

I-VAC Adult & Pediatric Learning Collaborative for COVID-19 Vaccination



Please use your first name and health center name when you join the session



Use the “**chat**” feature to let us know if you have a question



Please remember to **mute your microphone** unless speaking



If you can't connect audio via computer or lose computer audio at anytime, you can call in to session at **(669) 900-6833, Meeting ID 812-8864-4528##**

Disclosures

- No one in a position to control the education content of the activity has any relevant financial disclosures with ineligible companies to disclose.
- What gets said here today may change based on new data and recommendations
 - Knowledge is shared more rapidly through ECHO



Mission

Aims to establish and cultivate a robust knowledge network that builds community-based primary care capacity to reduce the serious health disparities affecting children and adults in underserved communities.

<http://www.echo-chicago.org/>

Impact

89%

show increased confidence in their skills after participating in training

91%

report at least change to their practice as a result of participating in training



Reach



6200+

professionals



1200+

organizations



46

states



9

countries

Breadth

36 topic areas, including:

- Complex pediatric asthma
- Pediatric obesity
- COVID-19
- Diabetes
- Geriatrics
- Resistant hypertension
- Childhood adversity & trauma
- Opioid use disorder
- Serious mental illness

} **pediatric populations**

} **adult populations**

} **behavioral health**

Session Essentials

- CME credits
 - Information to claim credits will be shared at the end of December
 - 1 session = 1 *AMA PRA Category 1 Credit*™
- Cases
 - SHARE a case with us
 - Specific patient case, general issue (testing, vaccine hesitancy, etc.) or operational/logistical issue
 - Web-based electronic case submission
 - If you would like to present a case at the next session, please let Patrick know at pgower@peds.bsd.uchicago.edu
- Session slides & recordings
 - Slides and recordings will be posted on <https://www.echo-chicago.org/topic/covid-19-in-adult-populations/> behind a firewall. Registration required to access



Epidemiology Updates

Track Covid-19 in the U.S.

Updated Sept. 11, 2023

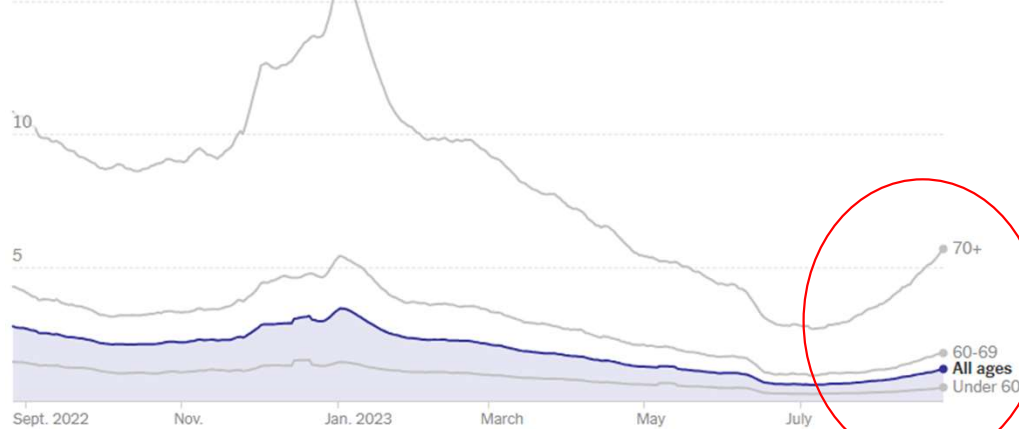
Daily Covid hospital admissions

Avg. on Aug. 26

3,954

14-day change
+29%

15 hospital admissions per 100,000



Primary series vaccination rate

69%

Total population

94%

Ages 65 and up

Bivalent booster rate

17%

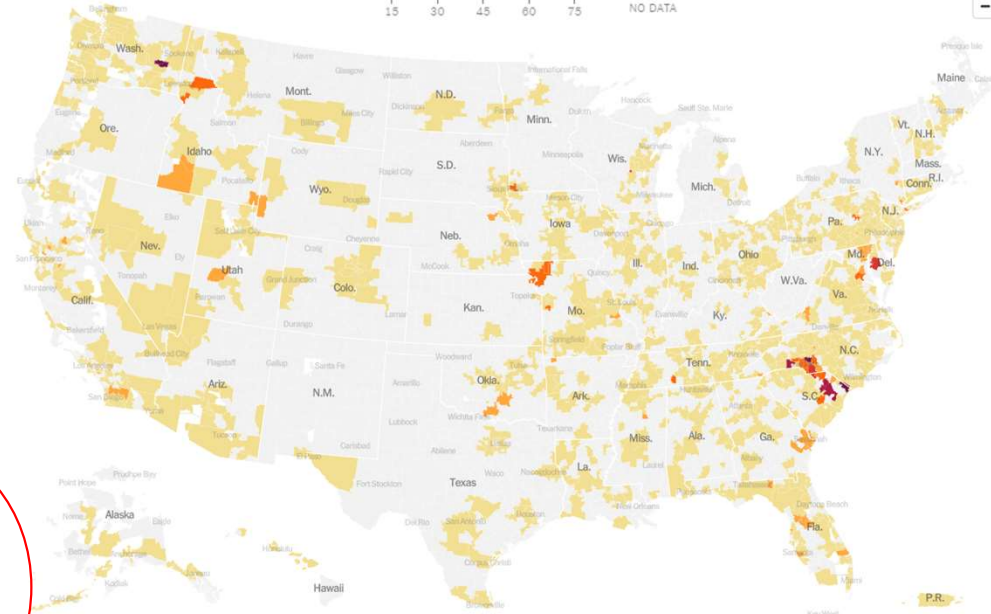
Total population

43%

Ages 65 and up

Current hospitalizations

COVID-19 PATIENTS PER 100,000 PEOPLE



COVID Continues to Rise, but Experts Remain Optimistic

- A steady uptick in cases since July and reports of worrisome new variants have fueled concern that the virus is poised to make a comeback this fall and winter
- There is no evidence that any of the variants in circulation cause more severe disease or evade immunity adroitly enough to render vaccines ineffective
- Hospital admissions for Covid increased by about 16 percent in the week ending Aug. 26, compared with the previous week. But the 17,400 new admissions were less than half the number in the same period last year, and about one-fifth the number in 2021

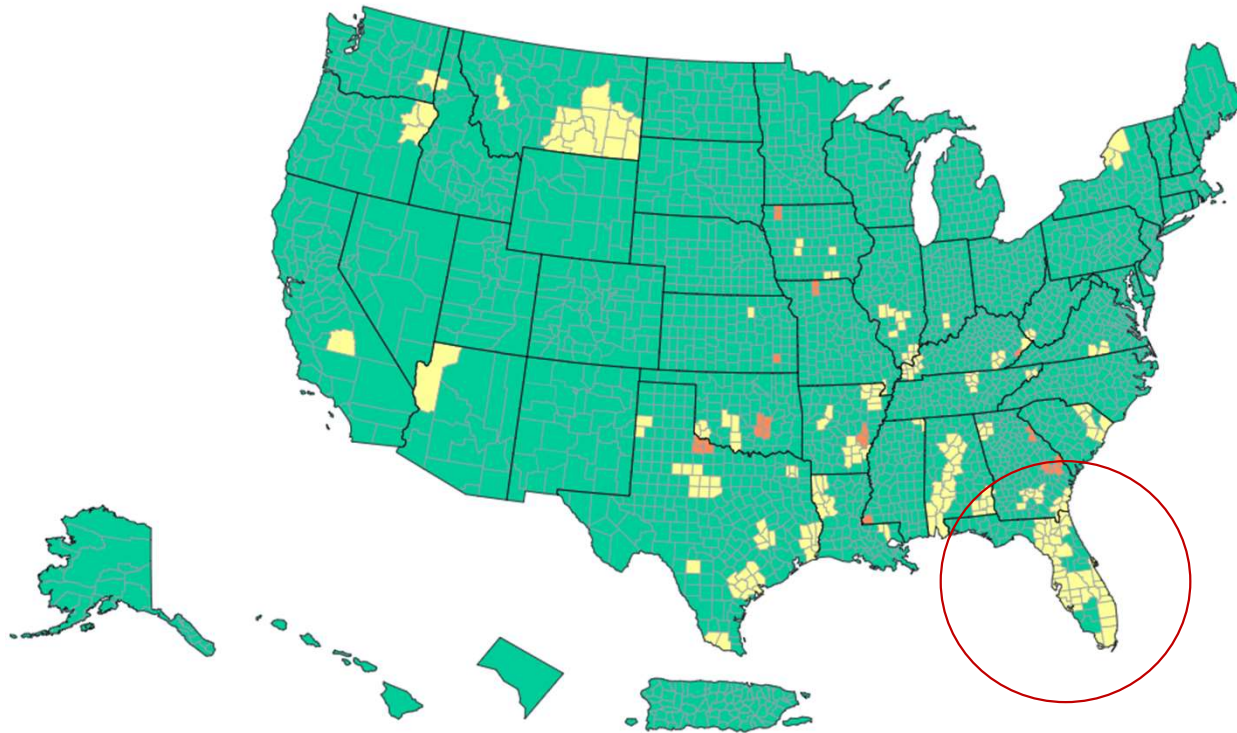
<https://www.nytimes.com/2023/09/07/health/covid-deaths-hospitalizations-vaccines.html?smid=url-share>

COVID-19 hospital admissions levels in U.S. by county
Based on new COVID-19 hospital admissions per 100,000 population

	Total	Percent	% Change
≥ 20.0	22	0.68%	0.22%
10.0 - 19.9	230	7.14%	0.4%
<10.0	2970	92.18%	-0.56%

Time Period: New COVID-19 hospital admissions per 100,000 population (7-day total) are calculated using data from the MMWR week (Sun-Sat) ending September 2, 2023.

Reported COVID-19 New Hospital Admissions Rate per 100,000 Population in the Past Week, by County - United States



Chicago's COVID-19 Risk Level is **LOW**



CHICAGO | COVID-19 Summary

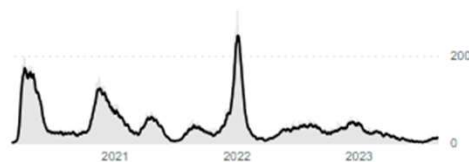
Data current as of Sep 07, 2023.
Data are updated Wednesdays at 5:30 p.m., except for City holidays.
All data are provisional and subject to change.

SUMMARY CASES CASES BY ZIP TESTS

[Learn how to use this dashboard.](#)

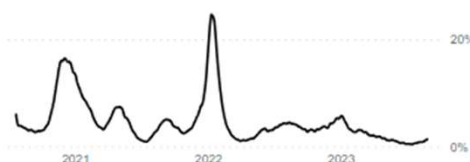
HOSPITALIZATIONS

13 ▲ **11 (+13%)** **53,520** **0.47**
Current daily avg Prior week Cumulative Daily rate per 100,000



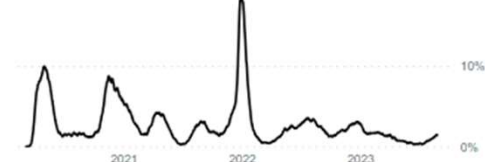
HOSPITAL BEDS IN USE

1.3% ▲ **1.0%**
Current daily avg Prior Week



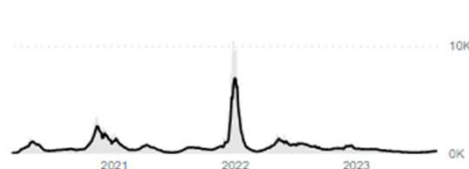
EMERGENCY ROOM VISITS

1.4% ▲ **1.3%**
Current daily avg Prior Week



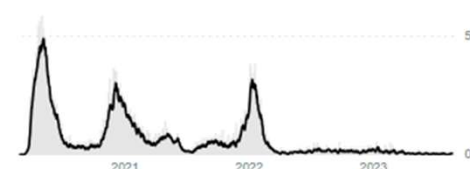
LABORATORY-CONFIRMED CASES

158 ▲ **154 (+3%)** **784,175** **5.73**
Current daily avg Prior week Cumulative Daily rate per 100,000



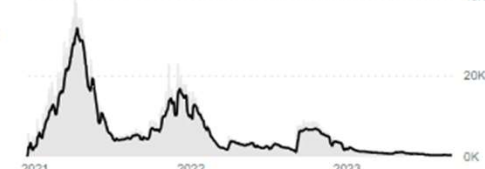
DEATHS

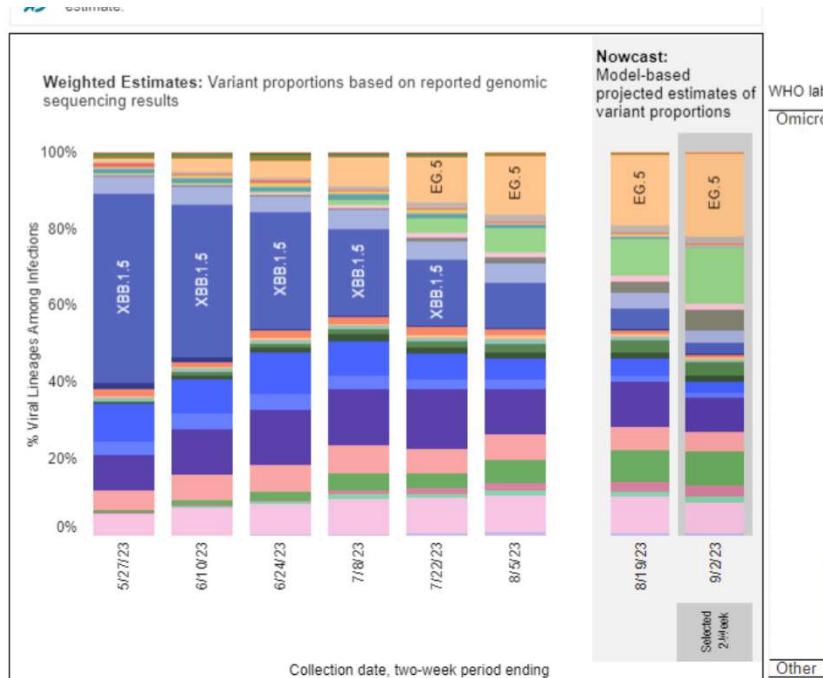
0.43 ▲ **0.14 (+200%)** **8,166** **0.02**
Current daily avg Prior week Cumulative Daily rate per 100,000



VACCINATIONS ADMINISTERED

151 ▼ **5,866,486** **23.8%**
Current daily avg Cumulative People with updated booster



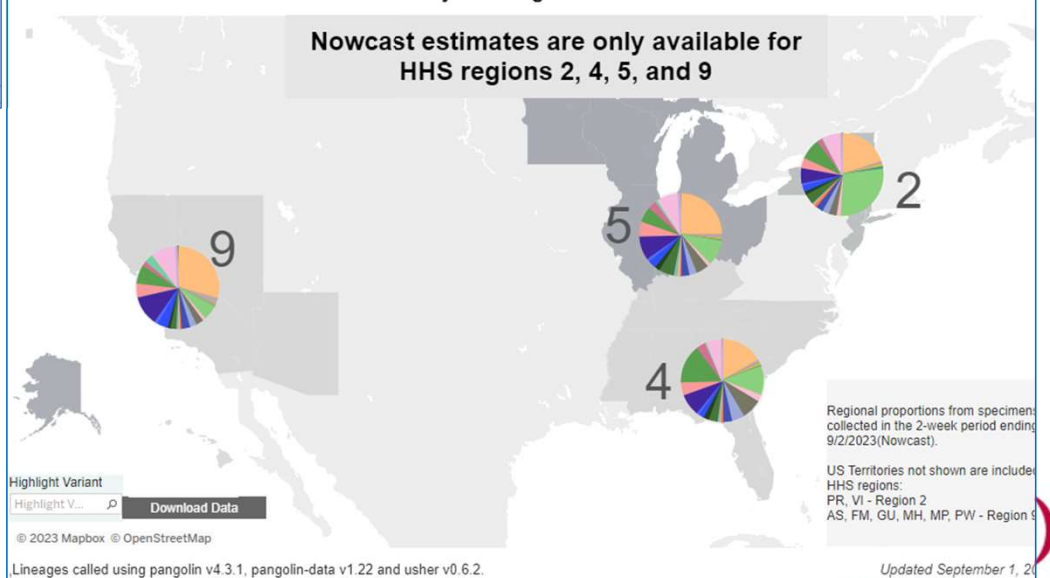


USA

WHO label	Lineage #	%Total	95%PI
Omicron	EG.5	21.5%	19.0-24.3%
	FL.1.5.1	14.5%	10.5-19.6%
	XBB.1.16.6	9.2%	7.6-11.0%
	XBB.1.16	8.9%	7.8-10.3%
	XBB.2.3	8.1%	7.0-9.2%
	HV.1	5.1%	3.3-7.9%
	XBB.1.16.1	5.0%	4.2-6.0%
	XBB.1.5.70	3.5%	2.6-4.7%
	XBB	3.3%	2.7-4.1%
	XBB.1.5	3.1%	2.6-3.7%
	XBB.1.9.1	3.0%	2.5-3.5%
	XBB.1.16.11	2.8%	1.8-4.5%
	EG.6.1	1.8%	1.2-2.7%
	GE.1	1.6%	1.1-2.4%
	XBB.1.5.72	1.6%	1.2-2.1%
	XBB.1.42.2	1.3%	0.7-2.3%
	XBB.1.9.2	1.1%	0.9-1.3%
	XBB.1.5.10	0.9%	0.7-1.2%
	XBB.1.5.68	0.8%	0.5-1.1%
	XBB.2.3.8	0.7%	0.4-1.2%
	FD.1.1	0.6%	0.4-0.8%
	FE.1.1	0.5%	0.3-0.8%
	XBB.1.5.59	0.4%	0.3-0.6%
	CH.1.1	0.4%	0.3-0.6%
	FL.1.1	0.1%	0.1-0.2%

Notice the overall heterogeneity in variants and the geographic differences:
- FL 1.5.1 is much greater in the NE

Nowcast Estimates for 8/20/2023 – 9/2/2023 by HHS Region



What about the New Variant – BA.2.86?

- BA.2.86, nicknamed Pirola, is a highly mutated new omicron variant that was first detected in Denmark in July 2023. The World Health Organization announced that, as of Sept. 6, 2023, BA.2.86 has been detected in 11 countries. It's an offshoot of earlier BA 2 strain, not XBB
- A preliminary study reported that BA.2.86 features 33 distinct spike mutations when compared to its precursor, BA.2, 14 of which are in the RBD (receptor binding domain) suggesting possible increased infectivity
- Researchers do not fully understand all these mutations yet:
 - A preliminary study found that BA.2.86 can escape the protective defenses of antibodies against the recent XBB sublineages. However, in contrast, another new study that has not yet been published found that neutralizing antibody responses against BA.2.86 were comparable to or slightly higher against the recent XBB sublineages.
- Has been discovered in 9 states as of September 8
- Moderna trial data confirmed updated vaccine generates a strong immune response against BA.2.86
 - generates an **8.7-fold increase** in neutralizing antibodies in humans against BA.2.86 (Pirola)
 - previously communicated results showing a similarly effective response against EG.5 and FL.1.5.1 variants

<https://theconversation.com/how-evasive-and-transmissible-is-the-newest-omicron-offshoot-ba-2-86-that-causes-covid-19-4-questions-answered-212453>

doi: <https://doi.org/10.1101/2023.09.01.555815>

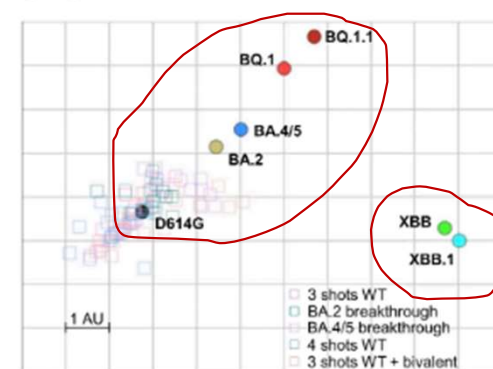
doi: <https://doi.org/10.1101/2023.09.04.556272>

<https://investors.modernatx.com/news/news-details/2023/Moderna-Clinical-Trial-Data-Confirm-Its-Updated-Covid-19-Vaccine-Generates-Strong-Immune-Response-in-Humans-Against-BA.2.86/default.aspx>

Why Update the COVID-19 Vaccine at all?

- SARS-CoV-2 continues to mutate quickly—about 2 times faster than the flu. It's normal to update vaccines when the virus mutates quickly. For example, we update vaccines for flu (which changes annually) and we don't update vaccines for measles (which hasn't mutated in a meaningful way for decades).
- The current Omicron variant (XBB) circulating is meaningfully different than other Omicron variants. The map below shows the differences, with XBB pretty distant. This suggests an updated vaccine with XBB would help our immune systems recognize the change.
- COVID-19 vaccines are waning in protection against hospitalization (62% effectiveness → 24%) and ICU admission, albeit with a smaller decline (69% → 52%). This is happening faster when exposed to XBB virus compared to other Omicron variants. Even though vaccine effectiveness is waning, the hospitals aren't filling up. This is because vaccine effectiveness now represents the incremental benefit above and beyond the baseline protection in the general population. This is different than when we first introduced vaccines and the general population had a very low immunity wall.
- B-cell data showed that our antibody factories are able to adapt and pump out updated antibodies. In other words, there is imprinting from initial exposure (as expected) but our system is still adaptable. This is good news because it means that updated vaccine formulas expand our protection. It's not all for nothing.
- T-cell data also showed clear 2-fold increases after an updated booster. This was the case regardless of prior infection.

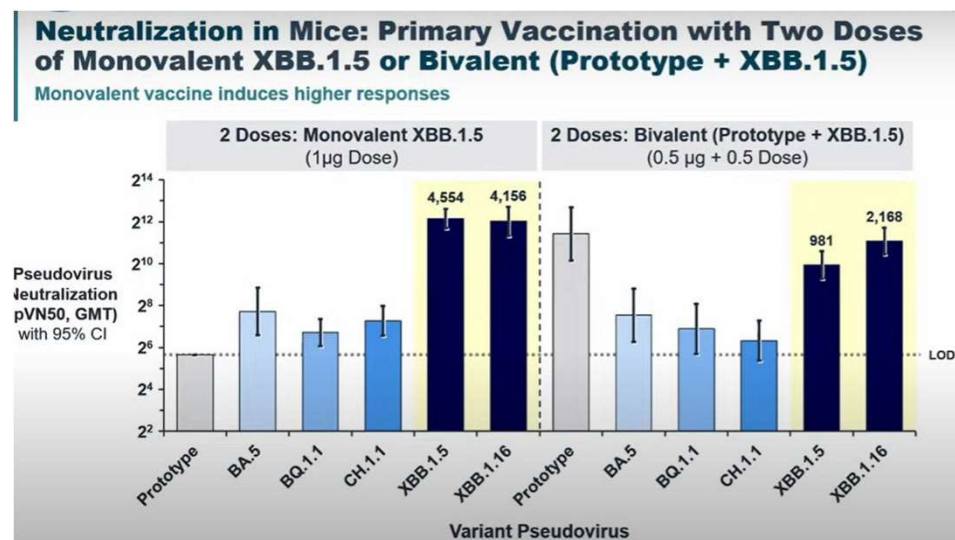
XBB Viruses Cluster Together Using Antigenic Cartography



Wang et al 2023
<https://doi.org/10.1016/j.cell.2022.12.018>

Why Monovalent and no Bivalent?

- Wasn't Bivalent better last year?
- WHO is not seeing any evidence that the earliest variant is still circulating.
- Including it could hurt as we keep teaching our immune system to recognize the old version of the virus rather than the new one.
- There really isn't anything else popping up except XBB variants.
- Novavax found that a monovalent vaccine may be more advantageous to mice's immune systems than a bivalent vaccine.
- Moderna found the same thing.



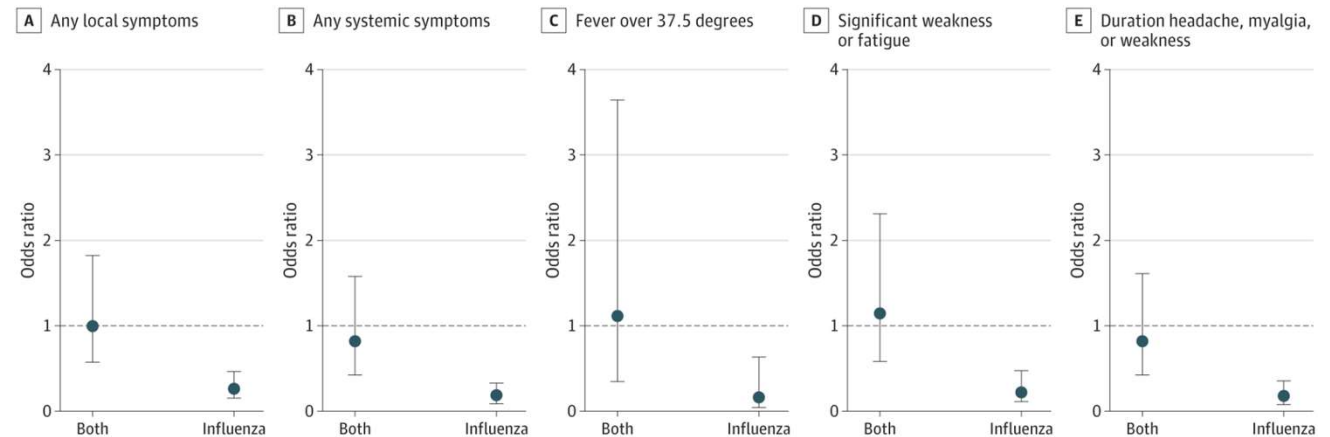
FDA Approves New Monovalent Booster

- The fall Covid-19 vaccine has an updated formula targeting XBB.1.5, which should be a good match to the currently circulating Omicron subvariant. Moderna, Pfizer, and ~~Novavax~~ all will have these available this week
- Plan is for one shot now for primary or booster dose:
 - Moderna: 6 months and older
 - Pfizer: 6 months and older
 - Novavax: 18 years and older

CDC ACIP Met Today and...

- Voted 13-1 to recommend updated Covid-19 vaccines for all Americans 6 months of age and older
 - There was some pre-meeting debate if the recommendation would be only for those at increased risk of serious disease (the NHS was more selective)
- The endorsement from the committee means the vaccines will be covered by public and private insurance plans.
- Also made recommendations for people who are moderately or severely immunocompromised. To be up-to-date, those with low immune function should have had at least three doses of Covid-19 vaccine, with at least one of those doses being an updated shot. They also have the option to get an additional updated vaccine later in the year.

Should I Get Influenza and COVID Vaccine Together?



- Prospective Cohort Study Israeli Health Care workers receiving both Influenza Vaccine and Omicron BA.4/BA.5–adapted bivalent (Pfizer/BioNTech) vaccine
- Coadministration was not associated with substantially inferior immune response or to more frequent adverse events compared with COVID-19 vaccine administration alone, supporting the coadministration of these vaccines.

FALL 2023 VACCINES

**What are
the options?**

**Who is
eligible?**

**How well do
they work?**

**When should
I get it?**

INFLUENZA



A shot that targets 4 strains of seasonal flu

6 months and older

Typically reduces the risk of going to the doctor by 40-60%

October is ideal, as vaccine protection wanes over a season

COVID-19



Updated vaccine formula targeting XBB - an Omicron subvariant

Options: Moderna and Pfizer (mRNA) and Novavax (protein)

TBD. CDC will decide in mid-to-late September

Last year, the fall COVID-19 vaccine provided 40-60% additional effectiveness against severe disease

For protection against **severe disease**, get it anytime

Protection against **infection**: It's best to get it right before a wave, which can be challenging to time

RSV (OLDER ADULTS)



2 options: GSK and Pfizer. They are slightly different in design, but only at a microscopic level

60 years and older

82-86% efficacy against severe disease

Protection is durable. Get when it's available; no need to juggle timing

RSV (PREGNANCY)



Pfizer is actively seeking approval

Pregnant people (then protection will pass to baby for protection in first 6 months of life).

82% efficacy in preventing hospitalization in first 3 months of life. 69% efficacy after 6 months

It's not available yet but once approved, get at 24 to 36 weeks of pregnancy

RSV ANTIBODY



A new monoclonal antibody by AstraZeneca. This is not a vaccine (doesn't teach the body to make antibodies) but rather a proactive medication (provides antibodies).

All infants <8 months. High-risk infants 8-19 months

Reduces risk of hospitalization and healthcare visits by ~80%

Will be available soon.

Protection lasts 4-6 months

By: Katelyn Jetelina, MPH PHD and Caitlin Rivers, MPH PHD. For more information go to Your Local Epidemiologist

Commercialization

Commercialization

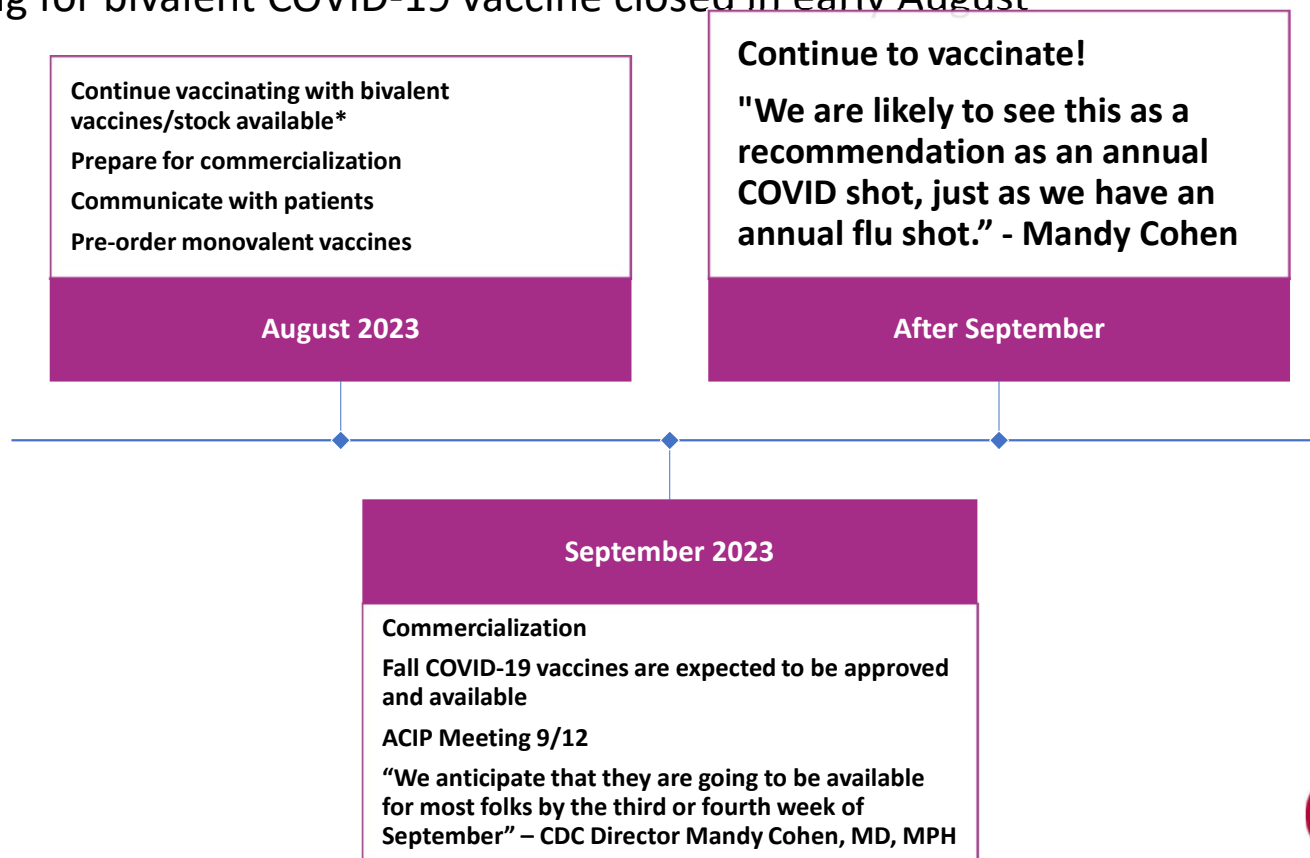
- Commercialization – the transition from direct government purchase to purchase by public and private consumers.
- There might be upfront costs for providers who provide COVID-19 vaccines.
 - Moderna: \$130/dose.
 - Pfizer: \$110-\$130/dose.
- The AAP is advocating for:
 - Longer invoice and payment schedules so that pediatricians can be reimbursed before having to purchase additional vaccines.
 - Simplified and improved labeling of COVID-19 vials to minimize errors in administration.
 - An easier return process for expired doses.
 - Single doses vials for all products.

Commercialization Cont.

- [HHS Commercialization Transition Guide](#): Sunsetting the US Government COVID-19 Vaccine Distribution Program.
 - Issued July 6, 2023
- Access: VFC program, Bridge Access Program for adults without insurance, coverage by private insurance.
- Ordering:
 - VFC & Private Stock: ordered through the same process as other commercial vaccines
 - Bridge Access: separate ordering process.

New Products Timeline

- Ordering for bivalent COVID-19 vaccine closed in early August



Expected Ordering

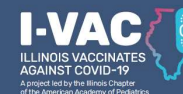
Expected

XBB.1.5 ordering

subject to change

FALL 2023 VACCINE ORDERING

Last updated August 17, 2023. Information is subject to change.



FORMULATION	CPT CODE	PRESENTATION	MINIMUM ORDER QTY	HOW TO ORDER	COST	DELIVERY TIME
Novavax						
Patient age 12 years and older	91304	Multi-dose vials containing 5 doses	50 doses	<ul style="list-style-type: none">Through VFC and other state programsWholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies
Pfizer						
Patient age 6 months–4 years	91318	Multi-dose vials containing 3 doses	30 doses	<ul style="list-style-type: none">Through VFC and other state programsPfizer Prime: 15% of an order that is received can be returnedWholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies
Patient age 5 years–11 years	91319	Single-dose vials	10 doses			
Patient age 12 years and older	91320	Single-dose vials or single-dose prefilled syringes*				
Moderna						
Patient age 6 months–11 years	91321	Single-dose vials that come in 10-count cartons	10 doses	<ul style="list-style-type: none">Through VFC and other state programsModerna Direct: 10% of an order that is received can be returnedWholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies, Moderna would begin shipping the vaccines after FDA approval
Patient age 12 years and older	91322	Single-dose prefilled syringes sold in 10-count cartons with a blister pack option				

*There will be limited quantities of prefilled syringes and they will not be available for initial stocking orders.

Sources: www.pfizer.com/news/announcements/pfizer-and-biontech-submit-applications-us-fda-omicron-xbb15-adapted-monovalent
<https://publications.aap.org/aapnews/news/25384?autologincheck=redirected>

illinoisvaccinates.com

CHICAGO



Preordering

- Illinois Department of Public Health:
 - [VFC COVID-19 Vaccine order link](#)
 - COVID-19 Vaccine Bridge Access Program
 - Due to limited quantities, Bridge Access Program vaccine will be available to a limited group of providers. Target providers include LHDs, FQHCs, RHCs.
 - Link will be sent to target group providers.

Storage and Handling – XBB.1.5

XBB.1.5 VACCINE STORAGE & HANDLING

Last updated August 31, 2023



AGE INDICATIONS AND FORMULATION	MODERNA		PFIZER				NOVAVAX
	6 Months–11 Years	12+ Years	6 Months–4 Years	5–11 Years	12+ Years	12+ Years Prefilled Syringe	12+ years
VIAL CAP COLOR	Unknown	Unknown	Yellow	Blue	Gray	N/A	Unknown
VIAL LABEL BORDER COLOR	Unknown	Unknown	Yellow	Blue	Gray	N/A	Unknown
PREPARATION	Do Not Dilute	Do Not Dilute	Dilute	Do Not Dilute	Do Not Dilute	N/A	Do Not Dilute
DOSE	0.25 mL	0.5 mL	3 mcg/ 0.3 mL dosage	10 mcg/ 0.3 mL dosage	30 mcg/ 0.3 mL dosage	30 mcg/ 0.3 mL dosage	5 mcg/ 0.5 mL dosage
DOSES PER VIAL	1	1	3	1	1	1 – Prefilled Syringe	5
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE	DO NOT STORE	12 Months	12 Months	18 Months	9 Months	DO NOT STORE
FREEZER (-50°C TO -15°C)	Until Expiration	Until Expiration	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE
REFRIGERATOR (2°C TO 8°C)	30 Days	30 Days	10 Weeks	10 Weeks	10 Weeks	10 Weeks	Until Expiration
ROOM TEMPERATURE (8°C TO 25°C)	24 Hours	24 Hours	12 Hours Prior to First Puncture	12 Hours Prior to Use	12 Hours Prior to Use	4–12 Hours*	Unknown
AFTER FIRST PUNCTURE (2°C TO 25°C)	N/A	N/A	Discard After 12 Hours	N/A	N/A	N/A	12 Hours

*Thawed in carton: 12 hours prior to use. Thawed outside of carton: Use within 4 hours of thawing.

Last
updated
September
1, 2023



Case

Questions?

Next Session: Tuesday, September 26th

For any questions, email us at
pgower@peds.bsd.uchicago.edu

*Funding for this project was made possible by the Office of Disease Control, through the
Illinois Department of Public Health.*

