# Progress and Opportunities in Pediatric RSV Prevention

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Future of Pediatrics

# Sarah Schaffer DeRoo, MD, MA

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# Learning Objectives

1. Characterize the burden and severity of pediatric RSV disease
2. Review recommendations for maternal and infant RSV immunization
3. Highlight successes in RSV prevention
4. Identify clinical nuances and opportunities for improvement

## Learning Objective #1:

Characterize the burden and severity of pediatric RSV disease

# What is RSV?

- Respiratory syncytial virus (RSV) is an RNA virus that causes respiratory tract infections
  - Nearly all children will have at least one RSV infection by the time they are 2 years old
- In pediatric patients, RSV commonly causes lower respiratory tract infections, including bronchiolitis and pneumonia
- Follows a seasonal pattern
  - October through March
  - May vary in other regions of the US



Jones JM, et al. *MMWR Morb Mortal Wkly Rep* 2023;72:920–925; Suh M, et al. *J Infect Dis*. 2022;226(Suppl 2):S154-S163.

# Burden of RSV Disease

- RSV is the leading cause of hospitalization among US infants
- 50,000-80,000 annual hospitalizations due to RSV in children <5 years
- Estimated 2.1 million children under 5 require medical attention per year
  - 3% are hospitalized
  - 25% are treated in emergency departments
  - 76% are treated by pediatric practices



Hall 2009, Jones 2023.

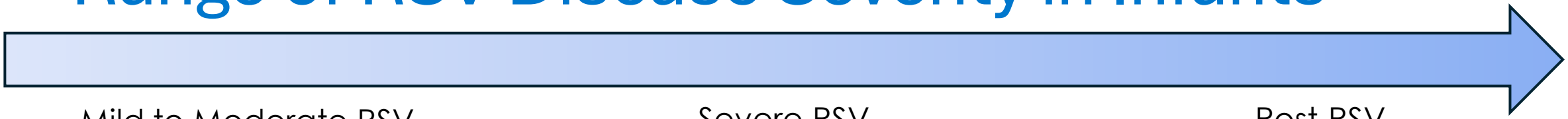
# Risk Factors for Severe RSV Disease

- Most RSV-related hospitalizations occur in healthy, term infants
- Certain populations are considered high risk for severe RSV disease, including infants and young children with:
  - Prematurity
  - Chronic lung disease or congenital heart disease
  - Weakened immune systems
  - Severe cystic fibrosis
  - Neuromuscular disorders (difficulty swallowing or clearing secretions)
  - American Indian and Alaska Native children



Hall 2013, CDC 2026.

# Range of RSV Disease Severity in Infants



## Mild to Moderate RSV

- **Early symptoms**: Runny nose, cough, decreased appetite
- **Infants (under 6 months):** Irritability, decreased activity, apnea. Fever may not be present.
- **Progression:** Increasing severity within a few days, worsening cough, wheezing, or difficulty breathing

## Severe RSV

**Bronchiolitis** or **pneumonia**

- Very young infants may develop apnea
- Hospitalized infants may need O2, fluids, and, rarely, ventilation
- Most infants recover with supportive care and are discharged within a few days

## Post-RSV

**Reactive airway disease**

- RSV infection in the first year of life is associated with wheezing and asthma

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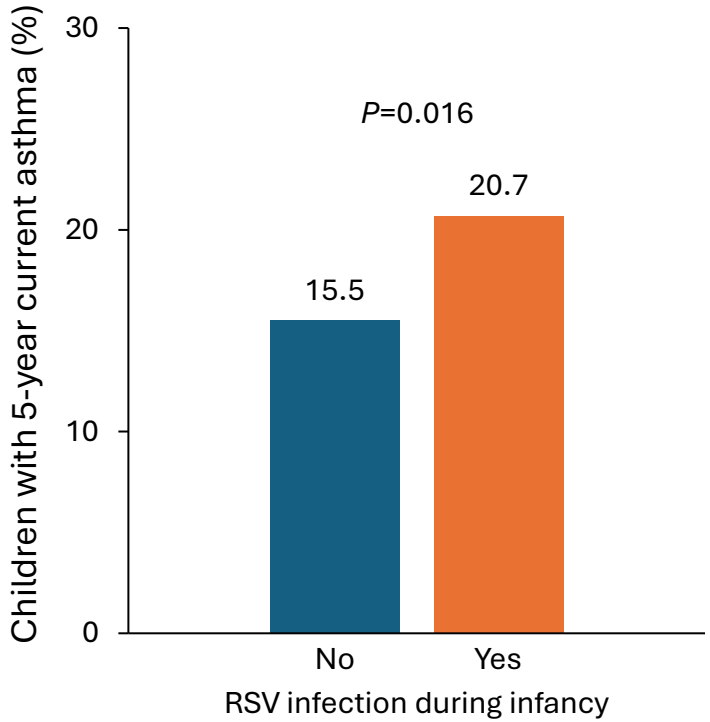
# Long-term Effects of RSV Infection During Infancy: Asthma & Recurrent Wheezing

- Population-based cohort study of healthy, term infants (N=1946) followed prospectively for 5 years
  - RSV infection status during the first year of life was available for 1741 children
- 54% of children had RSV infection during infancy (944 of 1741)
- Being uninfected: ~25% lower risk of 5-year current asthma*
- Recurrent wheeze was more common between 1-4 years of age in children infected with RSV during infancy

*5-year current asthma defined as parental report of (1) physician-diagnosed asthma or use of asthma medications at any time prior to age 5 years AND (2) asthma symptoms, asthma-related systemic steroid use, or acute healthcare utilization for asthma during the 12 months prior to the 5-year visit




~15% of 5-year current asthma could be prevented by RSV prevention in infancy

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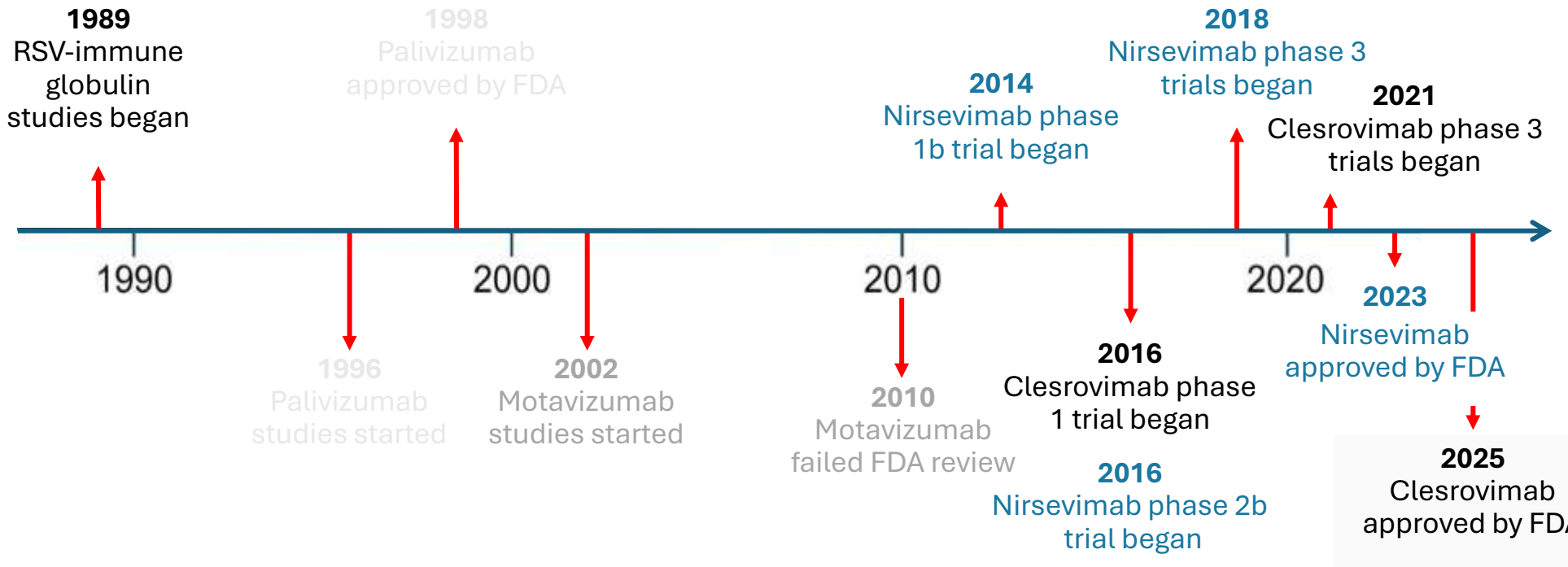
Rosas-Salazar 2023. Slide content courtesy of Domachowske 2025.

## Learning Objective #2:

Review recommendations for maternal and infant RSV immunization

# Timeline of Infant RSV Immunization Approvals

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Slide content courtesy of Domachowske 2025.

# Recommendations for Infants in their 1st RSV Season

- All infants <8 months should receive RSV prevention in their 1st RSV season
- Families may choose between one of two options:

Maternal RSVpreF vaccination between 32-36 weeks gestation

Infant immunization with monoclonal antibodies (nirsevimab or clesrovimab)

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Moulia 2025.

# Infant RSV Prevention

## Maternal Vaccination

- **Bivalent RSVpreF vaccine**
  - Abrysvo®
  - Pfizer
- FDA approved August 2023 for maternal vaccination
- Additionally, approved for adults 60+ and 18-59 who are at increased risk of severe RSV

## Monoclonal Antibodies

### Nirsevimab

Beyfortus®

Sanofi and AstraZeneca

FDA approved July 2023

- Neonates and infants for their 1st RSV season
- Children up to 24 months who are vulnerable to severe RSV for their 2nd RSV season

### Clesrovimab

Enflonsia™

Merck

FDA approved June 2025

- Neonates and infants for their 1st RSV season

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Fleming-Dutra 2023. Slide content courtesy of PRIME Education 2025.

# Case #1

- 3-day-old infant presents to establish newborn care following an uneventful vaginal delivery in November
- Mother received RSV vaccine with a prior pregnancy during the 2023-2024 RSV season
- **How should RSV be prevented in this infant?**

# Maternal RSVpreF Vaccine

- **Timing:** A single dose should be administered between weeks 32-36 of pregnancy between September and January
- **Antibody transfer:** Transplacental antibody transfer to fetus occurs within 2 weeks, but peaks at 5 weeks
- **Repeat vaccination:** If a RSVpreF vaccine was administered during a prior pregnancy, repeat vaccination is **not** recommended → limited data
- **Co-administration:** May be administered concurrently with other vaccines



Fleming-Dutra 2023; Jasset 2025.

# Case #2

- 2-day-old infant delivered at 38 weeks via vaginal delivery, no complications
- Mother remembers receiving vaccines during pregnancy, but does not remember which ones
- **Should this infant receive RSV monoclonal antibodies?**

# RSV Monoclonal Antibody

- **RSV monoclonal antibody is universally recommended for all infants <8 months old if:**
  - The mother is unvaccinated or vaccination status is unknown; or
  - <2 weeks since maternal RSV vaccination

  •**Timing:** A single dose of nirsevimab or clesrovimab should be administered:
  - Born Oct through Mar: As soon as possible after delivery, ideally within 1 week
  - Born Apr through Sept: At the start of RSV season

  •**Co-administration:** May be administered concurrently with other vaccines



Jones 2023.

# RSV Monoclonal Antibodies

**Nirsevimab**

- 1st and 2nd RSV seasons
- Dosing:
  - <5 kg: 50 mg
  - ≥5 kg: 100 mg
  - 2nd season: 200 mg

- **Clesrovimab**
  - 1st RSV season only
  - Dosing:
    - 105 mg regardless of weight

**Similar safety and efficacy profiles**

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Moulia 2025.

# Case #3

- 15-month-old ex-27 week toddler presents for well child care in October
- Toddler has a history of chronic lung disease for which he is followed by Pulmonology
- He received nirsevimab during the last RSV season
- **Should this toddler receive nirsevimab/clesrovimab this season?**

# Children 8-19 Months Old at High-Risk for Severe RSV Disease

- **Nirsevimab is recommended for high-risk children in their 2nd RSV season**

- Clesrovimab is not recommended

**BOX. Infants and children aged 8–19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second respiratory syncytial virus season**

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

**Abbreviation**: RSV = respiratory syncytial virus.



Jones 2023.

# Maternal Vaccination vs. Infant Monoclonal Antibodies

**Maternal vaccination**

•Advantages:

- Immediate protection for infant
- No injection required for infant

•Disadvantages:

- Limited timeframe for administration
- Potential for adverse pregnancy outcomes

**Infant monoclonal antibodies**

Advantages:

- Infant directly receives antibodies
- Duration of protection may be longer

Disadvantages:

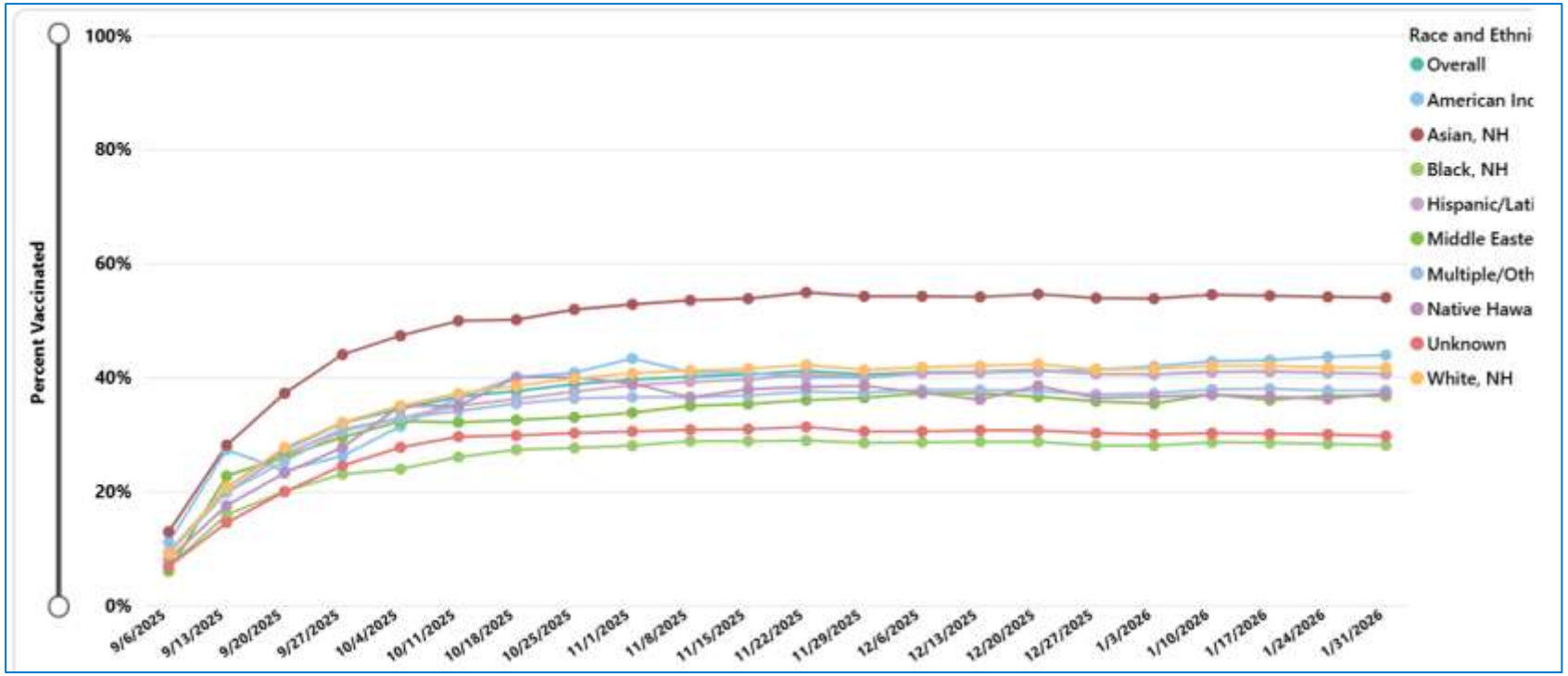
- Delayed administration leaves infant vulnerable to infection
- Cost

## Learning Objective #3:

Highlight successes in RSV prevention

# Maternal RSV Vaccination Coverage – National

- Maternal RSV vaccination coverage during the 2025-2026 RSV Season was 40.6%
- Disparities by race and ethnicity: 54.0% Asian, 28.1% Black



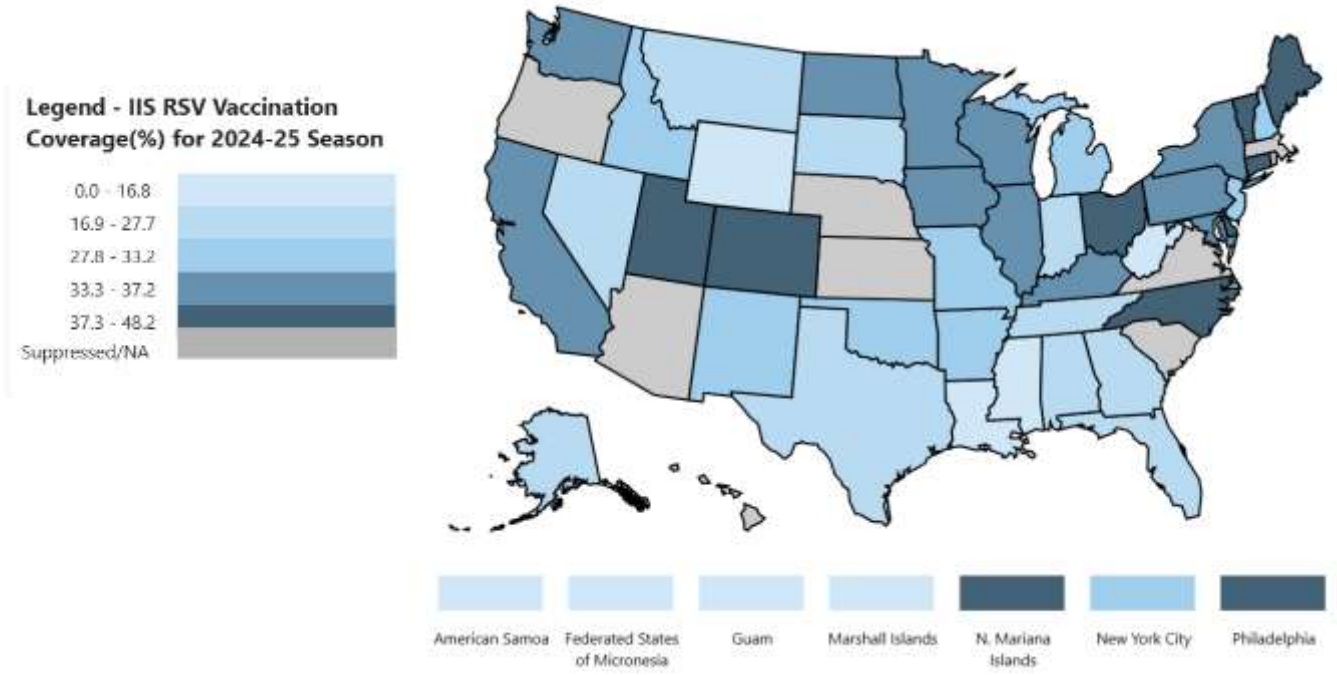



Centers for Disease Control and Prevention. RSVVaxView: Respiratory Syncytial Virus (RSV) Vaccination Coverage, Pregnant Women. 11 Mar 2026. https://www.cdc.gov/rsvvaxview/dashboard/pregnant-women-coverage.html.

# Infant RSV Monoclonal Antibody Coverage – National

- Data is from state immunization information systems, but data is not available from all jurisdictions

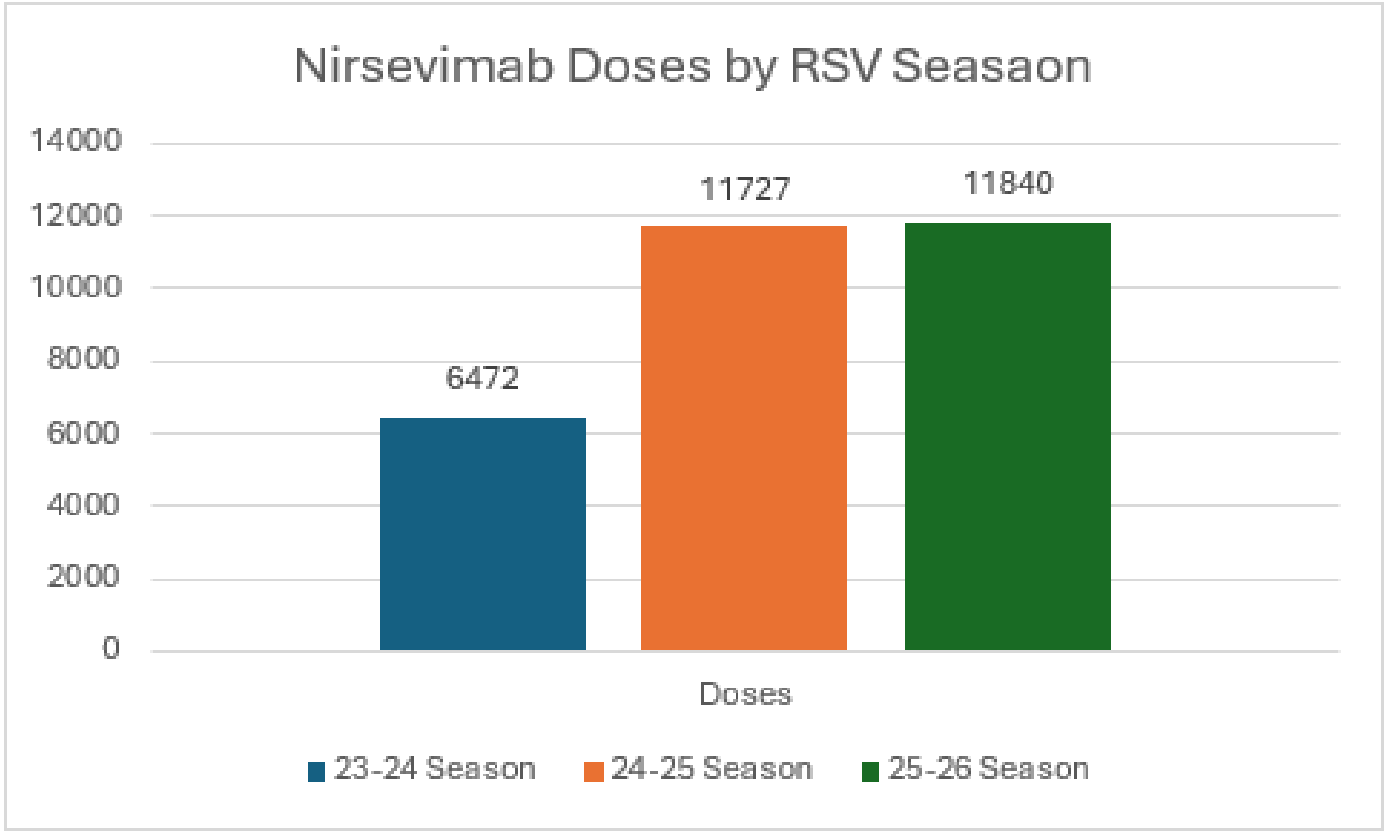
- No national estimates from CDC






Centers for Disease Control and Prevention. RSVVaxView: 2024-25 Nirsevimab Coverage, Children 0-7 months, United States. 15 Apr 2025. https://www.cdc.gov/rsvvaxview/dashboard/2024-25-nirsevimab-coverage-jurisdiction.html.

# RSV Immunization Coverage – PHN

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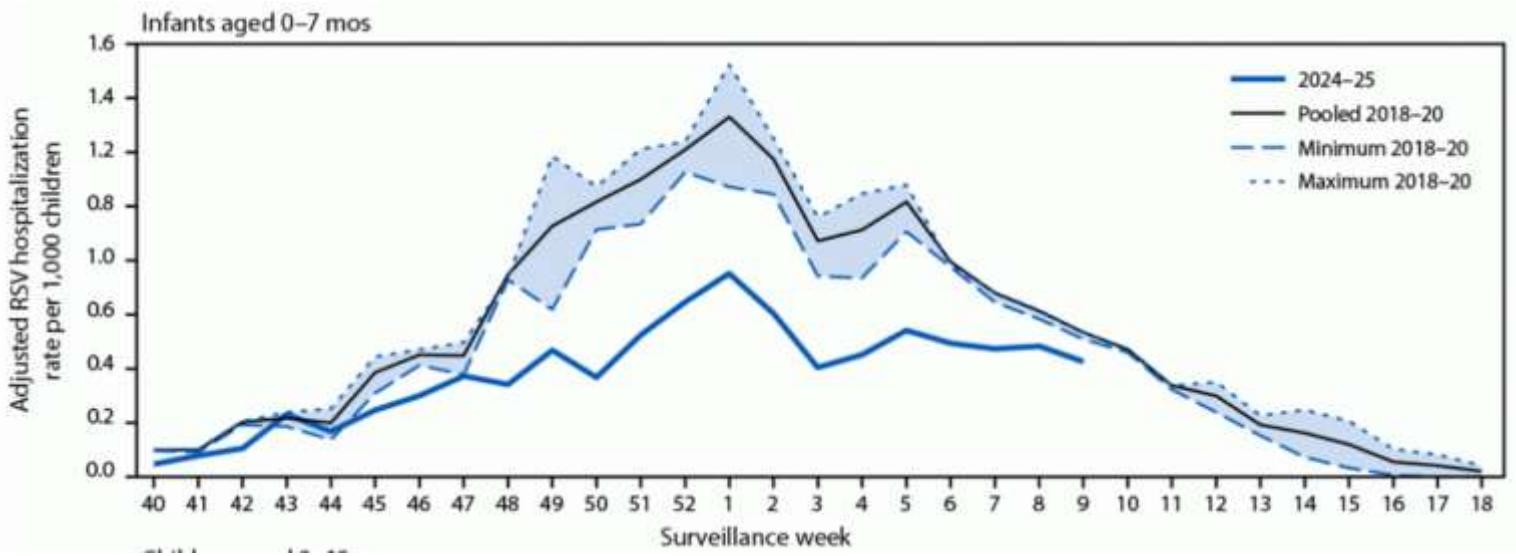
# RSV Immunization Coverage – Goldberg

- 2023-2024 Season: 831 of 2,162 infants <8 months received nirsevimab (38.4%)
  - Race and insurance type were associated with nirsevimab uptake in the univariable logistic regression model, but did not remain statistically significant in the multivariable model, suggesting potential interaction effects
  - Likely impacted by supply concerns
- 2024-2025 Season: 990 of 2,225 infants <8 months received nirsevimab (44.5%)
  - Maternal vaccination coverage data unavailable


Schaffer DeRoo S, Hossain T, Chandereng T, Lazerov J. Nirsevimab Uptake in a Pediatric Primary Care Network During the 2023-2024 RSV Season. JAMA Netw Open. 2025 Jul 1;8(7):e2520440. 2024-2025 data is unpublished.

# RSV-Related Hospitalizations

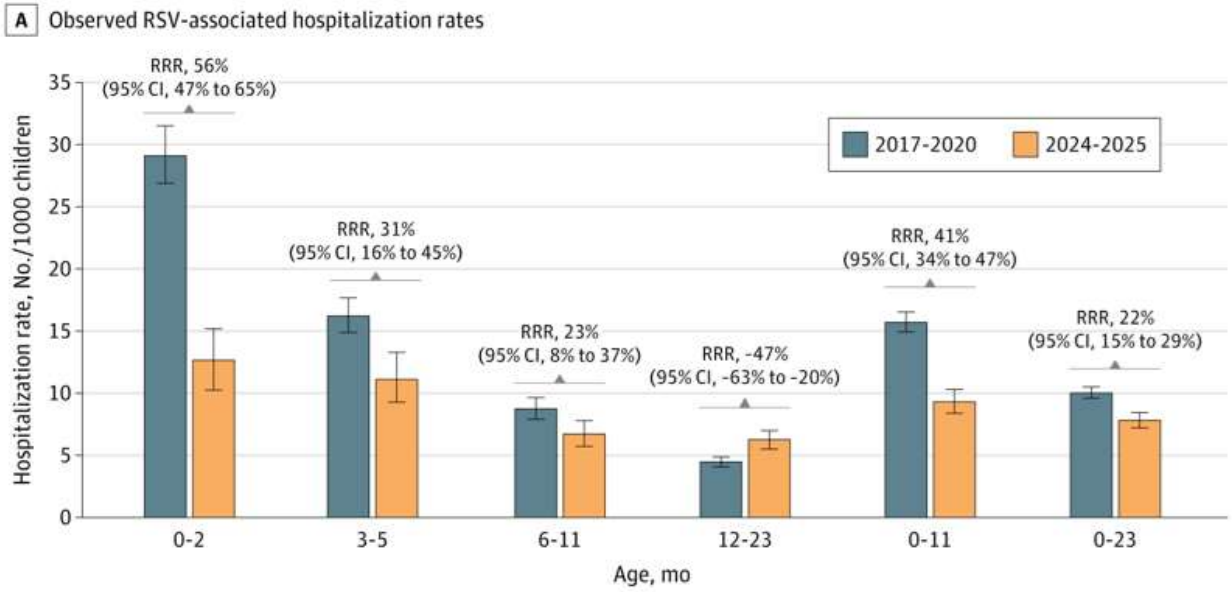
- Decreased RSV-related hospitalizations among infants <8 months during the 2024-2025 RSV season compared to pooled data from 2018-2020

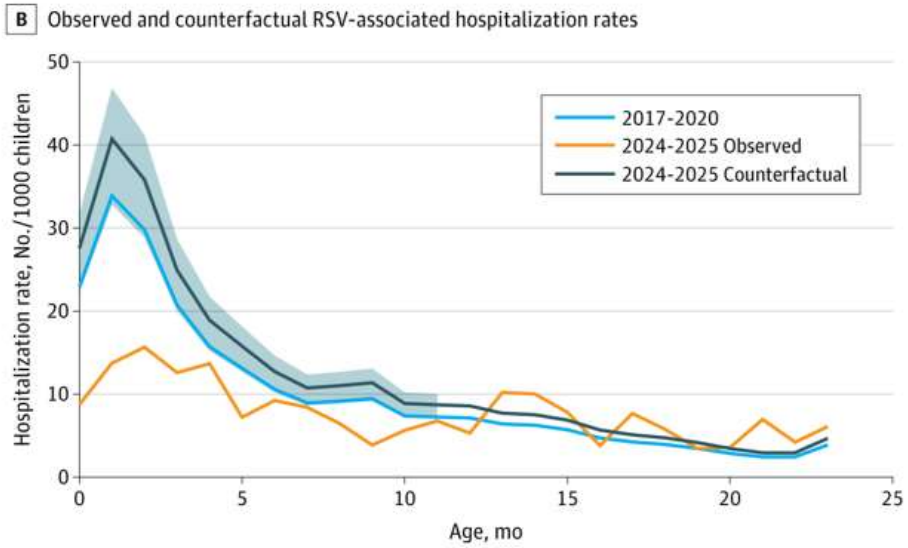





Patton ME, Moline HL, Whitaker M, et al. Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products — United States, October 2024–February 2025. MMWR Morb Mortal Wkly Rep 2025;74:273–81.

# RSV-Related Hospitalizations – By Age






Moline HL, Tannis A, Goldstein L, et al. Effectiveness and Impact of Maternal RSV Immunization and Nirsevimab on Medically Attended RSV in US Children. *JAMA Pediatr.* 2026;180(3):314–324.

# RSV-Related Hospitalizations & Outpatient Visits – Galicia, Spain (NIRSE-GAL)

- 12,492 infants followed over 18 months during 2023-2024 RSV season
- 85% decline in RSV-related hospitalizations during the 1st season
- 55% decline in RSV-related hospitalizations during the 2nd season
- 1st season outpatient visits declined by:
    - 31% for bronchitis or bronchiolitis
    - 33% for LRTI
    - 28% for asthma or wheezing

→ **Nirsevimab coverage: 94%**

→ **Protective even into second season**

## Learning Objective #4:

Identify clinical nuances and opportunities for improvement

# Case #4

- 6-month-old infant delivered at 37 weeks presents to establish care in October following a prolonged hospitalization for congenital heart disease
- Infant was placed on cardiopulmonary bypass during NICU stay for cardiac procedure
- Mother received RSV vaccine during week 32 of pregnancy and >2 weeks since time of delivery
- **Should this infant receive monoclonal antibodies?**

# Clinical Nuances

**RSV monoclonal antibody may be considered for infants born to vaccinated mothers in rare cases, when, based on the clinical judgment, the benefit is warranted**

Infants whose mothers may have a reduced immune response to the vaccine (eg, immunocompromised)

Infants whose mothers have conditions associated with reducing transplacental antibody transfer (eg, living with HIV)

Infants who have lost maternal antibodies due to procedures like cardiopulmonary bypass or ECMO

Infants at substantial increased risk for severe RSV (eg, congenital heart disease, or needing oxygen at discharge)

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AAP 2025. Slide content courtesy of PRIME Education 2025.

# Case #5

- 6-month-old born in June presents for well child care in December
- Infant had recent RSV infection in November, but did not require hospitalization
- **Parents are wondering if RSV monoclonal antibodies should be given?**

# Clinical Nuances

- RSV monoclonal antibodies should be administered to all infants <8 months even if the infant had a prior RSV infection
  - Exceptions may be made in case of supply concerns

- Children who are moderately or severely ill with current RSV infection should defer RSV monoclonal antibodies until recovery from the acute illness
  - There is no role for monoclonal antibodies during acute infections

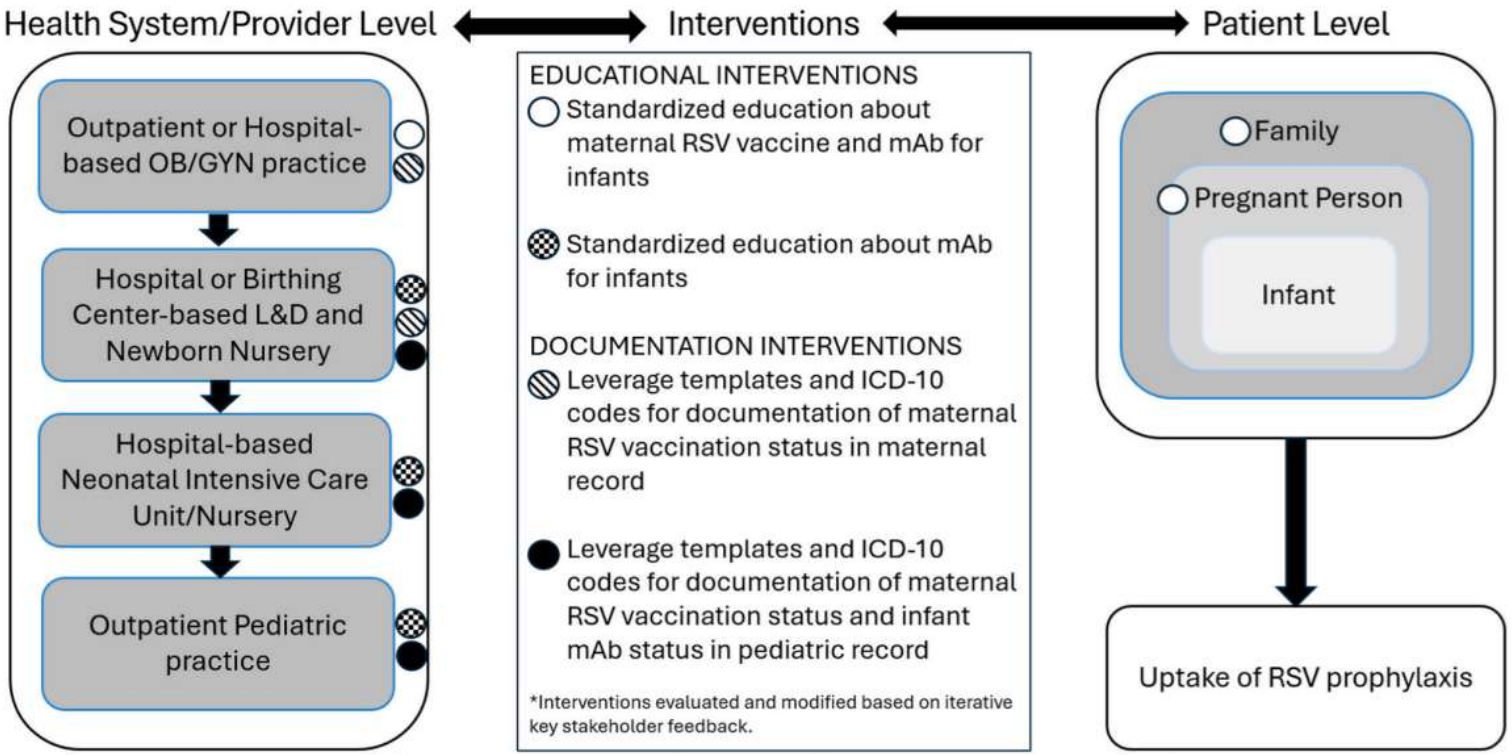


AAP 2024.

# Challenges in RSV Prevention

- Documentation of maternal and infant RSV immunization status
- Birth hospital administration & VFC enrollment
- Immunizing infants born outside of RSV season
- Lack of evidence-based communication strategies

# Framework for Implementation of Interventions to Improve RSV Prophylaxis Uptake in Diverse Healthcare Settings

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Hossain 2025.

# Talking Points

- No preference for maternal vaccination or infant monoclonal antibodies – choice depends on personal preference and timing of delivery
- Nirsevimab and clesrovimab are monoclonal antibodies – not vaccines
- Single dose is administered once during RSV season
- Timing matters

# Conclusions

- RSV prevention via maternal vaccination or infant immunization is safe and effective
- Notable observed reductions in hospitalizations in the US despite only limited coverage
- Notable observed reductions in outpatient visits in Spain – more study is needed to understand the impact on outpatient care
- Further study is needed to understand disparities in uptake of maternal vaccination
- Further study is needed to understand strategies for addressing reluctance to accept RSV immunization – currently relying on the vaccine hesitancy literature

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