risk should continue to be vaccinated §

Mpox outbreaks: Use of 2dose JYNNEOS for persons aged ≥ 18 years Mpox outbreaks: Use of 2-dose JYNNEOS for persons aged <18 years

-Updates about vaccine effectiveness and safety

Consider need for longer term vaccination strategy for 2-dose JYNNEOS

February 2023

June 2023

October 2023



^{*}February 2023 and June 2023 votes do not impact existing recommendations for the current mpox outbreak.

[§] https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html

JYNNEOS Vaccine Safety Review

Conclusions

- JYNNEOS post-licensure and post-authorization vaccine safety surveillance findings to date are consistent with those observed in clinical trials
- No new or unexpected safety concerns have been identified
- Serious adverse events were rare among adults, and none have been identified among persons aged <18 years
- VAERS and Vaccine Safety Datalink data do not suggest an increased risk for myocarditis or pericarditis following JYNNEOS, but the possibility of a small risk cannot be excluded



JYNNEOS Vaccine Effectiveness Review

Vaccine effectiveness of JYNNEOS against mpox ranges from 66%-89% for full vaccination and 36%-86% for partial vaccination

	Cases	Controls	Adjusted* VE (95% CI)						
Full vaccination (2 doses)									
Epic Cosmos case-control study	25	335	66% (47%- 78%)			-	-	—	
Multi-jurisdictional case-control study	14	122	76% (48%-89%)			-		—	-
New York State case-control study	2	19	89% (44%-98%)			-			—
Partial vaccination (1 dose)									_
Israel single-dose study	5	16	86% (59%-95%)			_	_		<u> </u>
Epic Cosmos case-control study	146	1000	36% (22%-47%)				1		
New York State case-control study	10	23	68% (25%-86%)		_				-
			0	1	20 Vacci	40 ne Effe	60 ctivenes	80 ss (%)	100



Morbidity and Mortality Weekly Report

Interim Clinical Treatment Considerations for Severe Manifestations of Mpox — United States, February 2023

BOX. Important clinical considerations for management of severe mpox* — United States, February 2023

Ocular infections

- Clinical manifestations: Symptoms include eye pain, redness, drainage, foreign body sensation, vision changes or loss,
 or periorbital swelling. Involvement of the ocular surface can manifest as blepharitis, conjunctivitis, or keratitis; discrete
 lesions might be present. Lesions can also occur on external areas including the eyelids.
- Diagnostic findings: In a patient with known or suspected mpox, ocular infection can be confirmed by testing swabs from periorbital, lid or intraocular lesions for OPXV by PCR.
- Treatment: Prompt initiation of tecovirimat and topical administration of trifluridine should be considered. Trifluridine
 can also be used prophylactically in patients with mpox who are at high risk of ocular infection (e.g., lesions near the
 eye). Other systemic MCMs should be considered on a case-by-case basis. Lubricants and topical antibiotics may be
 considered for symptomatic management and prevention of complications.
- Other considerations: Obtain ophthalmology consultation.[†] Adverse events might occur from prolonged use of
 trifluridine. In addition, one animal study suggests increased risk of corneal scarring when VIGIV is administered in the
 setting of OPXV keratitis. Extensive use of agents that can further irritate the eye, such as topical povidone-iodine, might be
 avoided. Appropriate measures to prevent, diagnose, and treat ocular coinfections and superinfections should be taken.

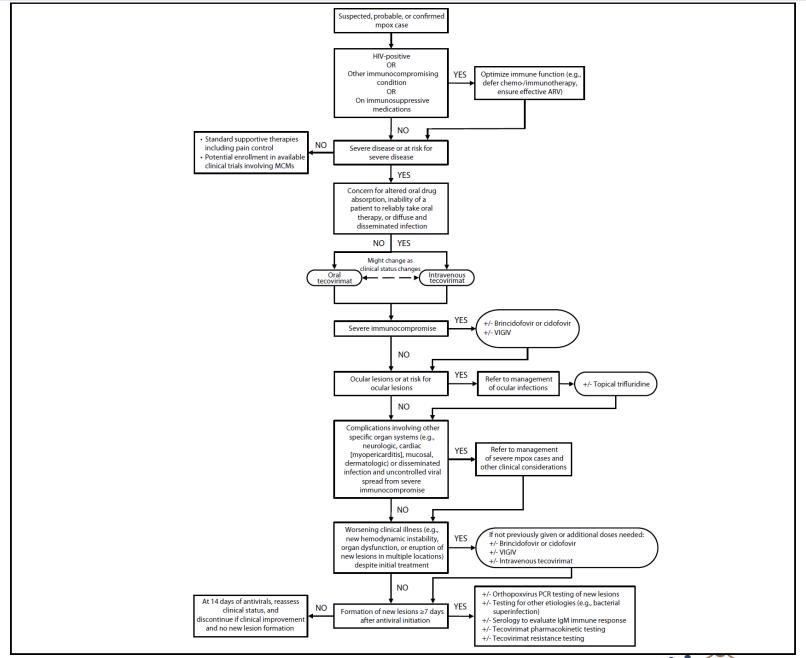
Neurologic complications

- Clinical manifestations: Encephalitis and myelitis can occur. Severe headache, back or neck pain, altered mental status, seizures, or focal neurologic deficits in a patient with mpox or recently recovered from mpox should prompt suspicion for neurologic complications.
- Diagnostic findings: CSF might demonstrate a lymphocytic-predominant pleocytosis with protein elevation and normal glucose; availability of mpox-specific CSF testing is limited and consultation with CDC is suggested. MRI might show lesions in the brain or spinal cord which might or might not enhance.
- Treatment: Treatment of mpox-associated neurologic disease should involve MCMs and might involve
 immunomodulatory or immunosuppressive therapy (e.g., steroids, intravenous immunoglobulin, or plasmapheresis or
 plasma exchange). Clinicians treating mpox-associated neurologic disease should weigh the risks and benefits of
 immunosuppressive agents when direct viral neuroinvasion is a possibility. Data suggest tecovirimat penetrates the CNS
 well; although brincidofovir, cidofovir, and VIGIV might penetrate the CNS, the extent is either uncertain
 (brincidofovir) or limited (cidofovir and VIGIV).
- Other considerations: Consider neurology consultation. Neurologic disease related to mpox might be because of direct
 viral invasion of the CNS or resultant autoimmune disease from antigenic stimulus. Other neurologic diseases with
 similar presentations should be investigated (e.g., infectious diseases such as viral encephalitides and syphilis, and
 autoimmune, parainfectious, and vascular conditions).

Myopericarditis

- Clinical manifestations: New complaints of chest pain, shortness of breath, or palpitations in a patient with ongoing or recent mpox should prompt consideration of myopericarditis.
- Diagnostic findings: Similar findings to those associated with myopericarditis from etiologies other than mpox might be observed, including elevations in cardiac biomarkers, changes in electrocardiogram and on cardiovascular MRI, and pathologic changes of the myocardium.
- Treatment: Standard of care for myopericarditis should be considered; MCMs might also play a role by limiting viral spread to myocytes or decreasing the production of viral antigens responsible for the inflammatory response.
- Other considerations: Consider cardiology consultation. Other causes of myopericarditis should be investigated, including other viral infections or recent receipt of a vaccination that can be associated with myopericarditis.





Q&A



Next Webinar is April 13th

- We will continue to have these webinars on a monthly cadence (2nd Thursday of each month from 12-1pm)
- These "Public Health Grand Rounds" webinars will transition to broader topics
- Dr. Talbot will provide an update on:
 - H5N1 Avian Influenza
 - Emerging infectious diseases diagnostics

