I-VAC Learning Collaborative for COVID-19 Vaccination

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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







Track Covid-19 in the U.S.





Wastewater Surveillance





Source: Wastewater data from Biobot Analytics





Wastewater Surveillance



Territories GU PR VI

Current SARS-CoV-2 Wastewater Viral Activity Level

Select a level to add or remove it from the visualization.

ufficient Data Moderate Jer High Minimal High Lon







Wastewater Surveillance

I-VAC

ILLINOIS VACCINATES

AGAINST COVID-19





https://www.cdc.gov/nwss/rv/COVID19-variants.html

Weighted and Nowcast Estimates in United States for 2-Week Periods in 8/6/2023 – 11/25/2023

Nowcast Estimates in United States for 11/12/2023 – 11/25/2023

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.







•FE.1.1 •XBB.1.42.2

What about the New Variant – BA.2.86?

- BA.2.86, <u>nicknamed Pirola</u>, 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





What's to come?

- <u>All eyes are still on JN.1</u>—a highly mutated variant. Some European countries are coming close to reaching 50% threshold of JN.1 cases. This is important because we will start seeing the epidemiological implications soon (i.e., its impact on cases and hospitalizations). Given current spread patterns, we expect JN.1 to become the next dominant variant worldwide.
- The U.S. is weeks behind European countries, but models show we should expect a Covid-19 peak in late December driven by JN.1. It's hard to know how high the peak will be given the complex immune landscape. We expect 22,000-45,000 daily Covid-19 hospitalizations at the peak this winter.







(Source: JPWeiland)





Chicago's COVID-19 Risk Level is LOW



SUMMARY	CASES C	ASES BY ZIP	TESTS	buillillary		Data	a are updated Wednesday All dat	rs at 5:30 p.m., e: a are provisional : ⑦ Le	xcept for City holidays and subject to change am how to use this dashboan
ଓ HOSPIT	ALIZATION	is		HOSPITAL BEDS IN	USE 🚯		BEMERGENC)	ROOM VIS	its 0
21 A Current daily avg	20 (+6%) Prior week	54,921 Cumulative	0.78 Daily rate per 100,000	1.9% ▲ Current daily avg	1.5 Prior?	5% ^{Week}	2.4% Current daily	avg	1.7% Prior Week
A	2022	2023	200		2023	20%	A	2022	2023
i LABORA	TORY-CO	NFIRMED	CASES	DEATHS				NS O	
151 V Current daily avg	Prior week	795,999 Cumulative	5.49 Daily rate per 100,000	0.00 V 0.86 (-100%) Current daily avg Prior week	8,218 Cumulative	0.00 Daily rate per 100,000	14,553 ▼ Weekly people vaccinated	275,839 Cumulative people up to date	10.0% % of people up to date
2021	2022	2023	10н ок			50 Allo 23	0et 2023	Nov 20	23 09





Influenza Like Illness



(Source: CDC; Annotated by YLE/Katelyn Jetelina)





Influenza Increasing



Flu hospitalizations per 100,000 in, United States. (Source: CDC; Annotations by KKJ)





Is It Too Late to Get a Flu Shot?

- Influenza season goes until spring, so getting the vaccine late can still give you some protection
- Experts, including those at the C.D.C., say it's better to get the vaccine late than to skip it entirely. Flu season runs from October to May, with a peak usually occurring in February
- Young, healthy persons may be at comparatively low risk for severe influenza but have greater exposure to influenza through school, work, or other activities. In these persons, vaccination reduces the risk for missing school or work and the inconvenience and costs associated with medical visits. Indirect benefits include protecting loved ones, such as older relatives or young children in the household





https://www.nytimes.com/2023/12/01/well/flu-shot-timing.html?smid=nytcore-ios-share&referringSource=articleShare



Flu Vaccines





Flu burden and Disease Prevention with Flu vaccine



Estimated Range of Annual Burden of Flu in the U.S. from 2010 – 2020 (CDC)





Influenza-Associated Hospitalizations



Source: CDC Fluview—FluSurv-NET, week ending February 11, 2023







Preliminary interim estimates—NVSN

- Through January 25, 2023, influenza vaccination significantly reduced laboratory confirmed medically attended influenza
 - 68% (95% CI: 46, 81) against pediatric hospitalizations
 - 42% (95% CI: 25, 56) against pediatric ED visits

Important protection against both A/H3N2 and A/H1N1 associated illness

Importance of Influenza, COVID-19 & Routine Vaccines



During October 2022, there were only 6% of PICU beds available across the state.



Since we do not have vaccines to protect against every disease, it is even more important to use the vaccines that we do have to keep children out of the hospital.



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-22/influenza-03-Olson-Lewis-Tenforde-508.pdf



Three networks to evaluate vaccine effectiveness against laboratory-confirmed influenza-associated outpatient visits, emergency department visits, and hospitalization

Vaccine effectiveness against laboratory confirmed influenza A* in hospital and ED settings, September 13, 2022–January 25, 2023**

	Influenza positive		Influenza negative ¹		Unadjusted		Adjusted ²	
	N vaccinated /Total	(%)	N vaccinated /Total	(%)	VE %	95% CI	VE %	95% CI
Influenza A								
All 6 mos – 17 years	123/640	19	750/2256	33	52	(41 to 62)	49	(36 to 60)
Inpatient	19/131	15	288/913	32	63	(39 to 78)	68	(46 to 81)
ED	104/507	21	461/1330	35	51	(38 to 62)	42	(25 to 56)
A/H3N2	98/478	21	750/2256	33	48	(34 to 59)	45	(29 to 58)
A/H1N1	23/139	17	750/2256	33	60	(37 to 75)	56	(28 to 72)

Vaccine Effectiveness





Pediatric flu deaths increased over the '22-'23 season (168 deaths). Vaccinated children 70% less likely to be hospitalized due to flu





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Seasons	Total Deaths	Deaths reported During the Week Ending 26 Aug 2023
2019-20	199	0
2020-21	1	0
2021-22	49	0
2022-23	172	0

Vaccination Status by Age Group among Infants, Children and Adolescents Ages ≤17 Years Hospitalized for COVID-19 — COVID-NET, January–June 2023



Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission. **Unvaccinated**: No reco<mark>rded doses of COVID-19 vaccine. **Vaccinated, but no bivalent booster**: Completed a primary series with or without 21 booster dose but did not receive an updated bivalent booster dose. **Updated bivalent booster**: Received updated bivalent booster dose. **Partially vaccinated**: Received at least one dose of COVID-19 but was not considered fully vaccinated at the time of a positive SARS-CoV-2 test. Persons with unknown vaccination status are excluded.</mark>

Pediatric vaccine preventable diseases: <u>Deaths</u> per year in the United States prior to recommended vaccines compared to COVID-19

	Hepatitis A ¹	¹ Meningococcal (ACWY) ² Varicella ³		Rubella ⁴	Rotavirus⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months-<18 yea
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	2022
Average deaths per year	3	8	16	17	20	≤1 year: 156 1–4 years: 101 5–19 years:292

¹Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8. ²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019. ³Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. J Infect Dis. 2000;182(2):383-390. doi:10.1086/315714

⁴Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63. ⁵ Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:5 ⁶ <u>http://wonder.cdc.gov/mcd-icd10-provisional.html</u> on Aug 1, 2023. COVID vaccine first introduced in 12-17 years in May 2021; in 5-11 years in November 2021 and in 6 months – 4 years in June 2022





VE against influenza-associated hospitalization among patients aged ≥18 years

Vaccine effectiveness against laboratory confirmed influenza A* in inpatient settings, October 1, 2022–January 31, 2023

Vaccine Effectiveness

_	Influenza positive		Influenza negative ¹		Unadjusted		Adjusted ²	
	N vaccinated /Total	(%)	N vaccinated /Total	(%)	VE %	95% CI	VE %	95% CI
≥18 years	219/701	31	921/2130	43	40	(29 to 50)	43	(30 to 54)
18–64 years	84/378	22	365/1021	36	49	(33 to 61)	51	(33 to 64)
≥65 years	135/323	42	556/1109	50	29	(8 to 44)	35	(13 to 52)
Immunocompromised	³ 45/122	37	238/474	50	42	(13 to 62)	44	(10 to 66)





Influenza vaccine effectiveness (VE) against influenza-associated hospitalization and emergency department / urgent care visits among adults aged ≥18 years

Vaccine effectiveness against laboratory confirmed influenza A in ED/UC settings, October 15, 2022–January 24, 2023*

						Vaccine E	ffectiven	ess
	Influenza positive		Influenza negative		Unadjusted		Ad	ljusted ¹
	N vaccinated /Total	(%)	N vaccinated /Total	(%)	VE %	95% CI	VE %	95% CI
All adults ≥18 years	3278/14011	(23)	15752/43196	(36)	47	(44 to 49)	44	(41 to 47)
18-64 years	1600/10590	(15)	6695/27545	(24)	45	(41 to 48)	46	(42 to 49)
≥65 years	1678/3421	(49)	9057/15651	(58)	30	(25 to 35)	39	(34 to 43)
Immunocompromised								
2	64/179	(36)	553/1363	(41)	18	(-13 to 41)	30	(-2 to 52)





Vaccine Safety Update: 2022-2023 Influenza Season

- ~173 million doses of influenza vaccine distributed in United States*
- Vaccine Adverse Event Reporting System (VAERS) (co-managed by CDC and FDA)
 - No new safety concerns identified for influenza vaccines
- Vaccine Safety Datalink (VSD) (collaboration between CDC and 9 integrated healthcare organizations)
 - ~5.5 million doses of influenza vaccine administered in VSD
 - No new safety concerns identified in influenza vaccine monitoring**
 - Statistical signal for ischemic stroke after Pfizer-BioNTech bivalent mRNA COVID-19 vaccine in persons aged ≥65 years detected in VSD analysis for COVID-19 vaccine safety monitoring, previously presented to ACIP***
 - Post-signal analysis in VSD found an elevated rate ratio for ischemic stroke after simultaneous vaccination with Pfizer-BioNTech bivalent mRNA COVID-19 vaccine and high-dose or adjuvanted influenza vaccine, which has attenuated over time
 - Separate analyses did not detect an elevated rate ratio for ischemic stroke after influenza vaccine administered without bivalent mRNA COVID-19 vaccine

* Weekly Flu Vaccination Dashboard | FluVaxView | Seasonal Influenza (Flu) | CDC

** Outcomes monitored in VSD: acute disseminated encephalomyelitis, anaphylaxis, Bell's Palsy, encephalitis, Guillain-Barré syndrome, seizures, transverse myelitis *** Shimabukuro T, ACIP presentation on April 19, 2023 mRNA COVID-19 bivalent booster vaccine safety update (cdc.gov)





4

2022-2023 Flu Vaccine Coverage Children 6 Months – 17 Years

AGAINST COVID-19



Summary as of the Week Ending February 11, 2023

- U.S. influenza activity rose early, peaking nationally during late November/early December
 - Percent of tests positive peaked at ~26%; currently ~1.7%
- Influenza A(H3N2) viruses have predominated, with co-circulation of influenza A(H1N1)pdm09 viruses.
- The cumulative influenza-associated hospitalization rate has leveled in recent weeks to ~59/100,000
- 111 influenza-associated pediatric deaths reported this far this season.
- Overall influenza activity is increased compared with the previous two seasons.
- U.S. influenza activity is currently low.





U.S. Influenza Vaccine Composition for 2023-24

- All vaccines available in the U.S. are quadrivalent.
- The 2023-24 composition includes updated influenza A(H1N1)pdm09 components.
- All U.S.-licensed influenza vaccines will include hemagglutinin derived from:
 - An influenza A/Victoria/4897/2022 (H1N1)pdm09-like virus (egg-based vaccines)
 An influenza A/Wisconsin/67/2022 (H1N1)pdm09-like virus (cell and recombinant vaccines)
 - An influenza A/Darwin/9/2021 (H3N2)-like virus (egg-based vaccines)
 An influenza A/Darwin/6/2021 (H3N2)-like virus (cell and recombinant vaccines)
 - An influenza B/Austria/1359417/2021-like virus (B/Victoria lineage)
 - An influenza B/Phuket/3073/2013-like virus (B/Yamagata lineage)

Vaccines and Related Biological Products Advisory Committee March 7, 2023 Meeting Announcement - 03/07/2023 | FDA





Influenza Vaccine

- Recommended for everyone 6 months+.
- Any licensed influenza vaccine appropriate by age and health status can be used.
- The AAP does not prefer any product over another for children and adolescents with no contraindications.
- LAIV should not given to individuals in close contact to immunocompromised people needing a protective environment.
- CAN be given to those with an egg allergy in medical setting where severe allergic reactions can be managed.





Influenza Vaccine

Influenza Vaccine Products for the 2023-2024 Influenza Season

Manufacturer	Trade Name	How Supplied	Mercury Content	Age Range	CVX	Vaccine Product Billing Code ²
	(vaccine abbreviation)*		(mcg Hg/0.5mL)		Coue	СРТ
AstraZeneca	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	149	90672
CSK	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older ³	150	90686
GSK	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older ³	150	90686
	Flublok (RIV4)	0.5 mL (single-dose syringe)	0	18 years & older	185	90682
	Fluzone (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older ³	150	90686
		0.5 mL (single-dose vial)	0	6 months & older ³	150	90686
Sanofi		5.0 mL multi-dose vial (0.25 mL dose)	25	6 through 35 months ³	158	90687
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older	158	90688
	Fluzone High-Dose (IIV4-HD)	0.7 mL (single-dose syringe)	0	65 years & older	197	90662
		5.0 mL multi-dose vial (0.25 mL dose)		6 through 35 months ³	158	90687
	Afluria (IIV4)	5.0 mL multi-dose vial (0.5 mL dose)	24.5	3 years & older	158	90688
Seqirus		0.5 mL (single-dose syringe)	0	3 years & older ³	150	90686
	Fluad (allV4)	0.5 mL (single-dose syringe)	0	65 years & older	205	90694
	Elucelyay (ccll)(4)	0.5 mL (single-dose syringe)	0	6 months & older ³	171	90674
	Flucelvax (ccl1V4)	5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older ³	186	90756

NOTES

 IIV4 = egg-based quadrivalent inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., cclIV4); RIV4 = quadrivalent recombinant hemagglutinin influenza vaccine (injectable); alIV4 = adjuvanted quadrivalent inactivated influenza vaccine.

 An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.

3. Dosing for infants and children age 6

- through 35 months: • Afluria 0.25 mL
- Fluarix 0.5 mL
- Flucelvax 0.5 mL
- FluLaval 0.5 mL
- Fluzone 0.25 mL or 0.5 mL

 Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.





Pediatric Flu Recommendations

- Recommended for: Anyone over the age of 6 months.
 - Vaccination generally recommended to begin in September.
 - Children that need two doses and pregnant people in the third trimester can consider vaccination during July or August.
 - Certain children may require two doses:



FIGURE 1

Number of 2023–2024 seasonal influenza vaccine doses recommended for children on the basis of age and previous vaccination history. ^a Must be at least 6 months of age to be eligible for influenza vaccine. ^b Second dose still required for children who turn 9 years between first and second dose.

Guideline change: People with egg allergies are no longer recommended to be vaccinated in a medical setting.





Proposed Recommendations for Vaccination of Persons with Egg Allergy

- All persons aged ≥6 months with egg allergy should receive influenza vaccine unless a contraindication exists. Any influenza vaccine that is otherwise appropriate for the recipient's age and health status can be used (egg based or non-egg based).
- Egg allergy in and of itself necessitates no additional safety measures for influenza vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg.
- Severe and life-threatening reactions to vaccines can rarely occur with any vaccine and in any vaccine recipient, regardless of allergy history. Providers are reminded that all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available. All vaccination providers should be familiar with their office emergency plan and be certified in cardiopulmonary resuscitation.





Timing of Influenza Vaccination Pregnant Persons in Third Trimester

 Vaccination during July and August can be considered because vaccination might reduce risk for influenza illness in their infants during the first months after birth, when they are too young to receive influenza vaccine.





Co-administration with other vaccines

- COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
- <u>Best practices</u> for multiple injections include:
- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.



Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Flu Season 2022-2023 How did we do?



Estimated Flu Burden*

From October 1, 2022 to April 30, 2023, there were an estimated:

27 - 54 Million

Flu Illnesses





300,000 - 650,000 Flu **Hospitalizations**

19,000 - 58,000 Flu **Deaths**

*CDC preliminary flu estimates for the United States

Flu Vaccine Effectiveness in Children

As of January 2023

Flu vaccination reduced

hospitalizations I

emergency department visits by 42%











Flu viruses constantly change, so our flu vaccines must also change from one season to the next. Experts do their best to match the vaccine formula to the flu virus we expect to see, but they don't always get it right, and no vaccine is perfect.

In 2022-2023, the flu shot did quite well at protecting people - especially kids and people with weakened immune systems - from getting really sick from the flu.

Come this fall, make sure everyone in your family gets a flu shot. Flu season will be here before you know it.











Questions?





Final Session in Cohort: Tuesday, December 19th

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.



