RSV Breakthroughs: The Latest in Prevention & Protection

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Dade County Pharmacy Association, InterAmerican Pharmacy Association, Broward County Pharmacy Association Sunday CE Program

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Disclosure

- I have no actual or potential conflict of interest in relation to this presentation

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Objectives

- Describe the epidemiology and burden of respiratory syncytial virus (RSV), particularly in high-risk populations
- Summarize the latest RSV prevention strategies, including newly approved vaccines and monoclonal antibodies
- Differentiate between RSV vaccines available for older adults and maternal immunization strategies for infant protection
- Analyze case studies to determine when pharmacological interventions (such as vaccines or monoclonal antibodies) should be initiated for high-risk patients
- Identify pharmacists' roles in RSV prevention, including patient education, vaccine administration, and advocating for immunization in high-risk populations

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What is Respiratory Syncytial Virus?

RSV = respiratory syncytial virus

Common respiratory virus

- For most of the country, spreads in the fall and winter

Difficult to distinguish from common cold, influenza, or COVID-19

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Centers for Disease Control and Prevention. About RSV. August 30, 2024. Accessed March 9, 2025.

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What about Florida and RSV?

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Florida RSV Season Region Breakdown

Florida Area	Counties	Season
Northwest	Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Okaloosa, Santa Rosa, Wakulla, Walton, and Washington	October – April (7 months)
North	Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Gilchrist, Hamilton, Lafayette, Levy, Madison, Nassau, Putnam, St. Johns, Suwannee, Taylor, and Union	September – March (7 months)
Central	Brevard, Citrus, Flagler, Hernando, Hillsborough, Lake, Marion, Orange, Osceola, Pasco, Pinellas, Seminole, Sumter, and Volusia	August – March (8 months)
Southwest	Charlotte, Collier, De Soto, Glades, Hardee, Hendry, Highlands, Lee, Manatee, Okeechobee, Polk, and Sarasota	September – April (8 months)
Southeast	Broward, Indian River, Martin, Miami-Dade, Monroe, Palm Beach, and St. Lucie	January – December (12 months)

Florida Department of Health. Respiratory Syncytial Virus (RSV) in Florida. March 3, 2025. Accessed March 9, 2025.
Florida Medicaid. RSV Season by Region. April 19, 2006. Accessed March 9, 2025.

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CDC Respiratory Illness Data Channel for Florida

Low overall respiratory illness activity

Low RSV-related emergency department visits

Low RSV-related wastewater viral activity

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Florida RSV Review Activity Summary for Week 10 (March 2-8, 2025)

- No change in emergency room visits
- Decreased RSV positivity rate
- Decreased RSV admissions
- 0 Weekly Outbreaks

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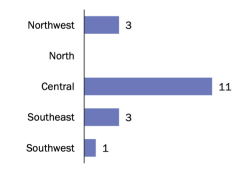
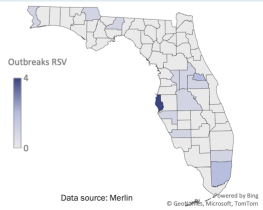
Figure 9: There have been a total of 18 outbreaks of RSV in the current season with 0 new outbreaks in the current week



No counties with outbreaks in current week



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RSV Transmission

- An individual with RSV coughs or sneezes
- Virus droplets can enter the eyes, nose, or mouth
- Direct contact with RSV
- An individual touches an RSV-contaminated surface and then their face before washing hands.

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Centers for Disease Control and Prevention. How RSV Spreads. August 30, 2024. Accessed March 9, 2025.

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RSV Transmission Continued

- Individuals with RSV are contagious for 3-8 days
  - Individuals can become contagious 1-2 days before showing symptoms symptoms
  - Infants and immunocompromised individuals can spread the virus for ~4 weeks or longer

RSV can survive on hard surfaces for many hours

RSV resides on soft surfaces for a shorter duration

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Centers for Disease Control and Prevention. How RSV Spreads. August 30, 2024. Accessed March 9, 2025.

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RSV Signs and Symptoms

- Runny nose
- Congestion
- Decreased appetite
- Coughing
- Sneezing
- Fever
- Wheezing

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Centers for Disease Control and Prevention. Symptoms and Care of RSV. August 30, 2024. Accessed March 9, 2025.

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HOW TO TELL THE DIFFERENCE BETWEEN FLU, RSV, COVID-19, AND THE COMMON COLD

Common symptoms may include cough, headaches, sneezing, runny nose, and congestion. Different symptoms may include:

Rarely
Sometimes
Often

	COLD	FLU	COVID-19	RSV
ACHES	✕✕	✕✕✕	✕✕	○
DIFFICULTY BREATHING	○	○	✕✕✕	✕✕
FATIGUE	✕✕	✕✕✕	✕✕✕	○
FEVER	○	✕✕✕	✕✕	✕✕
LOSS OF TASTE OR SMELL	○	○	✕✕	○
SORE THROAT	✕✕✕	✕✕	✕✕✕	○
WHEEZING	○	○	○	✕✕✕

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Image: https://www.nfid.org/resource/how-to-tell-the-difference-between-flu-rsv-covid-19-and-the-common-cold/

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Who is at Increased Risk of Getting Severe RSV?

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Severe RSV

- Commonly referred to as RSV infection that results in hospitalization
- Most severe cases require:
  - Additional oxygen
  - Intravenous fluids
  - Intubation with mechanical ventilation

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Centers for Disease Control and Prevention. About RSV. August 20, 2024. Accessed March 9, 2025.

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Patient Populations at Increased Risk for Severe RSV

- Infants and Young Children
- Older adults
- Immunocompromised

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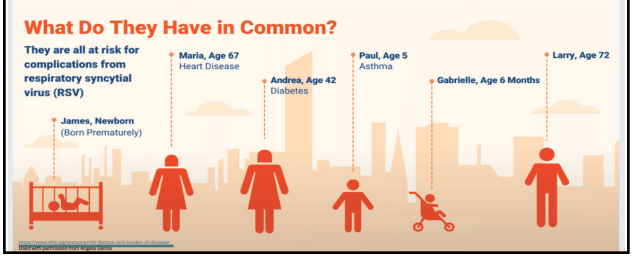
Key Facts about Respiratory Syncytial Virus



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RSV Emergency Department Visits by Age

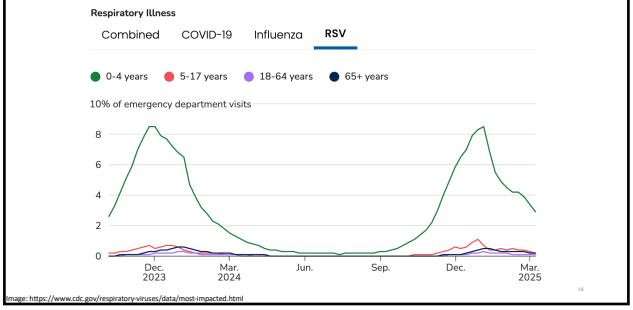

Image: https://www.cdc.gov/respiratory-viruses/data/most-impacted.html

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RSV Hospitalizations by Age

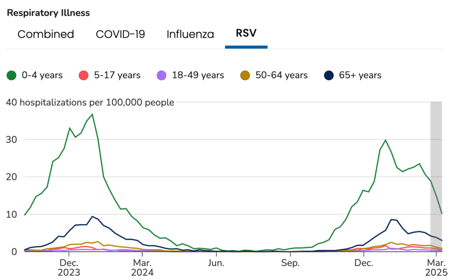

Image: https://www.cdc.gov/respiratory-viruses/data/most-impacted.html

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Nonpharmacologic Prevention of RSV

- Cover coughs and sneezes with tissue or upper shirt sleeve
- Wash hands with soap and water for at least 20 seconds
- Avoid close contact with others
- Clean frequently touched surfaces

Image: https://www.cdc.gov/rsv/infographic.html/index.html
RSV Prevention. Centers for Disease Control and Prevention.

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Knowledge Check

Which of the following populations is at highest risk for severe respiratory syncytial virus (RSV) infection?

A) Healthy adults
B) Infants, older adults, and individuals with compromised immune systems
C) College students living in dormitories
D) Children with mild upper respiratory infections

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Knowledge Check

Which of the following populations is at highest risk for severe respiratory syncytial virus (RSV) infection?

A) Healthy adults
B) Infants, older adults, and individuals with compromised immune systems
C) College students living in dormitories
D) Children with mild upper respiratory infections

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RSV in Infants and Young Children

~60,000-80,000 hospitalizations for children < 5 years of age

Almost every child gets infected with RSV by 2 years of age

- 2-3 of every 100 infants under 6 months of age are hospitalized

Severe RSV can result in:

- Bronchiolitis
- Pneumonia

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Centers for Disease Control and Prevention. RSV in Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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RSV Clinical Presentation in Infants and Young Children

- Runny nose
- Decreased appetite
- Cough (+ wheezing)
- Infant specific symptoms:
  - Irritability
  - Decreased activity
  - Apnea
  - Many present without fever

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Centers for Disease Control and Prevention. RSV in Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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Children at Greater Risk for RSV

- Infants
  - **Higher risk under 6 months of age**
- Premature Infants
- Chronic Lung Disease or Congenital Heart Disease
- Immunocompromised
- Severe Cystic Fibrosis
- Neuromuscular Disorders
- American Indian and Alaskan Native

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Centers for Disease Control and Prevention. RSV in Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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RSV Activity for Children < 5 Years of Age

Figure 14: ED visits in the southeast region decreased

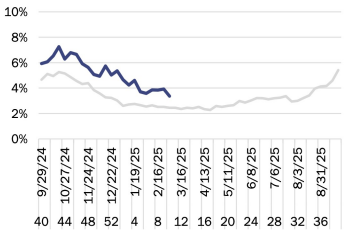

Image: https://www.floridahealth.gov/diseases-and-conditions/respiratory-illness/respiratory-syncytial-virus/_documents/2025-w10-rsv-summary.pdf

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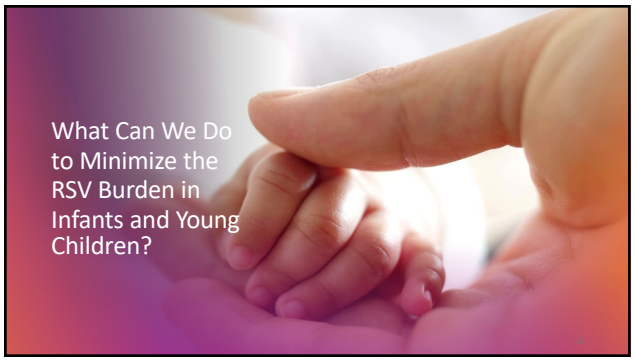

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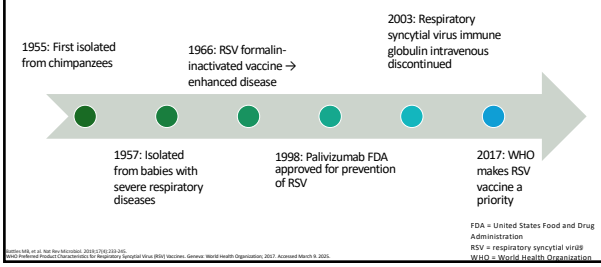
RSV Prevention Timeline



FDA = United States Food and Drug Administration
RSV = respiratory syncytial virus
WHO = World Health Organization

Griffiths MB, et al. Nat Rev Microbiol. 2019;17(4):233-245.
WHO Preferred Product Characteristics for Respiratory Syncytial Virus (RSV) Vaccines. Geneva: World Health Organization; 2017. Accessed March 9, 2025.

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RSV Pharmacologic Prevention in Infants and Young Children

Monoclonal antibodies

Vaccine (*for mother)

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FDA Approved Monoclonal Antibodies

Characteristics	Palivizumab (Synagis)	Nirsevimab (Beyfortus)
FDA Approval	1998	2023
FDA Approved Population	• BPD • Premature infants (≤ 35 weeks gestation) • Children with hemodynamically significant CHD	• 1st RSV season: Neonates/infants born before or during • 2nd RSV season: ≤ 24 months who remain vulnerable to severe RSV
Composition	Human (95%), Murine (5%)	Human IgG1K from Chinese Hamster Ovary cells
Mechanism of Action	Humanized monoclonal antibody Directed to an epitope in the A antigenic site of the F protein	F protein-directed fusion inhibitor
Dosing Initiation	Prior to RSV season	Prior to RSV season During RSV season
1st RSV Season Dosing	15 mg/kg IM monthly *Typically 5 doses	< 5 kg: 50 mg IM x 1 ≥ 5 kg: 100 mg IM x 1
Half-Life	20 days	71 days

BEYFORTUS™ (nirsevimab-alip) injection [package insert]. Swiftwater, PA: Sanofi Pasteur, Inc; 2024.
SYNAGIS® (palivizumab) injection. [package insert]. Waltham, MA: Sobi Inc; 2021.

BPD = bronchopulmonary dysplasia
CHD = congenital heart disease
IM = intramuscular
RSV = respiratory syncytial virus

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FDA Approved Monoclonal Antibodies Preparation Instructions

Palivizumab	Nirsevimab
•Withdraw specific dose volume with a needle aseptically from single use vial •Discard unused portion •Avoid dilution •Avoid shaking vial	•Single dose pre-filled luer lock syringe •50 mg = purple •100 mg = light blue

BEYFORTUS™ (nirsevimab-alip) injection [package insert]. Swiftwater, PA: Sanofi Pasteur, Inc; 2024.
SYNAGIS® (palivizumab) injection. [package insert]. Waltham, MA: Sobi Inc; 2021.

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Impact-RSV Trial (Palivizumab (Synagis))

Objective	• Assess the effectiveness of palivizumab in reducing the incidence of severe RSV-associated LRTIs in high-risk infants
Study Design	• Multicenter, randomized, placebo controlled, double-blind trial
Population	• High-risk infants in 1996-1997 season (N = 1,501 infants and young children) • Prematurity (< 35 weeks gestation), chronic lung or heart conditions
Findings	• Severe RSV hospitalization rate: 10.6% placebo vs. 4.8% high-risk palivizumab (55% reduction, p < 0.001)

Palivizumab, a Humanized Respiratory Syncytial Virus Monoclonal Antibody. Pediatrics. 1998;102(3):531-537.

LRTI = lower respiratory tract infection
RSV = respiratory syncytial virus

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Feltes TF, et al (Palivizumab (Synagis))

Objective	• To evaluate the effectiveness of palivizumab in reducing the incidence of RSV-related hospitalizations in high-risk children with hemodynamically significant heart disease
Study Design	• Multicenter, randomized, double-blind, placebo-controlled trial
Population	• High-risk children ≤ 24 months of age with hemodynamically significant congenital heart disease
Findings	• Reduced the incidence of RSV-related hospitalizations in high-risk children compared to placebo • Palivizumab was generally well-tolerated

Feltes TF, et al. J Pediatr. 2003;143(4):532-540. doi:10.1067/s0022-3476(03)00454-2

RSV = respiratory syncytial virus

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AAP Indications for Palivizumab Prophylaxis

First year of life

- Infants born < 29 weeks gestation
- Preterm infants with chronic lung disease of prematurity
  - Birth < 32 weeks gestation + require > 21% oxygen for ≥ 28 days after birth
- Infants with hemodynamically significant heart disease

Second year of life

- Children who require ≥ 28 days of supplemental oxygen after birth + continue to require medical intervention (supplemental O_2, chronic corticosteroid use, diuretic therapy)

American Academy of Pediatrics Committee on Infectious Diseases. Pediatrics. 2014 Dec;134(6):1221.

AAP = American Academy of Pediatrics

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Palivizumab (Synagis®)

Indication: second line agent for RSV prophylaxis in infants and young children

Administered 15 mg/kg/dose IM <u>monthly</u> during RSV season

- **Maximum of 5 doses**
- Stop doses once child is affected with RSV

Image: https://www.osfhealthcare.org/services/home-care/home-infusion-pharmacy/services/synagis-supply-program/
Image: https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Palivizumab_for_at-risk_patients/
Klein KC. Lower Respiratory Tract Infections. In: Benavides S, et al. eds. *Pediatric Pharmacotherapy, 2e*. American College of Clinical Pharmacy. 2020.
Zasowski EJ, Blackford M. Lower Respiratory Tract Infections. In: DiPiro JT, et al. eds. *Pharmacotherapy: A Pathophysiologic Approach, 12e*. McGraw Hill; 2023.

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Palivizumab (Synagis®)

Rare administration-related adverse effects (pain, redness, swelling, fever)

- Product is unable to be diluted
- Do not shake the vial
- Supportive care to treat adverse effects, anaphylaxis: administer epinephrine

Klein KC. Lower Respiratory Tract Infections. In: Benavides S, et al. eds. *Pediatric Pharmacotherapy, 2e*. American College of Clinical Pharmacy. 2020.
Rasowski EJ, Blackford M. Lower Respiratory Tract Infections. In: DiPiro JT, et al. eds. *Pharmacotherapy: A Pathophysiologic Approach, 12e*. McGraw Hill. 2023.

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Single-Dose Nirsevimab (Beyfortus) for Prevention of RSV in Pre-Term Infants

Objective	• To assess the efficacy of nirsevimab in preventing medically attended RSV LRTIs in healthy preterm infants compared to placebo
Study Design	• Randomized, placebo-controlled clinical trial (phase 2b)
Population	• Healthy preterm infants born between 29-35 weeks gestation, who are at increased risk for severe RSV infections (N= 1,453) • Timeframe: November 2016 - November 20217

Results	• Medically attended RSV-associated LRTI through 150 days*
	  • Nirsevimab 2.6% (n=25) vs. placebo 9.5% (n=46); 70.1% lower (95% CI, 52.3-81.2)
	• Hospitalization for RSV-associated LRTI through 150 days*
	  • Nirsevimab 0.8% (n=8) vs. placebo 4.1% (n=20); 78.4% lower (95% CI, 51.9-90.3)

Griffin MP, et al. N Engl J Med. 2020;383(5):415-425. doi:10.1056/NEJMoa1913556

LRTI = lower respiratory tract infection, RSV = respiratory syncytial virus *after administration of the dose

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Nirsevimab (Beyfortus) for Prevention of RSV in Healthy Late-Preterm and Term Infants (MELODY)

Study Design: Randomized, placebo-controlled trial (phase 3)

- Timeframe: July 23, 2019— July 2, 2020
- Total patients: 1,490 (99.2% received an injection)
  - Nirsevimab: n=994, placebo: n=496

Primary efficacy endpoint: medically attended RSV-associated LRTI through 150 days after the injection

- Nirsevimab: 1.2% (n=12) vs. placebo 5% (n=25)
- Nirsevimab efficacy 74.5% (95% CI, 49.6-87.1, p <0.001)

Secondary efficacy endpoint: hospitalization due to this condition through 150 days

- Nirsevimab: 0.6% (n=6) vs. placebo 1.6% (n=8)
- Nirsevimab efficacy 62.1% (95% CI, -8.6-86.8; p=0.07)

Hammitt LL, et al. N Engl J Med. 2022;386(9):837-846. doi:10.1056/NEJMoa2110275

CI = confidence interval
LRTI = lower respiratory tract infection
RSV = respiratory syncytial virus

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Safety of Nirsevimab (Beyfortus) for RSV in Infants with Heart or Lung Disease of Prematurity (MEDLEY)

Study design: Randomized, clinical controlled trial (phase 2-3 trial)
- Group 1: Nirsevimab or Group 2: palivizumab
- Population: preterm infants eligible to receive palivizumab
  - 925 infants enrolled: CHD-CLD cohort (n = 310), preterm cohort (n=615)

Adverse events similar between both groups

Deaths: Nirsevimab (n=5) vs. palivizumab (n=1)
- Thought to be unrelated to treatment

Medically attended RSV infections of the lower respiratory tract
- Nirsevimab 0.6% (n=4) vs. palivizumab 1% (n=3)

CHD = congenital heart disease
CLD = chronic lung disease
RSV = respiratory syncytial virus

Domachowske J, et al. N Engl J Med. 2022;386(9):892-894. doi:10.1056/NEJMc2112186

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Early Estimate of Nirsevimab (Beyfortus) Effectiveness for RSV Prevention

- Timeframe: October 2023 – February 2024
- Effectiveness: 90% against RSV-associated hospitalization in 699 infants during 1st RSV season
- Median time from nirsevimab to symptom onset = 45 days (IQR = 19-76)

IQR = interquartile range
RSV = respiratory syncytial virus

Moline HL, et al. MMWR Morb Mortal Wkly Rep 2024;73:209–214.

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Nirsevimab (Beyfortus®)

- **Single** IM injection (for neonates and infants born during or entering first RSV season)
- Additional dosages:
  - High risk for severe RSV 8-19 months of age: 2 x 100 mg in 2nd RSV season
- Common adverse reactions: rash, injection site reactions

Recommended Dosage of Beyfortus in Neonates and Infants Born During or Entering Their First RSV Season[5]

Body Weight at Time of Dosing	Recommended Dosage
Less than 5 kg	50 mg by IM injection
5 kg and greater	100 mg by IM injection

Image: https://content.govdelivery.com/
Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. August 30, 2024. Accessed March 9, 2025.
https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2f08fa60-f674-432d-801b-1f9514bd9b39&version=4

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Nirsevimab (Beyfortus) Precautions and Contraindications

Precautions

- High bleeding risk → administer according to ACIP general best practice guidelines for immunization
- Moderate or severe acute illness → recommend waiting until recovery

Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a product component

Adverse reactions should be reported to MedWatch/VAERS

ACIP = Advisory Committee on Immunization Practices
VAERS = Vaccine Adverse Event Reporting System

Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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CDC Recommendations for Prevention in Infants and Younger Children

Recommends either maternal RSV vaccination or infant immunization with RSV monoclonal antibody

- Nirsevimab (Beyfortus)
  - **First RSV season: all infants < 8 months***
  - Second RSV season: children 8-19 months at increased risk for severe RSV disease
- 1 dose **maternal vaccine (Abrysvo (Pfizer))** during weeks 32-36 gestation
  - Passes antibodies to infant (takes at least 2 weeks)

*See CDC Clinical Criteria

Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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CDC Pediatric RSV Nirsevimab Recommendations

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos
Respiratory syncytial virus (RSV-mAb [Nirsevimab])	1 dose depending on maternal RSV vaccination status, See notes					1 dose (8 through 19 months, See notes)			

First RSV Season*
- < 8 months age
- Born during or entering their first RSV season

Second RSV Season
- Children 8—19 months with/who are:
  - Chronic lung disease born prematurely
  - Severely immunocompromised
  - Severe cystic fibrosis
  - American Indian
  - Alaska Native

*See CDC clinical criteria

Centers for Disease Control and Prevention. Child and Adolescent Immunization Schedule by Age. Updated November 21, 2024. Accessed March 9, 2025.
Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. August 30, 2024. Accessed March 9, 2025.

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Clinical Criteria for Nirsevimab

Infants < 8 months born during or entering 1st RSV season

Meet one of the criteria:
- Mother received RSV vaccine ≤ 14 days prior to birth
- Maternal RSV vaccine status unknown
- Confirm no previous administration of maternal RSV vaccine

Ideal timing:
Within 1 week of birth OR shortly before RSV season

Dosing: Infants < 5 kg = 50 mg; Infants ≥5 kg = 100 mg

Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. Updated August 30, 2024. Accessed March 9, 2025.
American Academy of Pediatrics. Nirsevimab Administration Visual Guide. Updated September 10, 2024. Accessed March 9, 2025.

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Clinical Criteria for Nirsevimab Continued

Did mom receive maternal Abrysvo (RSV Vaccine, Pfizer) within 14 days of birth?

No → Did mom receive the vaccine more than 14 days from birth?

No → Administer Nirsevimab to infant

Yes → Administer Nirsevimab to infant

Yes → No need to administer Nirsevimab to infant

What if maternal RSV vaccine status was unknown?

-Administer Nirsevimab to infant

Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. Updated August 30, 2024. Accessed March 9, 2025.
American Academy of Pediatrics. Nirsevimab Administration Visual Guide. Updated September 10, 2024. Accessed March 9, 2025.

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Clinical Criteria for Nirsevimab Continued

Infants 8-19 months

Confirm increased risk for severe RSV disease (meets one of the following criteria):
- CLD with medical support 6 months prior to RSV season
- Severely immunocompromised
- Cystic fibrosis (severe lung disease OR weight-for-length < 10th percentile)
- American Indian
- Alaska Native

Ideal timing:
Shortly before or during RSV season

Maximum doses: 2
- 1 dose per RSV season
- *Exception: children with cardiac surgery with cardiopulmonary bypass

Dosing: 200 mg x 1 (two 100 mg injections)

Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. Updated August 30, 2024. Accessed March 9, 2025.
American Academy of Pediatrics. Nirsevimab Administration Visual Guide. Updated September 10, 2024. Accessed March 9, 2025.

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CLD = chronic lung disease

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Nirsevimab Administration Using Clinical Judgement

May be given outside of typical RSV season

Examples

- Travel to areas with increased RSV activity
- Concerns for follow-up

Nirsevimab for infants with mother who received RSV vaccine

- Infants born to mothers who did not mount an adequate immune response to RSV vaccine (immunocompromised)
- Infants born to mothers with medical conditions that decrease transplacental antibody transfer (HIV infection)
- Infants who have lost maternal antibodies (cardiopulmonary bypass or ECMO)
- Infants with substantial increased risk for severe RSV (hemodynamically significant congenital heart disease or ICU admission with oxygen at discharge)

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Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. Updated August 30, 2024. Accessed March 6, 2025.

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Can Nirsevimab Be Given With Other Vaccines?

Currently limited data

- Not expected to interfere with other vaccines

CDC Recommendations

- May be administered with other routine childhood vaccines
- No interval necessary with live vaccines

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Centers for Disease Control and Prevention. RSV Immunization Guidance for Infants and Young Children. Updated August 30, 2024. Accessed March 6, 2025.

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Can Palivizumab Still Be Administered?

If nirsevimab is unavailable or not feasible to administer

- High-risk infants who are recommended to receive palivizumab in the first or second year of life should receive palivizumab

If nirsevimab has already been administered for the current RSV season

- Do not administer palivizumab

If < 5 doses of palivizumab have been administered for current RSV season

- Administer nirsevimab ideally within 30 days (no more doses of palivizumab)

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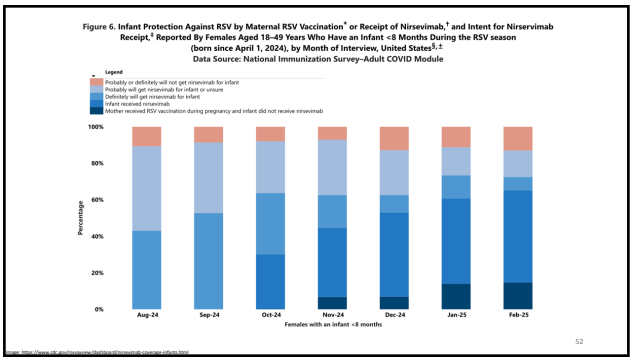


Figure 6. Infant Protection Against RSV by Maternal RSV Vaccination* or Receipt of Nirsevimab,† and Intent for Nirservimab Receipt,§ Reported By Females Aged 18–49 Years Who Have an Infant <8 Months During the RSV season (born since April 1, 2024), by Month of Interview, United States¶,‡
Data Source: National Immunization Survey–Adult COVID Module
Legend
Probably or definitely will not get nirsevimab for infant
Probably will get nirsevimab for infant or unsure
Definitely will get nirsevimab for infant
Infant received nirsevimab
Mother received RSV vaccination during pregnancy and infant did not receive nirsevimab
100%
80%
60%
40%
20%
0%
Percentage
Aug-24
Sep-24
Oct-24
Nov-24
Dec-24
Jan-25
Feb-25
Females with an infant <8 months
52

52

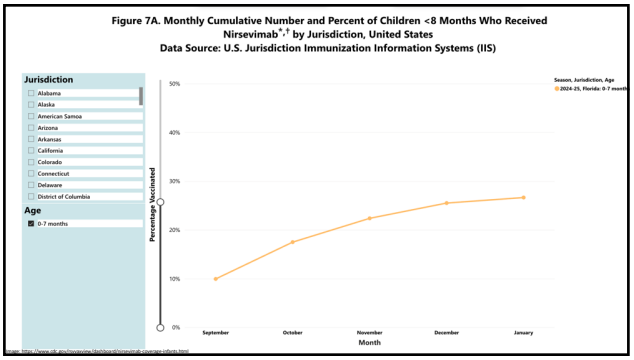


Figure 7A. Monthly Cumulative Number and Percent of Children <8 Months Who Received Nirsevimab*,† by Jurisdiction, United States
Data Source: U.S. Jurisdiction Immunization Information Systems (IIS)
Jurisdiction
Alabama
Alaska
American Samoa
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Age
0-7 months
Season, Jurisdiction, Age
2024-25, Florida, 0-7 months
50%
40%
30%
20%
10%
0%
Percentage Vaccinated
September
October
November
December
January
Month

53

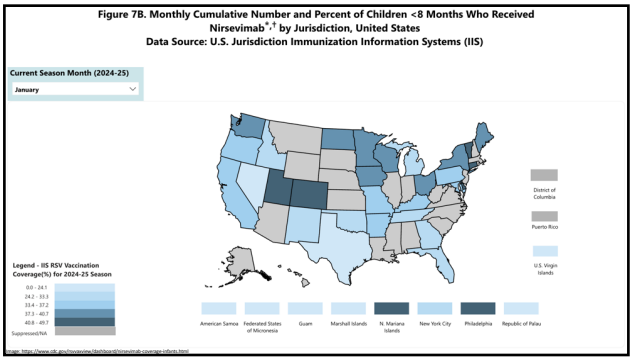


Figure 7B. Monthly Cumulative Number and Percent of Children <8 Months Who Received Nirsevimab*,† by Jurisdiction, United States
Data Source: U.S. Jurisdiction Immunization Information Systems (IIS)
Current Season Month (2024-25)
January
Legend - IIS RSV Vaccination Coverage(%) for 2024-25 Season
0.0 - 24.1
24.2 - 33.3
33.4 - 37.2
37.3 - 40.7
40.8 - 49.7
Suppressed/NA
District of Columbia
Puerto Rico
U.S. Virgin Islands
American Samoa
Federated States of Micronesia
Guam
Marshall Islands
N. Mariana Islands
New York City
Philadelphia
Republic of Palau

54

Question

Which of the following approved monoclonal antibodies is recommended by the CDC for the prevention of respiratory syncytial virus (RSV) infection in infants?

A) Palivizumab
B) Nirsevimab
C) Adalimumab
D) Rituximab

55

55

Question

Which of the following approved monoclonal antibodies is recommended by the CDC for the prevention of respiratory syncytial virus (RSV) infection in infants?

A) Palivizumab
B) Nirsevimab
C) Adalimumab
D) Rituximab

56

56

Case Study

You are a pharmacist working in a pediatric clinic during RSV season. A mother brings in her 2-month-old son, Noah, for his routine check-up. Noah was born at 29 weeks' gestation and spent six weeks in the neonatal intensive care unit (NICU) due to respiratory distress syndrome (RDS). He has no current oxygen requirements but has a history of bronchopulmonary dysplasia (BPD). The pediatrician asks whether Noah qualifies for RSV prevention with nirsevimab. His weight today is 4 kg.

Based on current guidelines, what is the most appropriate recommendation for RSV prevention in Noah?

A) Administer a single dose of nirsevimab (50 mg) today
B) Administer a single dose of nirsevimab (100 mg) today
C) Recommend monthly palivizumab injections throughout the RSV season instead of Nirsevimab
D) Do not administer RSV prophylaxis, as he is no longer in the NICU.

57

57

Case Study

You are a pharmacist working in a pediatric clinic during RSV season. A mother brings in her 2-month-old son, Noah, for his routine check-up. Noah was born at 29 weeks' gestation and spent six weeks in the neonatal intensive care unit (NICU) due to respiratory distress syndrome (RDS). He has no current oxygen requirements but has a history of bronchopulmonary dysplasia (BPD). The pediatrician asks whether Noah qualifies for RSV prevention with nirsevimab. His weight today is 4 kg.

Based on current guidelines, what is the most appropriate recommendation for RSV prevention in Noah?

A) Administer a single dose of nirsevimab (50 mg) today

B) Administer a single dose of nirsevimab (100 mg) today

C) Recommend monthly palivizumab injections throughout the RSV season instead of Nirsevimab

D) Do not administer RSV prophylaxis, as he is no longer in the NICU.

58

58

RSV Pharmacologic Prevention in Infants and Young Children

Monoclonal antibodies

Vaccine (*for mother)

59

59

MATISSE Study

Abrysvo (RSV Vaccine, Pfizer)

Objective	• To evaluate the efficacy and safety of maternal RSVpreF vaccination in preventing RSV-associated LRTI in infants followed for 1-2 years
Study Design	• Phase 3, double-blind, randomized, placebo- controlled trial • N = 3,682 pregnant participants (24-36 weeks gestation) vs. N = 3,676 placebo
Vaccine Efficacy:	• **Medically attended severe LRTI : 81.8% at 90 days** (99.5% CI, 40.6-96.3) & **69.4% at 180 days** (97.58% CI, 44.3-84.1) • **Medically attended RSV-associated LRTI: 57.1%** (99.5% CI, 14.7-79.8) • **Did not meet statistical success criterion**
Adverse Events	• Maternal- Muscle pain: 27% RSVpreF vs. 17% placebo • Headache: 31% RSVpreF vs. 28% placebo

60

Kampmann B, et al. N Engl J Med. 2023;388(16):1451-1464.

60

RSV Vaccines for RSV in Infants

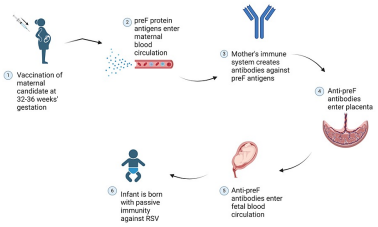
- No vaccines are available for RSV protection when administered directly to the infant
- Abrysvo (RSV Vaccine, Pfizer)
  - Routine single dose vaccination is recommended during pregnancy at **32 weeks 0 days – 36 weeks and 6 days gestation** during RSV season
  - Administer vaccine regardless of previous RSV infection
  - Additional doses NOT recommended for subsequent pregnancies
  - May be administered with Tdap, COVID-19, and/or influenza vaccines

61

Centers for Disease Control and Prevention. RSV Vaccine Guidance for Pregnant Women. August 30, 2024. Accessed March 15, 2025.

61

Abrysvo (RSV Vaccine, Pfizer) Maternal Antibody Transfer



62

Source: Patel M, et al. Cureus. 2024; 16(8): e68349.

62

Contraindications and Vaccine Safety Data in Pregnant Patients

Contraindications: anaphylaxis

Vaccine safety:

- Most common adverse events: injection site pain (40.6%), headache (31%), myalgia (26.5%), nausea (20%)
- Preterm births?
- Reports of pre-eclampsia, low birth weight (< 5.5 lbs), and neonatal jaundice

63

Abrysvo [package insert]. New York, NY: Pfizer Inc; 2025.
Centers for Disease Control and Prevention. RSV Vaccine Guidance for Pregnant Women. August 30, 2024. Accessed March 15, 2025.

63

Pregnant Patient Counseling for RSV Vaccine and Monoclonal Antibody

RSV Vaccine	Monoclonal Antibody
• Provides immediate protection at birth through 6 months of age for infant when vaccine is administered at least 14 days from birth • Reduces the number of vaccines the infant receives at birth • Can be given with other vaccines during pregnancy	• Antibody delivery directly to the newborn vs. placental transfer from maternal vaccination • Highly neutralizing to RSV site 0 of the RSV preF protein • More susceptible to resistance through RSV Pre-F mutations • Results in protection for up to 150 days • Give at birth, ideally or within first week of delivery

64

The American College of Obstetricians and Gynecologists. Maternal Respiratory Syncytial Virus Vaccination. September 2023. Accessed March 15, 2025.

64

CDC Sample Script to Counsel Pregnant Patients

"At this point in your pregnancy, you are eligible to get the RSV vaccine to protect your baby from a severe respiratory illness called RSV. RSV is a common seasonal viral infection that can cause babies to get very sick. It can make it hard for babies to breathe. We have two options for preventing severe RSV illness in babies. One option is a new vaccine that we give you during pregnancy. The vaccine causes you to make antibodies that you pass to your baby through the placenta. These antibodies help protect your baby early in their life."

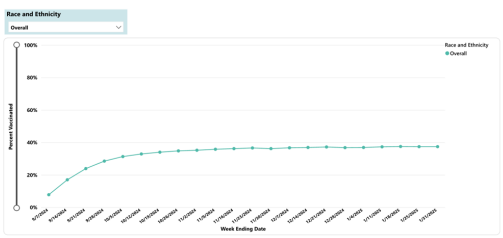
"The other option called nirsevimab can be given to your baby after birth and works similarly to protect your baby from RSV illness after delivery. One or the other is recommended, but both are not needed for most babies. Keep in mind though that there may be limited availability of nirsevimab this season once your baby is born."

65

Centers for Disease Control and Prevention. RSV Immunization Recommendations to Protect Infants and Children Slide Deck. Accessed March 15, 2025.

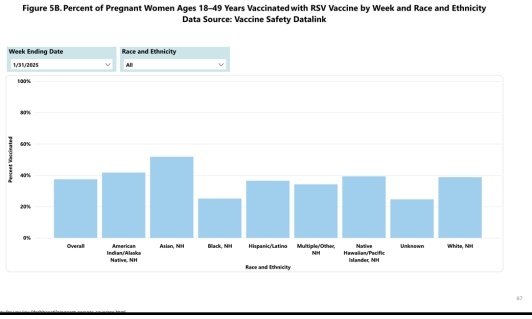
65

Figure 5A. Percent of Pregnant Women Ages 18–49 Years Vaccinated with RSV Vaccine Overall and by Race and Ethnicity
Data Source: Vaccine Safety Datalink



66

66



67

67

Case Study

Stacy is a 29 year old female who is 33 weeks pregnant. She was recommended the RSV vaccine by her OB-GYN. Which of the following RSV vaccines can you administer?

A. Abrysvo (RSV Vaccine, Pfizer)
B. Arexvy (RSV Vaccine, Adjuvanted, GSK)
C. MRESVIA (RSV Vaccine, Moderna)
D. None of the above

68

68

Case Study

Stacy is a 29 year old female who is 33 weeks pregnant. She was recommended the RSV vaccine by her OB-GYN. Which of the following RSV vaccines can you administer?

A. Abrysvo (RSV Vaccine, Pfizer)
B. Arexvy (RSV Vaccine, Adjuvanted, GSK)
C. MRESVIA (RSV Vaccine, Moderna)
D. None of the above

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Adult Populations with Greatest RSV Disease Burden

Older adults ≥ 75 years

High Risk Adults

- Chronic lung or heart disease
  - Exacerbate asthma, COPD, or CHF
- Weakened immune system
- Severe obesity, severe diabetes
- Living in nursing homes/ LTCF

CHF = congestive heart failure
COPD = chronic obstructive pulmonary disease
LTCF = long-term care facilities

71

Centers for Disease Control and Prevention. RSV in Adults. July 3, 2024. Accessed August 20, 2024.
Source: https://www.cdc.gov/rsv/adults/index.html?CDC_AAref_Val=https://www.cdc.gov/rsv/clinical/index.html

71

Older Adults (≥ 65 years) Comorbid Condition Considerations

Likelihood of being hospitalized for RSV

- Asthma (~2.3 or 2.5 x)
- Diabetes (~2.4 or 6.4 x)
- Coronary Artery Disease (~3.8 or 6.5 x)
- Congestive Heart Failure (~4 or 7.6 x)
  - *Adults ≥ 60 years
- Chronic Obstructive Pulmonary Disease (~3.5 or 13.4 x)

Branche AR, et al. *Clin Infect Dis*. 2022;74(6):1004-1011.
Mesa-Frias M, et al. J Manag Care Spec Pharm. 2022;28(7):753-765.

72

RSV Vaccine Patient Populations

Pregnant Adults	Adults ≥ 60 years

• FDA approved
  • Active immunization of individuals 32-36 weeks gestation to prevent RSV LRTD and severe LRTD in infants aged birth-6 months
• Abrysvo (RSV Vaccine, Pfizer)
	• FDA Approved
	  • Active immunization to prevent RSV LRTD
	• Arexvy (RSV Vaccine, Adjuvanted, GSK)
	  • *Also FDA approved for ages 50-59 years
	• Abrysvo (RSV Vaccine, Pfizer)
	  • *Also FDA approved for ages 18-59 years
	• MRESVIA (RSV Vaccine, Moderna)

Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Pregnant People. Updated September 29, 2023. Accessed April 28, 2024.
Centers for Disease Control and Prevention. RSV Vaccination for Older Adults 60 Years of Age and Over. Updated: March 1, 2024. Accessed April 28, 2024.
ABRYSVO. [package insert]. Madison, NJ: Pfizer Inc; 2023.
MRESVIA [package insert]. Moderna US, Inc.; 2024.

LRTD = lower respiratory tract disease
RSV = respiratory syncytial virus

73

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AReSVi-006 Study

Arexvy (RSV Vaccine, Adjuvanted, GSK)

Objective	• To show vaccine efficacy against RSV-related LRTD, confirmed by RT-PCR during one RSV season
Study Design	• Phase 3, randomized, double-blind, placebo-controlled trial in older adults ≥ 60 years (N = 12,467 RSVPreF3 and N=12,499 placebo)
Vaccine Efficacy (Median Follow Up = 6.7 months)	• **82.6% for RT-PCR-confirmed RSV-related LRTD** (96.95% CI, 57.9-94.1) • 7 cases (1.0 per 1,000 participant-years) RSVPreF3 vs. 40 cases (5.8 per 1,000 participant-years) placebo • **94.1% against severe RSV-related LRTD** (95% CI, 62.4-99.9) • **71.7% against RSV-related acute respiratory infection** (95% CI, 56.2-82.3)
Adverse Events	• Injection site pain: 60.9% RSVPreF3 vs. 9.3% placebo • Fatigue: 33.6% RSVPreF3 vs. 16.1% placebo • Serious adverse events/ potential immune-mediated diseases similar

Papi A, et al. N Engl J Med. 2023;388(7):595-608. doi:10.1056/NEJMoa2209604

CI = confidence interval
LRTD = lower-respiratory-tract disease
RSV= respiratory syncytial virus
RT-PCR = reverse transcriptase polymerase chain reaction

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RENOIR Study

Abrysvo (RSV Vaccine, Pfizer)

Objective	• To assess the efficacy and safety of RSVpreF vaccine in preventing RSV-associated LRTI during 1st RSV season
Study Design	• Phase 3, randomized, double-blind, placebo-controlled trial in older adults ≥ 60 years (N = 17,215 RSVpreF and N = 17,069 placebo)

Vaccine Efficacy	• **RSV-associated LRTI with ≥ 2 s/sx: 66.7%** (96.66% CI, 28.8-85.8)
	  • RSVpreF (n = 11; 1.19 cases per 1,000 person-years) vs. placebo (n = 33; 3.58 cases per 1,000 person-years)
	• **RSV-associated LRTI with ≥ 3 s/sx: 85.7%** (96.66% CI, 32.0-98.7)
	  • RSVpreF (n = 2; 0.22 cases per 1,000 person-years) vs. placebo (n = 14; 1.52 cases per 1,000 person-years)
	• **RSV-associated acute respiratory illness: 62.1%** (95% CI, 37.1-77.9)
	  • RSVpreF (n = 22; 2.38 cases per 1,000 person-years) vs. placebo (n = 58; 6.30 cases per 1,000 person-years)

Adverse Events	• Local reactions: RSVpreF (12%) vs. placebo (7%) • Systemic events: RSVpreF (27%) vs. placebo (26%)

Walsh EE, et al. N Engl J Med. 2023;388(16):1465-1477.

LRTI = lower respiratory tract infection
RSV = respiratory syncytial virus
S/sx = signs or symptoms

75

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MRESVIA (RSV Vaccine, Moderna)

ConquerRSV Study

Objective	• Assess safety and efficacy of mRNA-1345 vaccine in preventing RSV-associated LRTD
Study Design	• Ongoing, randomized, double-blind, placebo-controlled, phase 2-3 trial in older adults ≥ 60 years (N = 17,793 vaccine and N = 17,748 placebo)
Vaccine Efficacy	• **Prevention of RSV-associated LRTD (≥ 2 s/sx): 83.7%** (95.88% CI, 66.0-92.2, p < 0.001) • 9 cases vaccine vs. 55 placebo • **Prevention of RSV-associated LRTD (≥ 3 s/sx): 82.4%** (96.36% CI, 34.8-95.3, p = 0.008) • 3 cases vaccine vs. 17 placebo • **Prevention of RSV-associated acute respiratory disease: 68.4%** (95% CI, 50.9-79.7) • 26 cases vaccine vs. 82 placebo
Adverse Events	• Injection site pain: 56.3% vaccine vs. 13.7% placebo • Systemic adverse reactions: 47.7% vaccine vs. 32.9% placebo

CI = confidence interval
LRTD = lower respiratory tract disease
RSV = respiratory syncytial virus
S/Sx = signs or symptoms

Wilson E, et al. N Engl J Med. 2023;389(24):2233-2244.

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RSV Prevention Timeline Continued

May 2023:
FDA licensed 2 vaccines for adults ≥ 60 years: Arexvy (RSV Vaccine, Adjuvanted, GSK) and Abrysvo (RSV Vaccine, Pfizer)

July 2023:
Nirsevimab FDA approved for RSV prevention

August 2023:
- FDA approved Abrysvo (RSV Vaccine, Pfizer) for pregnant persons to prevent RSV in infant
- ACIP and CDC recommended Nirsevimab to prevent severe RSV disease

September 2023:
ACIP and CDC recommend Abrysvo (RSV Vaccine, Pfizer) for pregnant persons (32-36 weeks gestation)

June 2024:
FDA approved additional vaccine for adults ≥ 60 years: MRESVIA (RSV Vaccine, Moderna)

ACIP = Advisory Committee on Immunization Practices
CDC = Centers for Disease Control and Prevention
FDA = United States Food and Drug Administration
RSV = respiratory syncytial virus

Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.
Fleming-Dutra KE, et al. MMWR Morb Mortal Wkly Rep 2023;72:1115–1122.
MRESVIA [package insert]. Moderna US, Inc.; 2024.

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	Arexvy (RSV Vaccine, Adjuvanted, GSK)	Abrysvo (RSV Vaccine, Pfizer)
Indication	Active immunization for RSV LRTD prevention	
FDA Approved Age Group	≥ 60 years of age 50-59 years at increased risk for RSV LRTD	≥ 60 years of age Pregnancy (32-36 weeks gestation) 18-59 years at increased risk for RSV LRTD
Dosing	Single dose (0.5 mL) IM	
Dosage Forms	Suspension Requires reconstitution	Solution
Storage	Before reconstitution: 2°C and 8°C (36°F and 46°F) After reconstitution: • Administer immediately OR • Store at 2°C and 8°C (36°F to 46°F) or up to 25°C (77°F) for up to 4 hours	After Reconstitution: • Administer immediately OR • Store 15ºC to 30ºC (59ºF to 86ºF)] for up to 4 hours

Arexvy [package insert]. Rixensart, Belgium: GlaxoSmithKline Biologicals; 2025.
Abrysvo [package insert]. New York, NY: Pfizer Inc; 2025.

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	MRESVIA (RSV Vaccine, Moderna)
Indication	Active immunization for RSV LRTD prevention
FDA Approved Age Group	≥ 60 years of age
Dosing	Single dose (0.5 mL) IM
Dosage Forms	Suspension
Storage	Frozen: -40°C to -15°C (-40°F to 5°F) After thawing: • Pre-filled plastic syringes: 2°C to 8°C (36°F to 46°F) x 90 days before use • May be stored between 8°C to 25°C (46°F to 77°F) x 24 hours after removal from refrigerator

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MRESVIA (package insert). Moderna US, Inc.; 2024.

79

Preparation Instructions for Arexvy (RSV Vaccine, Adjuvanted, GSK)

Supplied as two vials that are combined prior to administration

- Lyophilized antigen component reconstituted with an adjuvant suspension component

Inspect for particulate matter/ discoloration

- If present → avoid administration

80

Arexvy (package insert). Rixensart, Belgium: GlaxoSmithKline Biologicals; 2025.

80

Abrysvo (RSV Vaccine, Pfizer) Presentations and Reconstitution

Act-O-Vial Presentation

- Lyophilized antigen component and sterile water component

Vial and Prefilled Syringe Presentation

- Lyophilized antigen component, prefilled syringe with sterile water, and vial adapter

Vial and Vial Presentation

- Lyophilized antigen component and sterile water diluent vial

81

Abrysvo (package insert). New York, NY: Pfizer Inc; 2025.

81

Preparation Instructions for MRESVIA (RSV Vaccine, Moderna)

Configuration	Thaw in Refrigerator	Thaw at Room Temperature
Carton of 1 pre-filled syringe in a blister pack Carton of 2 pre-filled syringes in a blister pack	• Thaw between 2-8°C (36-46°F) x 100 minutes • Let the syringe be at room temperature x 10-20 minutes before administration	• Thaw between 15-25°C (59-77°F) x 40 minutes • If thawed at room temperature, the vaccine is ready for administration
Carton of 10 pre-filled syringes in blister packs	• Thaw between 2-8°C (36-46°F) x 160 minutes • Let the syringe be at room temperature x 10-20 minutes before administration	• Thaw between 15-25°C (59°F to 77°F) x 80 minutes • If thawed at room temperature, the vaccine is ready for administration

MRESVIA (package insert). Moderna US, Inc.; 2024.

82

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Case Study

You are working in your community pharmacy and receive a shipment of all three RSV vaccines. You have been asked by a team member about storage conditions for the vaccines. Which of the following vaccines is required to be initially stored in the freezer?

A. Arexvy (RSV Vaccine, Adjuvanted, GSK)
B. Abrysvo (RSV Vaccine, Pfizer)
C. MRESVIA (RSV Vaccine, Moderna)
D. None of the above

83

83

Case Study

You are working in your community pharmacy and receive a shipment of all three RSV vaccines. You have been asked by a team member about storage conditions for the vaccines. Which of the following vaccines is required to be initially stored in the freezer?

A. Arexvy (RSV Vaccine, Adjuvanted, GSK)
B. Abrysvo (RSV Vaccine, Pfizer)
C. MRESVIA (RSV Vaccine, Moderna)
D. None of the above

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84

CDC RSV Vaccination Recommendations in Adults

Vaccine	19-26 years	27-49 years	50-64 years	≥ 65 years	
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy. (See notes)			60-74 years (See Notes)	≥ 75 years

60-74 years (special situations)
- 1 lifetime dose if increased risk of severe RSV disease
  - Arexvy (RSV Vaccine, Adjuvanted, GSK)
  - Abrysvo (RSV Vaccine, Pfizer)
  - MRESVIA (RSV Vaccine, Moderna)
- Additional doses not recommended at this time

≥ 75 years (routine vaccination)
- 1 lifetime dose
  - Arexvy (RSV Vaccine, Adjuvanted, GSK)
  - Abrysvo (RSV Vaccine, Pfizer)
  - MRESVIA (RSV Vaccine, Moderna)
- Additional doses not recommended at this time

85

Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.

85

Risk Factors for Severe RSV Disease

- Chronic cardiovascular disease
- Chronic lung or respiratory disease
- End stage renal disease or dialysis-dependent
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy or other end-organ damage
- Diabetes mellitus requiring treatment with insulin or sodium-glucose cotransporter 2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions

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Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.

86

Risk Factors for Severe RSV Disease Continued

- Chronic liver disease
- Chronic hematologic conditions
- Severe obesity (BMI ≥ 40)
- Moderate or severe immunocompromised
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines to increase risk

87

Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.

87

Common Adverse Reactions for RSV Vaccines

	Arexvy (RSV Vaccine, Adjuvanted, GSK)	Abrysvo (RSV Vaccine, Pfizer)	MRESVIA (RSV Vaccine, Moderna)
Ages ≥ 60 years	• Injection site pain (60.9%) • Fatigue (33.6%) • Myalgia (28.9%) • Headache (27.2%) • Arthralgia (18.1%)	• Fatigue (15.7%) • Headache (12.9%) • Injection site pain (10.7%) • Muscle pain (10.2%)	• Injection site pain (55.9%) • Fatigue (30.8%) • Headache (26.7%) • Myalgia (25.6%) • Arthralgia (21.7%) • Axillary swelling/ tenderness (15.2%) • Chills (11.6%)
Ages 50-59 years	• Injection site pain (75.8%) • Fatigue (39.8%) • Myalgia (35.6%) • Headache (31.7%) • Arthralgia (23.4%) • Erythema (13.2%) • Swelling (10.4%)	• Injection site pain (35.3%) • Muscle pain (24.4%) • Joint pain (12.4%) • Nausea (11.8%)	-
Ages 18-50 years	-		

Arexvy [package insert]. Rixensart, Belgium: GlaxoSmithKline Biologicals; 2024.
Abrysvo [package insert]. New York, NY Pfizer Inc; 2025.
MRESVIA [package insert]. Moderna US, Inc.; 2024.

88

88

RSV Vaccines Contraindications and Precautions

Contraindications

- Severe allergic reaction (anaphylaxis) to a vaccine component

Precautions

- Moderate or severe acute illness with/ without fever
- Guillain Barré Syndrome

89

Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.
Centers for Disease Control and Prevention. Appendix- Guide to Contraindications and Precautions to Commonly Used Vaccines. November 21, 2024. Accessed March 9, 2025.

89

Guillain-Barré Syndrome (GBS) Warning

In January 2025, FDA required labeling changes to Abrysvo (Pfizer) and Arexvy (Adjuvanted, GSK) regarding GBS to the Warnings and Precautions section

- Postmarking data found increased risk within 42 days after vaccination for both vaccines in adults ≥ 65 years of age
- Abrysvo 9 excess cases of GBS per million vs. Arexvy 7 excess cases of GBS per million doses
- No data on mRESVIA currently

90

Food and Drug Administration. FDA Requires Guillain-Barre Syndrome (GBS) Warning in the Prescribing Information for RSV Vaccines Abrysvo and Arexvy. Updated January 7, 2025. Accessed March 10, 2025.

90

Can RSV Vaccines be Administered with Other Vaccines?

May be coadministered with other adult vaccines

- May increase common side effects

Data is currently limited on immunogenicity

- Limited data on coadministration with other respiratory virus vaccines may result in lower antibody titers
- Unknown clinical significance currently

91

Centers for Disease Control and Prevention. RSV Vaccine Guidance for Older Adults. November 21, 2024. Accessed March 9, 2025.

91

Vaccines Based Off of CDC Indication

	AREXVY (GSK)*	mRESVIA® (Moderna)	Abrysvo (RSV Vaccine, Pfizer)
Pregnant patients during weeks 32-36 gestation			X
Adults ≥ 75 years	X	X	X
Adults 60-74 years at **increased risk of severe RSV disease**	X	X	X

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Centers for Disease Control and Prevention. Adult Immunization Schedule by Age. November 21, 2024. Accessed March 9, 2025.

92

Vaccine Efficacy for 2023-2024 RSV Season

	GSK Arexvy	Pfizer's Abrysvo	Moderna's mResvia
Prevention of RSV-associated emergency department encounters	77%	79%	Not determined
Prevention of RSV-associated hospitalizations in adults 60 and older	83%	73%	Not determined

93

Centers for Disease Control and Prevention. RSV Vaccine Guidance for Older Adults. November 21, 2024. Accessed March 9, 2025.

93

Guideline Updates Commenting on RSV Vaccine

COPD GOLD 2025	• "RSV Vaccination for individuals aged >/= 60 years and/or with chronic heart or lung disease, as recommended by the CDC (Evidence A)"
ADA Diabetes Standards of Care 2024	• "Older adults ≥60 years of age with diabetes appear to be a risk group"
ACOG Influenza in Pregnancy: Prevention and Treatment 2024	• "The ACOG recommends a single dose of Pfizer's RSV vaccine (Abrysvo) for eligible pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation who do not have a planned delivery within 2 weeks, using seasonal administration, to prevent RSV lower respiratory tract infection (LRTI) in infants"

The American College of Obstetricians and Gynecologists. Maternal Respiratory Syncytial Virus Vaccination. September 2023. Accessed March 15, 2025.
American Diabetes Association Professional Practice Committee. Diabetes Care 1 January 2025; 48 (Supplement_1): S14–S85.
Global Initiative for Chronic Obstructive Lung Disease. 2025 Report.

ACOG = American College of Obstetricians and Gynecologists
ADA = American Diabetes Association
RSV = respiratory syncytial virus

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RSV Vaccination in the United States (Adults 75+)

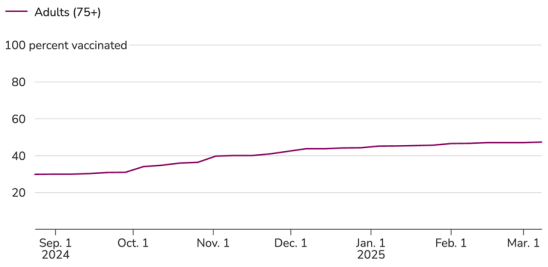

Image: https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html

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Figure 2A. Monthly Cumulative Number and Percent of Adults 75 Years and Older Who Received 1+ RSV Vaccination Doses*,† by Jurisdiction, United States
Data Source: U.S. Jurisdiction Immunization Information Systems (IIS)

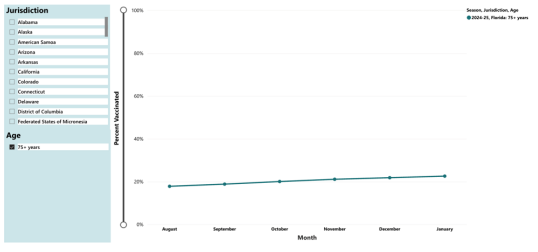

Image: https://www.cdc.gov/nceziview/dash/data#/adults-60-admin-coverage-jurisdiction.html

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RSV Vaccination Intent in the United States for Adults 75+

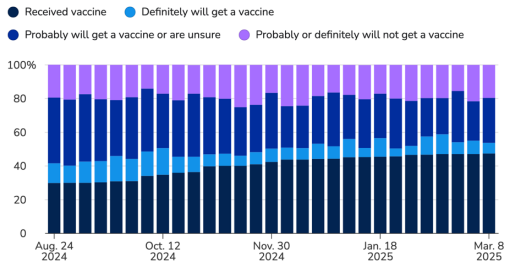

Image: https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html

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Case Study

Mr. Johnson is a 72-year-old male with a history of chronic obstructive pulmonary disease (COPD), hypertension, and type 2 diabetes mellitus. He visits your pharmacy for his annual influenza and COVID-19 booster vaccinations. During the consultation, he mentions that he has been hospitalized twice in the past three years due to respiratory infections and asks whether he should also receive the RSV vaccine.

Based on current RSV vaccination guidelines for older adults, what is the most appropriate recommendation for Mr. Johnson?

A) Administer a single dose of an FDA-approved RSV vaccine today
B) Advise Mr. Johnson that RSV vaccination is only recommended for individuals over 80 years old
C) Tell Mr. Johnson that he does not need the RSV vaccine since he is already receiving the flu and COVID-19 vaccines
D) Recommend waiting until RSV season begins before receiving the vaccine to ensure maximum protection

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Pharmacist's Role

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Pharmacist Role with RSV Vaccines

- Screening high-risk patients for RSV prevention
- Counseling patients and caregivers on RSV prevention measures
- Administration and adherence monitoring of vaccines
- Addressing vaccine hesitancy and misinformation

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RSV: Independent Community Pharmacy Impact in Promoting Prevention Through Immunization

Objective	• To assess patient knowledge about RSV and to provide patients with information about the virus and the vaccination
Study Design	• A multisite cross-sectional pilot study from September 2023-March 2024 in the independent community pharmacy setting • Included patients aged 60 years and older who completed a survey
Results	• 78% of participants had not received any education from their healthcare provider about RSV • 63% of participants consented to receive a vaccine on the day of the survey
Authors' Conclusion	• There is a critical care of community pharmacies in healthcare delivery and need for enhanced educational efforts to support vaccination programs

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Vasilinin A, et al. J Pharm Technol. Published online October 19, 2024.

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Conversation Starter Examples

"If it is okay with you, I would like to spend 4 or 5 minutes to talk about RSV vaccines and your health"

"I took some time to review your medication history. Having [COPD, asthma, heart failure, diabetes, etc.] puts many people of getting sicker if they get RSV. Would you be interested in setting up an appointment for the RSV vaccine?"

"Your baby is due in the winter. There is a new RSV vaccine that you can get while still pregnant to protect your baby over the winter. Do you have a few minutes to discuss?"

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American Pharmacists Association. Focus on RSV in Adults. 2024. Accessed March 3, 2025.

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Resources for Pharmacists to Keep Track of RSV

CDC RSVVaxView Weekly RSV Vaccination Dashboard

- Provides data summary on:
  - Adults ≥ 60 years (also ≥ 65 years)
  - Vaccine Administration and Coverage by Jurisdiction
    - Specify Florida
  - Adult Vaccinations Administered
  - Pregnant Persons Coverage
  - Nirsevimab Coverage and Intent for Infants
  - Nirsevimab Administration and Coverage by Jurisdiction
    - Specify Florida

Florida Department of Health: Florida RSV Review Activity Summary

Centers for Disease Control and Prevention. Weekly Respiratory Syncytial Virus (RSV) Vaccination Dashboard.
Florida Department of Health. Respiratory Syncytial Virus (RSV) in Florida.

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Question

Which of the following best describes the pharmacist's role in RSV vaccination efforts for older adults?

A) Pharmacists can administer RSV vaccines but should only offer them to patients who specifically request them

B) Pharmacists play a key role in identifying eligible patients, providing education on RSV risks, and administering the vaccine as part of routine immunization services

C) Pharmacists should defer all RSV vaccine discussions to physicians, as they are the primary providers responsible for vaccine recommendations

D) Pharmacists should prioritize RSV vaccination efforts only for adults over 75, as younger individuals do not benefit from immunization.

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NFID Key Strategic Priorities

National Foundation for Infectious Diseases. Call to Action: Reduce the Burden of RSV Across the Lifespan. Updated January 2022. Accessed April 28, 2022.

NFID = National Foundation for Infectious Diseases
RSV = respiratory syncytial virus

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Ethnic Health Disparities

Non-Hispanic Blacks	Alaska Native and American Indian
•Higher rates of RSV-associated deaths in ages 1-4 years •ICU admission rates age < 6 months 1.2-1.6x higher	•Hospitalization rates 4-10x higher

Hansen CL, et al. J Infect Dis. 2022;226(Suppl 2):S255-S266. doi:10.1093/infdis/jiac187

RSV = respiratory syncytial virus

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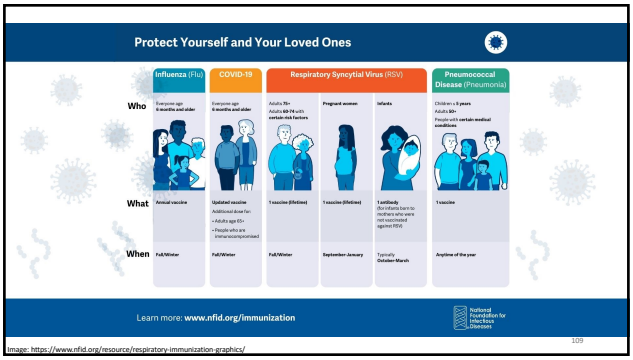

Image: https://www.nfid.org/resource/respiratory-immunization-graphics/

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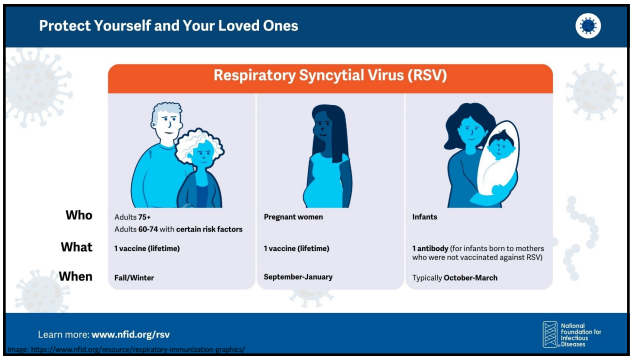

Image: https://www.nfid.org/resource/respiratory-immunization-graphics/

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Conclusion

- RSV has the highest risk in infants, elderly, and immunocompromised populations
- Prevention strategies:
  - Nonpharmacologic
  - Monoclonal antibodies: infants
  - Vaccines: maternal, older adults
- Pharmacists play a key role in the RSV prevention

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RSV Breakthroughs: The Latest in Prevention & Protection

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Dade County Pharmacy Association, InterAmerican Pharmacy Association, Broward County Pharmacy Association Sunday CE Program

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