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Immunization Webinar Series

Preparing for Respiratory Virus Season: Flu, COVID-19, and Respiratory Syncytial Virus (RSV)

Susan Sirota, MD, FAAP

CME Accreditation Statement

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HELLO!

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Susan Sirota, MD, FAAP

- ▶ Primary Care Pediatrician, PediaTrust Pediatric Partners in Highland Park and Vernon Hills, IL
- ▶ Chairperson, PediaTrust Board of Managers
- ▶ Assistant Professor, Clinical Pediatrics, Northwestern Feinberg School of Medicine

Learning Objectives

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As a result of this webinar, participants will be able to:

Summarize 2023 clinical guidance for use of COVID-19, flu, and RSV immunizations.

Recall considerations for administering multiple vaccines to eligible patients.

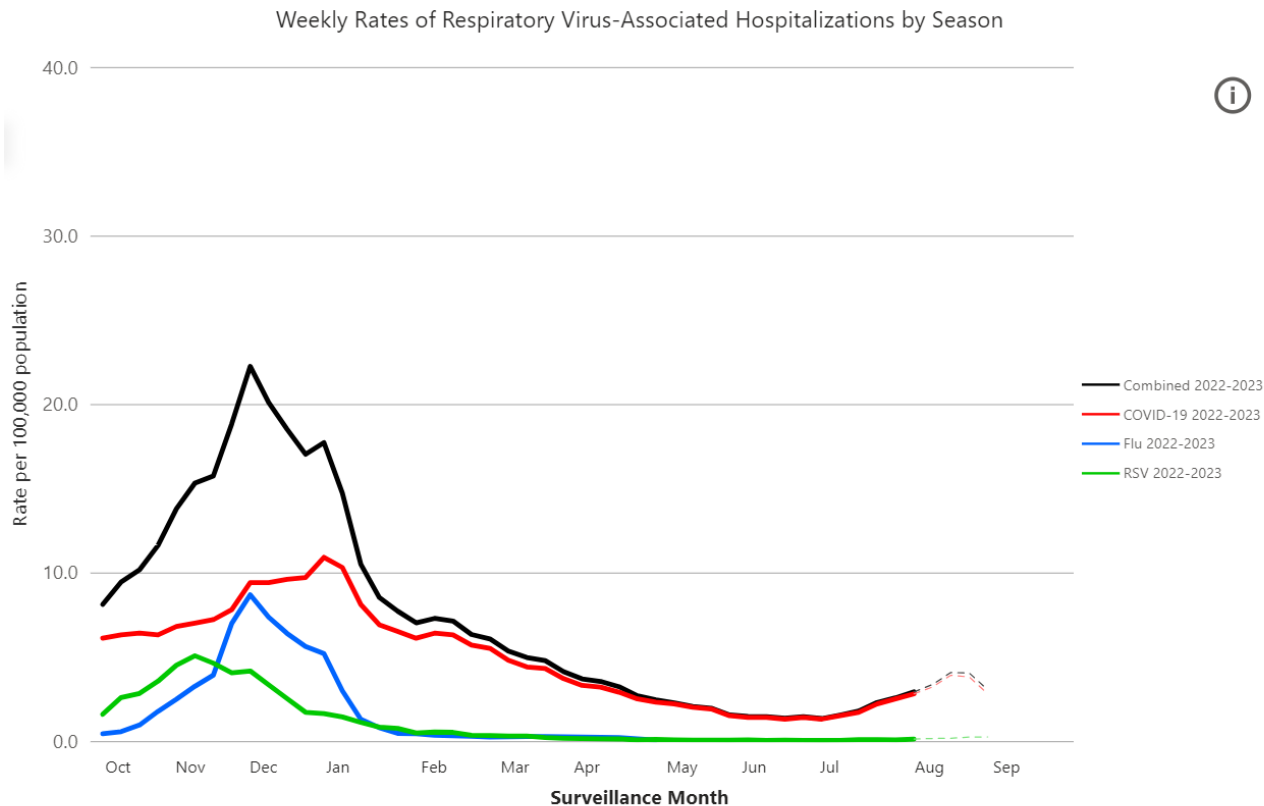
Recognize the impact of respiratory viruses on pediatric health outcomes.

Identify strategies to increase vaccine uptake during respiratory virus season.

Background

2022 – 2023 Respiratory Virus Season

The 2023-2024 season is expected to be like last year's?



Data last updated: September 13, 2023. | Accessibility: Right click on the graph area to display options such as show data as table and copy visual.

Flu Vaccines

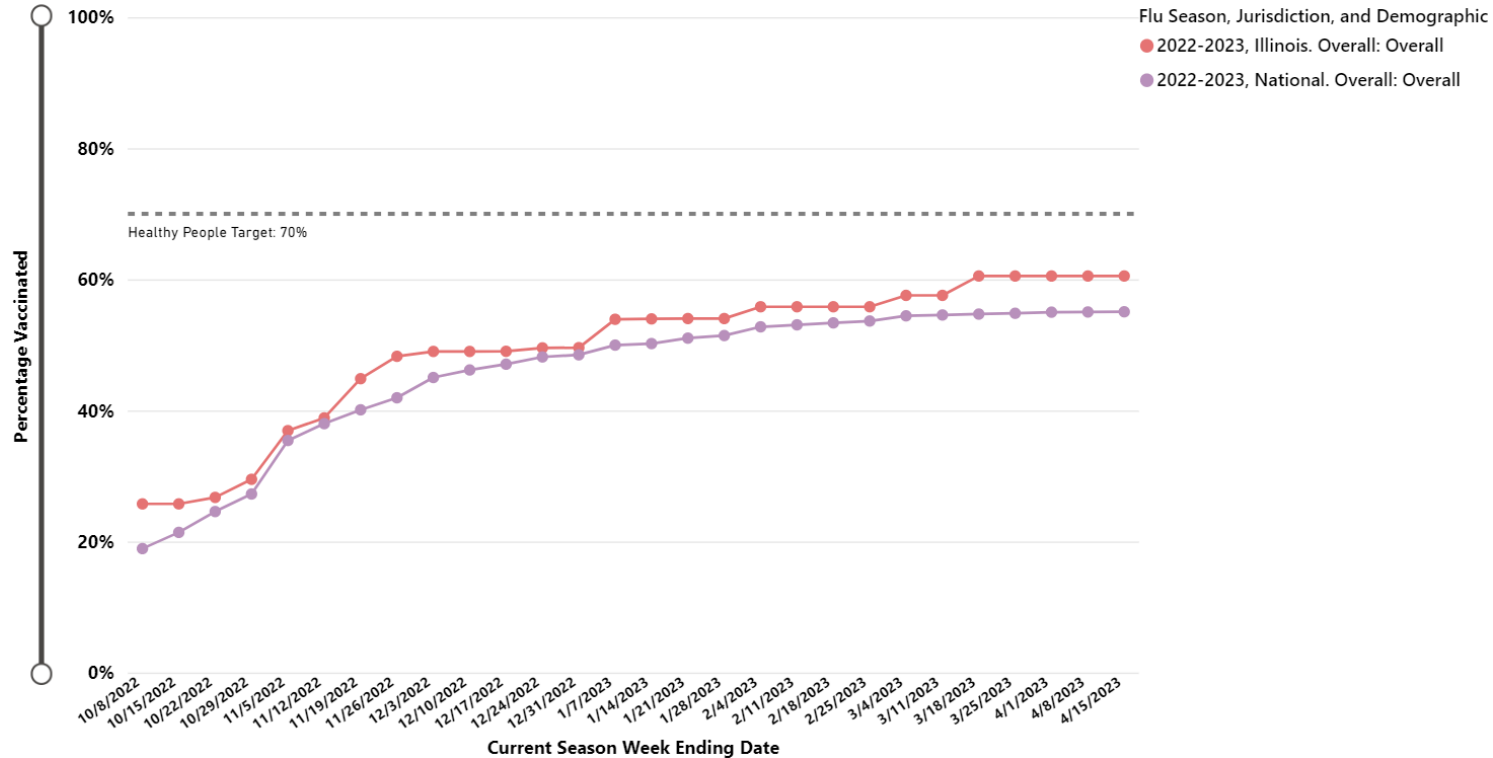
2022-2023 Flu Vaccine Coverage Children 6 Months – 17 Years

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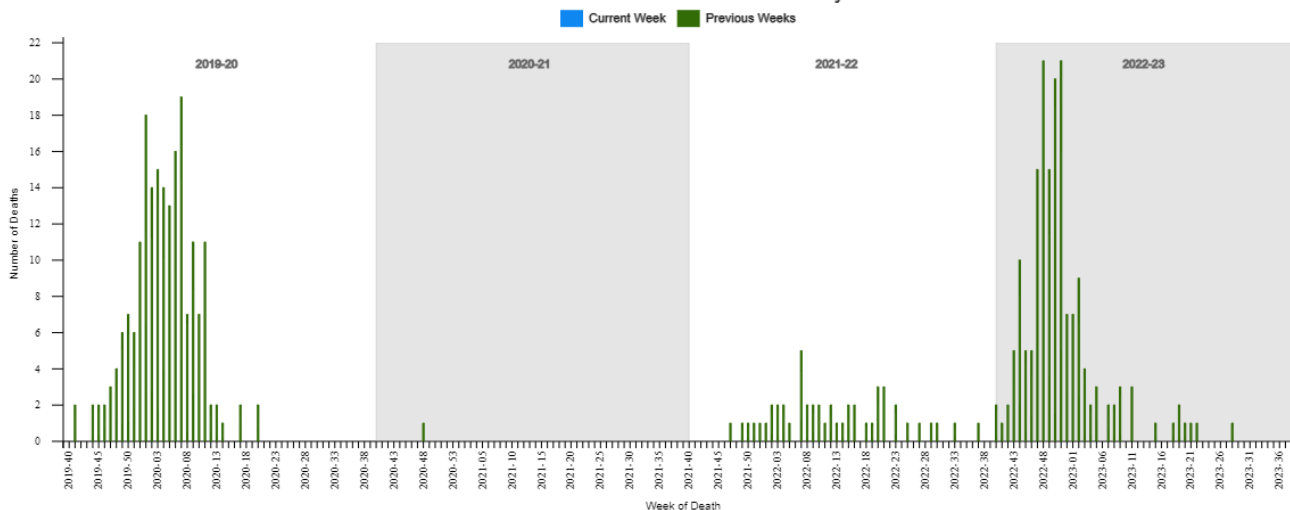
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Number of Influenza-Associated Pediatric Deaths by Week of Death



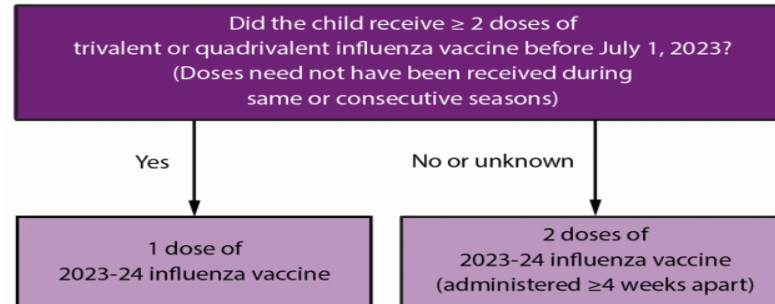
Seasons	Total Deaths	Deaths reported During the Week Ending 26 Aug 2023
2019-20	199	0
2020-21	1	0
2021-22	49	0
2022-23	172	0

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

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:



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

Flu Recommendations: Dosing

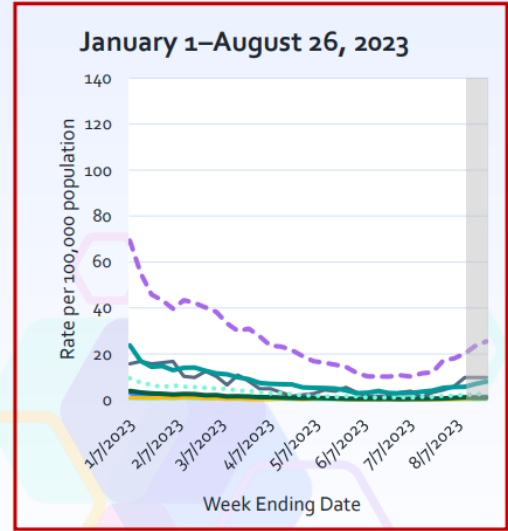
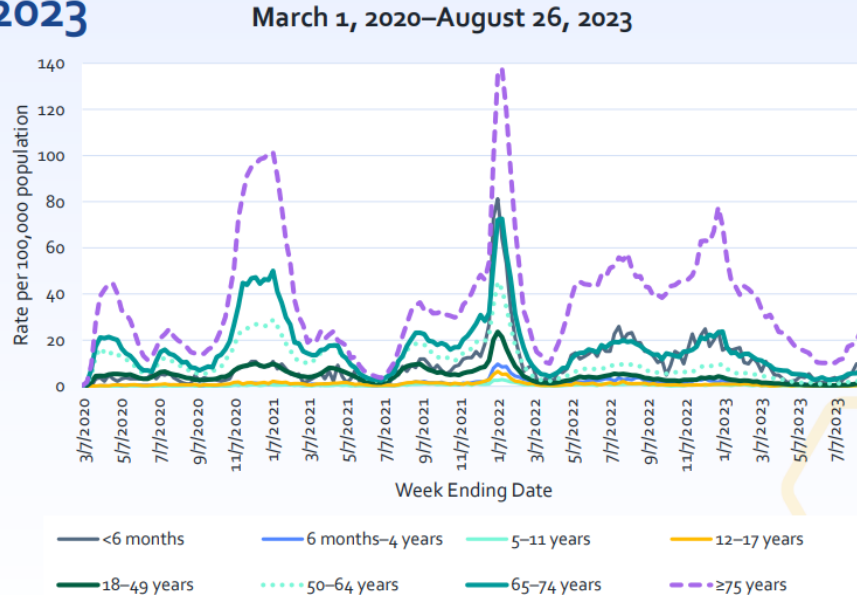
- ▶ Children 6mo-36mo:
 - ▶ 0.25mL Afluria Quadrivalent.
 - ▶ 0.5 Fluarix Quadrivalent.
 - ▶ 0.25mL or 0.5mL Fluzone Quadrivalent.
 - ▶ 0.5mL FluLaval Quadrivalent.
- ▶ 3yrs and older:
 - ▶ 0.5mL for most vaccines.
- ▶ The AAP does not prefer any product over another for children and adolescents with no contraindications.



COVID-19 Vaccines

- More than 90% of currently circulating viruses are XBB lineage viruses with 1-2 additional substitutions in RBD in comparison to XBB.1.5
- BA.2.86 is a newly detected lineage with > 30 amino acid substitutions in spike
 - Thus far, the number of viruses detected is still low
 - Sequence numbers are too low to calculate proportion (<0.05%)
- Preliminary pseudovirus neutralization data generated by multiple labs do not indicate a large reduction in neutralizing activity against BA.2.86
- CDC has generated a BA.2.86 isolate, is currently working on titrations before neutralization and has begun distribution to external laboratories for further examination

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations — COVID-NET, March 2020–August 26, 2023

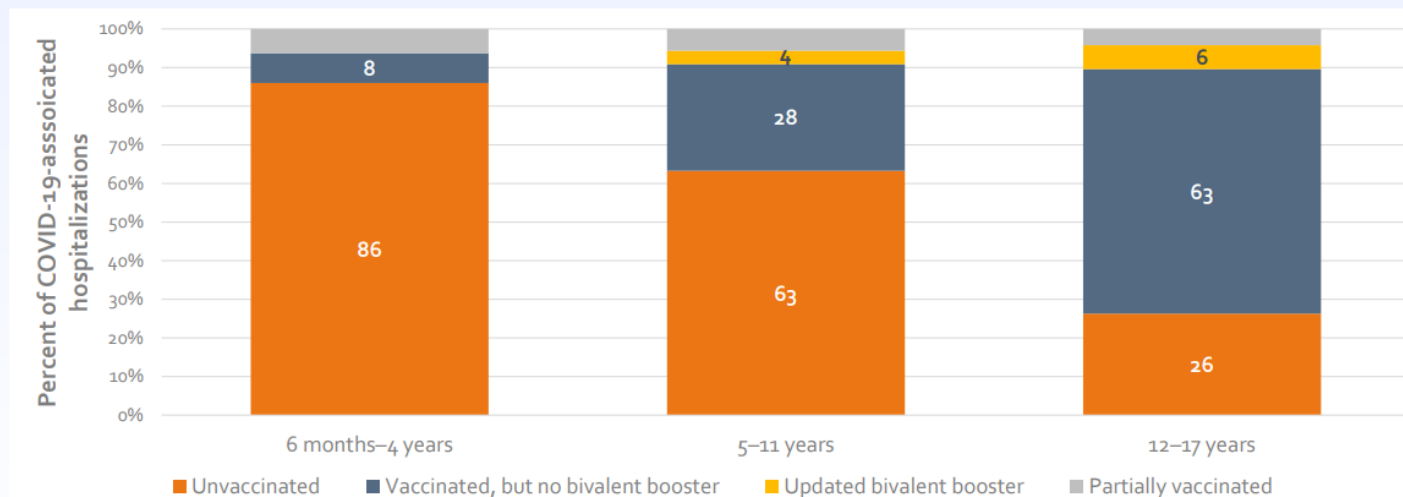


Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years

COVID-19-associated hospitalizations

- Hospitalization rates increased in all age groups since mid-July
- Hospitalization rates highest in older adults and infants <6 months
- Most children <5 years hospitalized with COVID-19 illness have no underlying medical conditions
 - A higher proportion of hospitalized children and adolescents 5-17 years have underlying medical conditions
 - Most hospitalized adults have multiple underlying medical conditions
- COVID-19 continues to cause severe illness; clinical outcomes generally comparable to influenza-associated hospitalizations
- Most children and adults hospitalized for COVID-19 since January 2023 had not received an updated bivalent booster

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 recorded doses of COVID-19 vaccine. **Vaccinated, but no bivalent booster:** Completed a primary series with or without ≥ 1 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.

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

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19 ⁶
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months–<18 years
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 Dis 2008; 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.

⁵Glass 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:S5–11

⁶<http://wonder.cdc.gov/mcd-icd10-provisional.html> 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 23 years in June 2022



- ▶ September 11, 2023 (FDA):
 - ▶ Approval of Comirnaty (COVID-19 Vaccine, mRNA) (2023-2024 Formula) was granted to BioNTech Manufacturing GmbH. The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) was issued to Pfizer Inc.
 - ▶ Approval of Spikevax (COVID-19 Vaccine, mRNA) (2023-2024 Formula) was granted to ModernaTX Inc. and the EUA amendment for the Moderna COVID-19 Vaccine (2023-2024 Formula) was issued to ModernaTX Inc.
- ▶ September 12, 2023 – ACIP voted in favor of recommending the 2023 – 2024 COVID-19 vaccine formulation for everyone 6 months and older.
 - ▶ CDC also signed off.



- ▶ Bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.
- ▶ The original Novavax COVID-19 vaccine remains authorized for use as a 2-dose primary series for those ages 12+ and as a booster dose for those ages 18+ in limited situations.
 - ▶ Authorizations or approvals for 2023 – 2024 Novavax COVID-19 vaccine will be determined by FDA with CDC recommendations to follow.

Commercialization – Patient Access



- ▶ Vaccines For Children (VFC) program: COVID-19 vaccines to children who qualify at no cost.
- ▶ Bridge Access Program for COVID-19 Vaccines and Treatments: Adults with no insurance will have access to COVID-19 vaccines at no cost.
 - ▶ Through state immunization programs, local health departments, HRSA-supported health centers, and pharmacies.
- ▶ Patients with private insurance access the same way they access other vaccinations.



- ▶ This variant has multiple genetic differences from previous versions of SARS-CoV-2.
 - ▶ 30+ mutations in the spike as compared with the XBB recombinant variants (XBB.1.5, EG.5.1, and FL.1.5.1) and mutations are seen across other components of the virus.
 - ▶ Better at escaping immunity but showing lower infectivity.
- ▶ Early studies are showing that the upcoming XBB 1.5. vaccines protect against BA.2.86.
- ▶ “At the moment there’s no reason for alarm. All of us wish this was behind us, but it’s not. Facing that fact this virus, in one version or another, will be with us for many years to come, rather than denialism and complacency, is critical”. – Eric Topol

2023–2024 COVID-19 VACCINE

Monovalent XBB.1.5

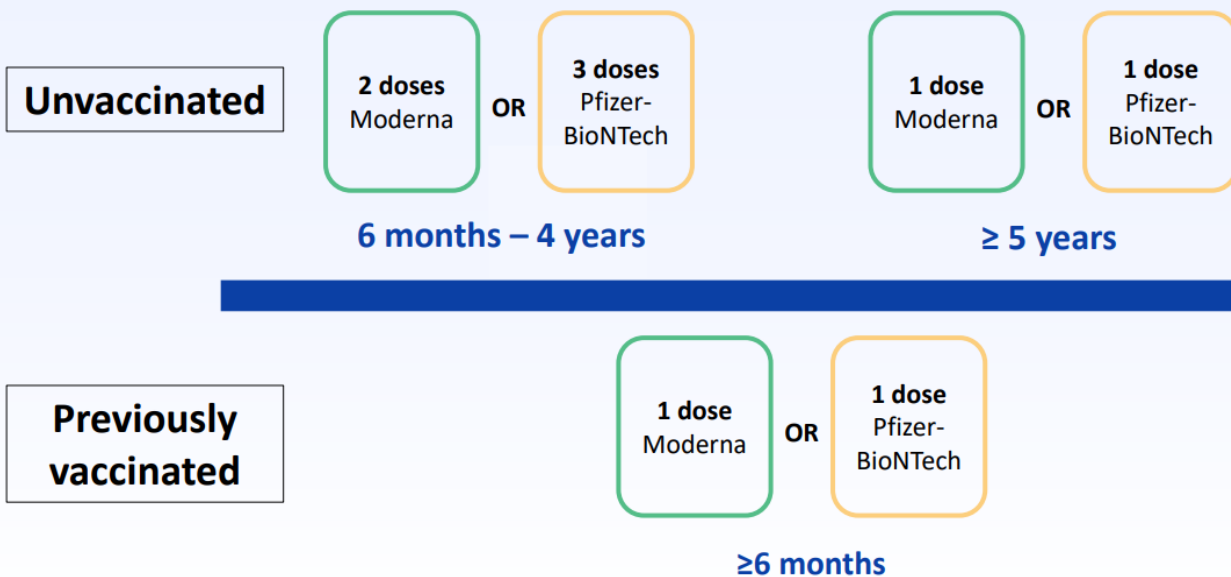
Last updated September 13, 2023



AGE INDICATIONS AND FORMULATION	MODERNA		PFIZER			
	6 Months–11 Years	12+ Years	6 Months–4 Years	5–11 Years	12+ Years	12+ Years Prefilled Syringe
VIAL CAP COLOR	Dark Blue	Dark Blue	Yellow	Blue	Gray	N/A
VIAL LABEL BORDER COLOR	Green	Dark Blue	Yellow	Blue	Gray	N/A
PREPARATION	Do Not Dilute	Do Not Dilute	Dilute	Do Not Dilute	Do Not Dilute	N/A
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
DOSES PER VIAL	1	5 or 1	3	1	1	1 – Prefilled Syringe
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE	DO NOT STORE	12 Months	12 Months	18 Months	9 Months
FREEZER (-50°C TO -15°C)	Until Expiration	Until Expiration	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
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*
AFTER FIRST PUNCTURE (2°C TO 25°C)	N/A	12 Hours or Discard After Single Use	Discard After 12 Hours	N/A	N/A	N/A

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

Proposed 2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines



Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

Updated Clinical Guidance



- ▶ Pfizer eligibility:
 - ▶ 6mo-4yrs:
 - ◆ Unvaccinated individuals receive three doses - first two are given three weeks apart, third dose given 8+ weeks after the second.
 - ◆ At least one dose of any Pfizer vaccine – first dose administered at least 3 weeks after the previous, second dose given 8+ weeks after.
 - ◆ 2-4 doses of any Pfizer vaccine - one dose 8+ weeks after previous.
 - ▶ 5-11yrs regardless of vaccination status:
 - ◆ One dose 2+ months after the previous dose.
 - ▶ Immunocompromised individuals 6mo-11yrs:
 - ◆ Three doses each 1+ months apart.
 - ◆ At least 1 dose should be with a 2023-2024 formula.
 - ▶ ALL individuals 12yrs and older:
 - ◆ One dose 2+ months after the last dose of any COVID vaccine.

Updated Clinical Guidance



- ▶ Moderna eligibility:
 - ▶ 6mo-4yrs:
 - ◆ Unvaccinated individuals receive two doses – second given 1+ month after the first.
 - ◆ At least one dose of any Moderna vaccine including bivalent– one dose administered given 1+ month after the first.
 - ◆ 2 or more doses including bivalent- one dose 2+ months after previous.
 - ▶ 5-11yrs regardless of vaccination status:
 - ◆ One dose 2+ months after the previous dose.
 - ▶ Immunocompromised individuals 6mo-11yrs:
 - ◆ Three doses each 1+ months apart
 - ◆ At least 1 dose should be with a 2023-2024 formula.
 - ▶ ALL individuals 12yrs and older:
 - ◆ One dose 2+ months after the last dose of any COVID vaccine.

COVID-19 VACCINATION SCHEDULE AND DOSING

AGES 6 MONTHS TO 4 YEARS

27

Dosing Charts

UNVACCINATED

dose/injection volume

Moderna 2023-2024:
(Do NOT dilute before use)
Dark Blue Cap (green label)

Pfizer 2023-2024:
(dilute before use)
Yellow Cap



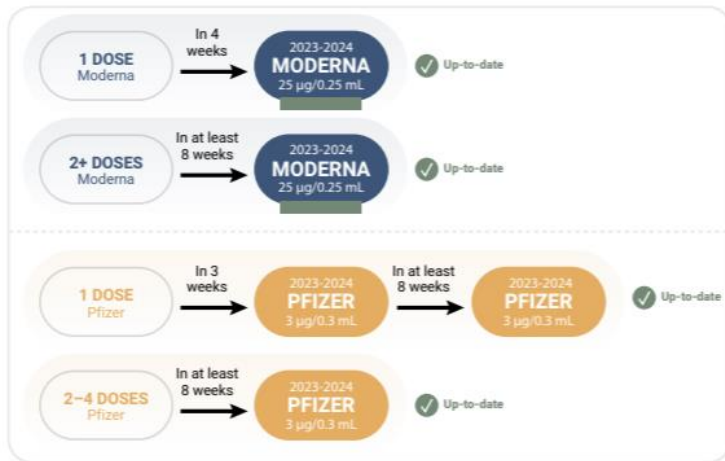
PREVIOUSLY VACCINATED

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna 2023-2024:
(Do NOT dilute before use)
Dark Blue Cap (green label)

Pfizer 2023-2024:
(dilute before use)
Yellow Cap



*Additional doses are recommended for immunocompromised individuals. Please refer to the CDC for specific guidance.

COVID-19 VACCINATION SCHEDULE AND DOSING

AGES 5 TO 11 YEARS

UNVACCINATED

dose/injection volume

Moderna 2023-2024:

(Do NOT dilute before use)
Dark Blue Cap (green label)

Pfizer 2023-2024:

(Do NOT dilute before use)
Blue Cap



PREVIOUSLY VACCINATED

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna 2023-2024:

(Do NOT dilute before use)
Dark Blue Cap (green label)

Pfizer 2023-2024:

(Do NOT dilute before use)
Blue Cap



***Additional doses are recommended for immunocompromised individuals. Please refer to the CDC for specific guidance.**

COVID-19 VACCINATION SCHEDULE AND DOSING

AGES 12 YEARS AND OLDER

UNVACCINATED

dose/injection volume

Moderna 2023-2024:

(Do NOT dilute before use)

Dark Blue Cap (dark blue label)

Pfizer 2023-2024:

(Do NOT dilute before use)

Gray Cap



PREVIOUSLY VACCINATED

dose/injection volume



Previously Received
COVID-19 Vaccines

Moderna 2023-2024:

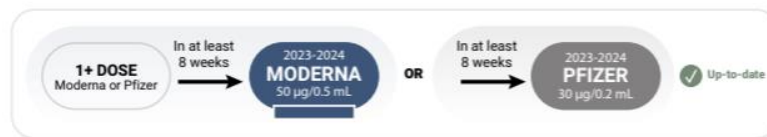
(Do NOT dilute before use)

Dark Blue Cap (dark blue label)

Pfizer 2023-2024:

(Do NOT dilute before use)

Gray Cap



***Additional doses are recommended for immunocompromised individuals. Please refer to the CDC for specific guidance.**

RSV Prevention

RSV Burden Estimates



- ▶ Each year in the United States, RSV leads to approximately:
 - ▶ 2.1 million outpatient (non-hospitalization) visits among children younger than 5 years old.
 - ▶ 58,000-80,000 hospitalizations among children younger than 5 years old.
 - ▶ 100–300 deaths in children younger than 5 years old.



- ▶ The CDC released a health advisory on 9/5/23 regarding increased RSV activity in the Southeastern US.
 - ▶ Season onset threshold = polymerase chain reaction (PCR) test positivity of 3.0%.
 - ▶ PCR positivity in Florida has been above 3% since the end of July and above 5% since the beginning of August.

- ▶ Providers should be prepared to implement newly available RSV prevention tools.

Nirsevimab (Beyfortus™) Indication



- ▶ Neonates and infants born during or entering their first RSV season.
 - ▶ Dosage is based on body weight:
 - ◆ <5 kg should be administered a 50 mg dose.
 - ◆ ≥5 kg should be administered a 100 mg dose.
- ▶ Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
 - ▶ Single 200 mg dose administered as 2 IM injections.

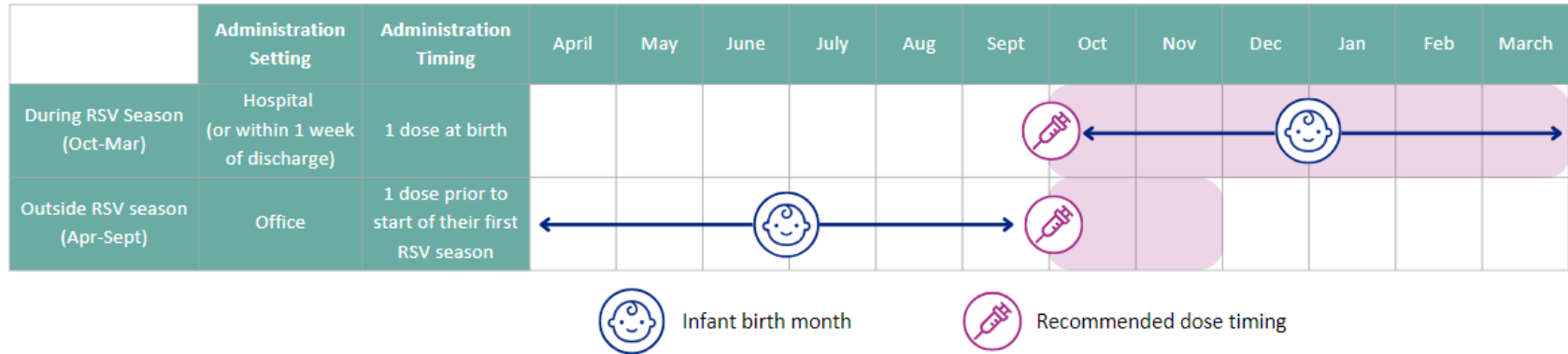
Preparation and Administration

- ▶ Available in 50mg and 100mg pre-filled syringes (single use):
 - ▶ 50 mg: purple plunger rod.
 - ▶ 100mg: light blue plunger rod.
- ▶ Should not be mixed with any vaccines or medications in the same syringe or vial.
- ▶ Administered intramuscularly as one or two injections.
 - ▶ Preferably in the anterolateral aspect of the thigh.
 - ◆ Gluteal muscle should not be used due to risk of damage to the sciatic nerve.





- ▶ The best timing for Beyfortus dosing is just before or at the start of the RSV season or at birth for infants born during the RSV season.



Provides passive immunization that extends through 5 months regardless of infant birth month.



- ▶ Can be co-administered.
 - ▶ This can help avoid multiple appointments.
- ▶ Optimal timing and eligibility for respiratory virus prevention may vary by product.
 - ▶ E.g. An infant born in June should receive Nirsevimab in October, but wouldn't be eligible for a COVID-19 or flu vaccine until December.

Contraindications/Warnings

Contraindications:

- ▶ Infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of its excipients.
 - ▶ Excipients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.

Warnings/Precautions:

- ▶ Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies.
 - ▶ Initiate appropriate medications and/or supportive therapy if signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur.
- As with other intramuscular (IM) injections, nirsevimab-alip should be given with caution to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

Palivizumab or Nirsevimab? Both?



What should I do if nirsevimab is not available for my patient who is at high risk for severe RSV illness?

- ▶ If nirsevimab is unavailable and the child is eligible to receive palivizumab, then palivizumab should be administered. If < 5 doses of palivizumab are administered and nirsevimab becomes available, the child should receive 1 dose of nirsevimab. No further palivizumab should be administered following receipt of nirsevimab.

Is there a minimum interval between palivizumab and nirsevimab, if an infant has received at least 1 dose (but less than 5 doses) of palivizumab?

- ▶ The recommended interval between the last dose of palivizumab and a dose of nirsevimab is 30 days (similar to the interval if the infant were to receive another dose of palivizumab).

Is there a minimum interval between palivizumab and nirsevimab, if an infant has received at least 1 dose (but less than 5 doses) of palivizumab?

- ▶ The recommended interval between the last dose of palivizumab and a dose of nirsevimab is 1 month (similar to the interval if the infant were to receive another dose of palivizumab).

Additional RSV Products



- ▶ Maternal (Abrysvo)
 - ▶ The FDA has approved the vaccine.
 - ▶ 32-36 weeks gestational age as a single IM dose.
 - ▶ The CDC meets October 25-27 to determine policy.
- ▶ Older Adults (Arexvy & Abrysvo)
 - ▶ FDA & CDC approved.
 - ▶ Single dose for adults 60+.
 - ▶ Using shared clinical decision-making.

Increasing Vaccine Confidence



- ▶ When people spread misinformation, they often believe the information they are sharing.
- ▶ Disinformation is crafted and disseminated with the intent to mislead others.
- ▶ Example: If a political leader claims that COVID-19 is no worse than the flu, despite knowing otherwise, that is disinformation. When an individual hears this, believes it, and then shares it, that is misinformation.
- ▶ A strong recommendation from a trusted healthcare provider is the best predictor of vaccination.
- ▶ Increasing vaccine confidence can help combat misinformation and disinformation.

Increasing Vaccine Confidence



- ▶ The trust that patients, their families, and providers have in:
 - ▶ recommended vaccines.
 - ▶ providers who administer the vaccines.
 - ▶ the processes and policies that lead to vaccine development.
 - ▶ licensure, or authorization.
 - ▶ manufacturing.
 - ▶ recommendations for use.
- ▶ Health literacy is important
 - ▶ Take time to walk through complicated concepts – what do these new terms mean and how will it impact them.

Increasing Vaccine Uptake

Simplify Scheduling

- ▶ Alert patients when vaccines are coming.
- ▶ Automatically schedule return visits.

Implementing Outreach

- ▶ Use phone calls, mail cards and reminders, text messages, and patient portals.
- ▶ Turn all visits into vaccinating visits.

Be Creative in Your Approach

- ▶ Educate and encourage.
- ▶ Listen and find answers and common ground.
- ▶ Celebrate getting vaccinations.



Increasing Vaccine Uptake



Using Motivational Interviewing

- ▶ Can help people manage mixed feelings and move toward a healthy behavior change consistent with their values and needs used evidence based and culturally sensitive tactics to speak to the patient about vaccination.
- ▶ OARS
 - ▶ Opened ended questions.
 - ▶ Offer affirmations.
 - ▶ Use reflective listening.
 - ▶ Summarize the visit .

Questions?

Upcoming Events

- ▶ Bi-weekly COVID-19 Commercialization Updates
 - ▶ Friday, September 29 at 12PM
- ▶ Illinois Vaccinates Against COVID-19 (I-VAC) Virtual OBGYN Bootcamp
 - ▶ Thursday, September 28th from 8:00AM – 12:30PM
- ▶ Vaccine Summits – In-Person!
 - ▶ September 21
 - ▶ October 3
 - ▶ October 11

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Thank You!