## Welcome to our session

Protection Against Winter Respiratory Viruses: An Update on the RSV, COVID, and Flu Vaccines

AZ COMMUNITY GRAND ROUNDS



### AZ COMMUNITY GRAND ROUNDS Session Panel R. Nicholas Staab, MD, MSPH Assistant Medical Director Maricopa County Department of Public Health Joel Terriquez, MD, FIDSA, CIC Medical Director, Bureau of Infectious Disease and Immunizations Arizona Department of Health Services Nathan B. Price, MD Associate Professor, Pediatrics University of Arizona College of Medicine

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### Financial Disclosure

No individuals in control of the educational content have any relevant financial relationships.



### Respiratory Season 2024-25 Vaccine Updates

**October 2, 2024** 





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### Fall and Winter Immunization Guide



### Why Vaccinate

Share with others...why do you get COVID/Flu/RSV vaccines?

- Re-normalize vaccination
- Instead of sharing with people why they should get vaccinated share why you choose vaccination
- Your Local Epidemiologist (YLE) <u>series</u> on lessons learned from rolling out COVID vaccines



### Why get a COVID-19 Vaccine

- Help prevent serious illness and death due to COVID-19 for both children and adults
- Help prevent you from needing to go to the hospital due to COVID-19
- Be a less risky way to protect yourself compared to getting sick with the virus that causes COVID-19
- Lower long-term risk for cardiovascular complications after COVID-19





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Morbidity and Mortality Weekly Report

September 26, 2024

#### COVID-19–Associated Hospitalizations and Maternal Vaccination Among Infants Aged <6 Months — COVID-NET, 12 States, October 2022–April 2024

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FIGURE 1. Weekly COVID-19-associated hospitalization rates (3-week moving average) among children and adolescents aged <18 years,\* by age group — COVID-19-Associated Hospitalization Surveillance Network, 12 states,<sup>†</sup> October 1, 2022–April 30, 2024



Return

# New Data – COVID vaccine in pregnancy

 Percentage of hospitalized infants whose mothers had been vaccinated during pregnancy was 18% during October 2022– September 2023 and decreased to <5% during October 2023– April 2024



### Why RSV for Infants

- In the US, between 58,000 and 80,000 children under the age of five are hospitalized each year due to respiratory syncytial virus (RSV)
- Nirsevimab was 79% effective at preventing RSV-associated lower respiratory tract infections (LRTIs) and 80.6% effective at preventing RSV-associated LRTIs that led to hospitalization
- 100 to 500 children under five die from RSV each year



### **Immunizations to Protect Against Severe RSV**

	Who Does It Protect?	Type of Product	Who Is It Recommended For?	When Is It Available?
Reg to	Adults 60 and over	RSV vaccine	Adults ages 60-74 who are at increased risk of severe RSV AND Everyone ages 75 and older	Available any time, but best time to get vaccinated is late summer and early fall
	Babies	RSV antibody (nirsevimab) given to baby	All infants whose mother did not receive RSV vaccine during preg- nancy, and some children ages 8-19 months who are at increased risk for severe RSV	October through March*
MO	Babies	RSV vaccine (Pfizer's ABRYSVO) given to mother during pregnancy	All pregnant people during weeks 32-36 of their pregnancy	September through January

#### www.cdc.gov/rsv

\*Recommended timing of administration in most of the continental United States. Recommended timing of administration may differ in some areas, based on state, local, or territorial guidance.



#### Timing of RSV Immunizations for Infants and Pregnant People





#### Maternal Respiratory Syncytial Virus Vaccination and Receipt of Respiratory Syncytial Virus Antibody (Nirsevimab) by Infants Aged <8 Months — United States, April 2024

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September 26, 2024

https://www.cdc.gov/mmwr/volumes/73/wr/mm7338a2.htm?s\_cid=mm7338a2\_w

Among 678 women at 32–36 weeks' gestation during September 2023–January 2024, <mark>32.6%</mark> reported receipt of an RSV vaccine any time during pregnancy. Among 866 women with an infant born during August 2023– March 2024, 44.6% reported receipt of nirsevimab by the infant. Overall, 55.8% of infants were protected by maternal RSV vaccine, nirsevimab, or both.



FIGURE. Main reason for not receiving respiratory syncytial virus vaccine among unvaccinated pregnant or Return recently pregnant women (N = 433) (A)\* and probably or definitely not receiving respiratory syncytial virus antibody (nirsevimab) for unprotected infants (N = 240) (B)<sup>†,§</sup> – Internet panel survey, United States, April 2024



Maternal RSV





• It is safe, and a proven strategy to improve vaccination rates, to get multiple vaccines together at the same time.



### **Thank You**

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### Influenza, COVID-19, RSV:

Preparing ourselves for the next respiratory season

Joel Terriquez, MD, FIDSA, CIC

**Medical Director** 

Bureau of Infectious Diseases Services/Bureau of immunizations Services

### National trends

- Overall seasonal influenza activity remains low nationally
- CDC estimates
  - 35 million illnesses
  - 400,000 hospitalizations
  - 21,000 deaths so far this season.
- 0.1% test positivity (8.6% cumulative)
- 0.08% mortality



	Week 38	Data Cumulative since October 1, 2023 (Week 40)
No. of specimens tested	46,909	4,101,482
No. of positive specimens (%)	267 (0.1%)	352,669 (8.6%)
Positive specimens by type		
Influenza A	232 (86.9%)	244,062 (69.2%)
Influenza B	35 (13.1%)	108,596 (30.8%)

### National trends

Percentage of Outpatient Visits for Respiratory Illness by Age Group Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2023-2024 Season



- The percentage of visits for respiratory illness reported increased in the 0-4 years age group
- Remained stable in all other age groups in Week 38.
- 200 influenza pediatric deaths

Number of Influenza-Associated Pediatric Deaths by Week of Death, 2020-2021 season to 2023-2024 season



### National trends



- 25,423 influenza confirmed hospitalizations
- The peak weekly hospitalization rate this season was 8.9 per 100,000 population and occurred during week 52.
  - 21,520 (84.6%) were associated with influenza A virus
  - 3,772 (14.8%) with influenza B virus
  - 55 (0.2%) with influenza A virus and influenza B virus co-infection
- Among those with influenza A
  - 4,485 (67.6%) were A(H1N1) pdm09
  - 2,151 (32.4%) were A(H3N2)

### **Respiratory Virus**

### Surveillance

- Laboratory Reporting of positive tests for influenza
- Outpatient influenza-like illness (ILI) surveillance
- Virologic surveillance
- Influenza-associated pediatric deaths
- Investigation of unusual influenza-related occurrences (outbreaks & novel viruses)





### Arizona-Influenza

- Influenza activity is higher than the 5-season average
- 55,679 cases this season
- 18% increase compared to previous season (week 37)
- Influenza-like illness 1.6% of the outpatient visits
- 4 pediatric deaths this season

In the past week, there were 77 laboratory confirmed influenza cases.



### Arizona- COVID-19

- 140,199 cases this season
- 43% decrease compared to previous season (week 37)
- 25% decrease compared to the previous week
- The Omicron FLiRT variants (KP.1 and KP.2) are the dominant variants in Arizona.
- CDC reports 11.6% test positivity

In the past week, there were 1,948 laboratory confirmed COVID-19 cases.





### Arizona- RSV

- 19,394 cases this season
- 94% decrease compared to previous season (week 37)
- 25% decrease compared to previous week.
- CDC reports 0.43% test positivity

In the past week, there were 2 laboratory confirmed RSV cases.



Number of Lab-Confirmed RSV Cases Reported, by Week of Report: 2018–2023

### Virologic Surveillance

#### **Novel Influenza Virus Detection**

 Detect a novel influenza virus among influenza positive surveillance specimens tested across all jurisdictions

#### **Vaccine Virus Selection**

 Monitor antigenic and genetic changes in currently circulating influenza viruses to inform vaccine virus selection.

#### **Antiviral Resistance**

 Detect antiviral resistant virus(es) among influenza positive surveillance specimens tested across all jurisdictions

#### Situational Awareness for Seasonal Influenza

 Determine the beginning and end of the influenza season and monitor the prevalence and spread of influenza viruses throughout the year.



### **Specimen Submitter Network**

- Influenza testing occurs in a variety of settings including physician offices, laboratories, ambulatory care settings, medical examiner's office, and hospital and commercial laboratories.
- When selecting submitters, feasibility and representativeness (age, geography, disease severity).



Figure 1. The US influenza virologic surveillance system is a tiered system. The same specimens answer various clinical and surveillance questions throughout the system with only a subset of specimens advancing to each subsequent level.



#### Influenza Virus Characterization

CDC performs <u>genetic</u> and <u>antigenic</u> characterization of U.S. viruses submitted from state and local public health laboratories according to the Right Size Roadmap submission guidance. These data are used to compare how similar the currently circulating influenza viruses are to the reference viruses representing viruses contained in the current influenza vaccines. The data are also used to monitor evolutionary changes that continually occur in influenza viruses circulating in humans. CDC also tests susceptibility of circulating influenza viruses to antiviral medications including the neuraminidase inhibitors (oseltamivir, zanamivir, and peramivir) and the PA endonuclease inhibitor baloxavir.

CDC has genetically characterized 5,235 influenza viruses collected since October 1, 2023.

	Genetic Characterization					
Virus Subtype or Lineage	Total No. of Subtype/Lineage Tested	HA Clade	Number (% of subtype/lineage tested)	HA Subclade	Number (% of subtype/lineage tested)	
A/H1	1,924					
		6B.1A.5a	1,924 (100%)	2a	462 (24.0%)	
				2a.1	1,462 (76.0%)	
A/H3	1,835					
		3C.2a1b.2a	1,835 (100%)	2a.1b	1 (0.1%)	
				2a.3a	1 (0.1%)	
				2a.3a.1	1,832 (99.8%)	
				2b	1 (0.1%)	
B/Victoria	1,476					
		V1A	1,476 (100%)	3a.2	1,476 (100%)	
B/Yamagata	0					
		Y3	0	Y3	0 (0%)	

#### Assessment of Virus Susceptibility to Antiviral Medications

CDC assesses susceptibility of influenza viruses to the antiviral medications including the neuraminidase inhibitors (oseltamivir, zanamivir, and peramivir) and the PA endonuclease inhibitor baloxavir using next generation sequence analysis supplemented by laboratory assays. Information about antiviral susceptibility test methods can be found at <u>U.S.</u> <u>Influenza Surveillance: Purpose and Methods | CDC</u>.

Viruses collected in the U.S. since October 1, 2023, were tested for antiviral susceptibility as follows:

Antiviral Medication		Total Viruses	A/H1	A/H3	B/Victoria	
Neuraminidase Inhibitors	Oseltamivir	Viruses Tested	5,147	1,898	1,805	1,444
		Reduced Inhibition	1 (0.02%)	1 (0.1%)	0 (0.00%)	0 (0.00%)
		Highly Reduced Inhibition	5 (0.1%)	5 (0.3%)	0 (0.00%)	0 (0.00%)
	Peramivir	Viruses Tested	5,147	1,898	1,805	1,444
		Reduced Inhibition	3 (0.1%)	0 (0.00%)	0 (0.00%)	3 (0.2%)
		Highly Reduced Inhibition	6 (0.11%)	5 (0.3%)	0 (0.00%)	1 (0.1%)
	Zanamivir	Viruses Tested	5,147	1,898	1,805	1,444
		Reduced Inhibition	1 (0.02%)	0 (0.00%)	0 (0.00%)	1 (0.07%)
		Highly Reduced Inhibition	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
PA Cap- Dependent Endonuclease Inhibitor	Baloxavir	Viruses Tested	5,060	1,847	1,782	1,431
		Decreased Susceptibility	1 (0.02%)	0 (0.0%)	1 (0.1%)	0 (0.0%)

Fluview

### 2024-25 Flu Vaccine Composition

The composition of flu vaccines has been updated. Flu vaccines for the U.S. 2024-2025 season will contain the following:

#### Egg-based vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Thailand/8/2022 (H3N2)-like virus; and (Updated)
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

#### Cell- or recombinant-based vaccines

- an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- an A/Massachusetts/18/2022 (H3N2)-like virus; and (Updated)
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus.



### What comes next?

- COVID-19 and influenza vaccines are readily available
- Covered by commercial health insurance, including AHCCCS (Medicaid)
- Local health departments and community-based organizations also offer Influenza and COVID-19 vaccinations.
- Mobile COVID-19 vaccine program
- Vaccines for Children program



	Beyfortus (Nirsevimab)	Arexvy (GSK)	Abrysvo (Pfizer)
Indicated Age	All infants < 8mo High risk < 19mo	60yo+	60yo+ (or pregnancy)
Effectiveness	75% decrease in medically-attended LTRI	75% reduction in 2+ symptoms	75% reduction in 2+ symptoms
Safe in Pregnancy?	N/A	Untested	Yes; reduces newborn infxns
Mechanism	Monoclonal Ab	pre-fusion F protein w/ adjuvant	pre-fusion F protein



### THANK YOU

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# Update on the RSV, COVID and Flu Vaccines

#### Nathan Price, MD

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### Potential Conflicts of Interest

- Consulted for DSM-Firmenrich
  - Won't discuss anything related today

### Respiratory Syncytial Virus (RSV)

- Seasonal October-March
  - Usually peaks January/February
    - Longer season in FL and tropical areas
- Annual burden of disease in children
  - 100-300 deaths
  - 58,000-80,000 hospitalizations
  - 520,000 ED visits
  - 1.5 million outpatient visits
- Annual burden of disease of older adults
  - 6,000-10,000 deaths
  - 60,000-160,000 hospitalizations

### Higher risk for increased severity of RSV

- Infants
  - Especially premature infants
- Comorbidities
  - Chronic lung disease
  - Cardiac disease
  - Immune compromised
  - Cystic fibrosis
  - Neuromuscular disorders (especially with problems swallowing secretions)
- American Indian/Alaska Native children

### Preventing RSV

- Passive immunization (monoclonal antibody)
  - Palavizumab (Synagis)
  - Nirsevimab (Beyfortus)
- Active immunization (vaccines)
  - Adults only, 1 time dose (not annual)
    - ≥75y, or 60-74y with increased risk
      - Arexvy (GSK), mResvia (Moderna), Abrysvo (Pfizer)
    - Pregnant people 32-36 weeks gestation, September-January
      - Abrysvo
  - 1960s vaccine in infants increased severity leading to 2 deaths in the clinical trial

### Maternal Vaccination During Pregnancy: Abrysvo

- Efficacy data from clinical trials
  - Within 3 months of vaccination
    - Protection against infant hospitalization: 68%
    - Protection against RSV related healthcare visit: 57%
  - Within 6 months
    - Hospitalization: 57%
    - Healthcare visit: 51%
- Not enough data to know real world efficacy from last season

### Palavizumab (Synagis)

- Recently was only indicated for about 5% of children
  - Decreased hospitalization rate (about 50% relative risk reduction)
    - Didn't prevent infection or decrease mortality rate
    - Monthly doses
    - Relatively expensive
- Can be used in the indicated high risk patients if nirsevimab isn't available
  - Minimal discussion on palivizumab by AAP and CDC now that nirsevimab is a available

### Nirsevimab (Beyfortus)

- Single dose, less expensive than Palavizumab
- Clinical trial efficacy
  - Any healthcare visit 79%
  - Hospitalization 80%
- Real world data: 80-90% effective

### Nirsevimab (Beyfortus): Who Should be Immunized

- All infants <8 months born during or entering 1<sup>st</sup> RSV season (October through end of March, some flexibility depending on area)
  - Exception: maternal vaccination
    - Exception to the exception: immunocompromised mother, receipt of vaccine <14 days prior to delivery, infant ECMO or cardiopulmonary bypass, substantial risk of severe RSV disease (still on O2 after ICU stay, hemodynamically significant cardiac disease)
- High risk 8-19 months old during 2<sup>nd</sup> RSV season
  - Chronic lung disease with O2 requirement within last 6 months prior to onset of RSV season
  - Severe immunocompromise
  - Cystic fibrosis with severe lung disease or <10% weight
  - American Indian, Alaska Native
- Not recommended  $\geq 8$  months without high risk, or  $\geq 20$  months



AAP Red Book 2024

### Influenza

- Variability in timing of onset of the season
  - Low-level transmission year-round, but the season usually starts after October
    - Most likely Dec-Feb
  - A strains tend to circulate earlier than B strains
- Antiviral therapy only has a small effect on disease
- Historically ~80% of peds deaths occur in eligible, unvaccinated children 6 months and older
  - Almost half had no underlying medical conditions

### CDC Flu View



2023-24 Influenza Season Week 38 ending Sep 21, 2024





#### Number of Influenza-Associated Pediatric Deaths by Week of Death



Seasons	Total Deaths	Influenza A	Influenza B	Influenza A/B Not Distinguished	Influenza A and B
2020-21	1	0	1	0	0
2021-22	49	47	2	0	0
2022-23	187	173	14	0	0
2023-24	199	104	91	0	3

### Flu Vaccine

- Content determined by prior season and latest circulating strains in surveillance centers worldwide
  - 2024-2025 is a trivalent vaccine
    - A/VictoriaH1N1 or A/WisconsinH1N1, A/ThailandH3N2 or A/MassachusettsH3N2, B/Austria
    - B/Yamagata eliminated since it hasn't been seen since 2020

### Flu Vaccine

- Glass half empty: 38% effectiveness against Flu A, 50% Flu B in 2018
- Glass half full
  - Estimated to prevent annually up to:
    - 6.7 million illnesses
    - 3.1 million outpatient visits
    - 87,000 hospitalizations
    - 10,000 deaths
  - Decreased morbidity when infected compared to unimmunized
    - Mechanical ventilation, vasopressor use, ICU admission

### Flu Vaccine Options

- Inactivated Influenza Vaccines (IIV3)
  - Egg grown: Fluzone, Fluarix, FluLaval, Afluria
    - Egg allergy is NOT a contraindication
  - ≥6 months old
  - High dose and adjuvanted IIV3 options for adults  $\geq$ 65 years
- Cell culture (canine kidney cells): Flucelvax
  - $\geq$  6 months old
- Live Attenuated (LAIV): FluMist
  - 2-49 years old
  - Not used for patients with asthma, immunocompromised, severely immunocompromised close contacts, etc
  - FDA just approved for home administration
- Recombinant (RIV4): Flublok
  - Insect cell based
  - $\geq$  18 years
  - Needleless administration (Jet Injector)

### Flu Vaccine

- Recommended all persons ≥6 months (unless contraindicated)
- Start now and continue through the season
  - Including someone who already became infected since other strains may circulate later (ie Flu B)
  - Consider timing/dose in high-risk adults

### SARS-CoV-2 (COVID-19)

- Established endemicity, frequent resurgences based on new strains
  - Continues to affect children, sometimes severely
  - We don't have very effective antiviral therapy for severe disease



covid.cdc.gov/covid-data-tracker/#demographicsovertime

### SARS-CoV-2 Variants

Weighted and Nowcast Estimates in United States for 2-Week Periods in 6/9/2024 – 9/28/2024

Nowcast Estimates in United States for 9/15/2024 – 9/28/2024



\*\* These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

# Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed. While all lineages are tracked by CDC, those named lineages not enumerated in this graphic are aggregated with their parent lineages, based on Pango lineage definitions, described in more detail here:

https://web.archive.org/web/20240116214031/https://www.pango.network/the-pango-nomenclature-system/statement-of-nomenclature-rules.

### COVID Vaccination in Children

- Potential Benefit
  - Decrease infection rates and transmission to others
  - Decrease disease severity
  - Decrease risk of MIS-C, long COVID
- Potential Risk
  - Myocarditis in adolescent and young adults after mRNA vaccine
    - Higher risk with infection compared to vaccine
    - Almost all cases were mild and self limited

### Current COVID Vaccines in the US

- 2024-2025 vaccines are monovalent based on the Omicron lineage
  - mRNA, KP.2 strain based
    - Pfizer-BioNTech and Moderna
      - ≥6 months of age
  - Subunit, JN.1 strain based
    - Novavax
      - ≥12 years of age

# COVID Vaccine Schedule 2024-2025 formulation

- Initial, not moderately/severely immune compromised
  - 6m-4y
    - 2 doses Moderna, 3 doses Pfizer-BioNTech
  - 5-11y
    - 1 dose Moderna or Pfizer-BioNTech
  - ≥12y
    - 1 dose Moderna or Pfizer-BioNTech
    - 2 doses Novavax
- Previously vaccinated not moderately/severely immunocompromised
  - Generally a single dose of the 2024-2025 formulation

### References

- Grohskopf et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices - United States, 2024-25 Influenza Season. MMWR Recomm Rep. 2024 Aug 29;73(5):1-25.
- Red Book: 2024–2027 Report of the Committee on Infectious Diseases (33rd Edition)
- www.cdc.gov

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