

Effectiveness and impact of maternal RSV immunization and nirsevimab on medically attended RSV in US children

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INTRODUCTION

Protecting infants from severe RSV in their first RSV season

In 2023, 2 RSV prevention products—the long-acting monoclonal antibody, nirsevimab, and a maternal RSV vaccine—became available¹

Infant RSV coverage

~60%-65% of infants were protected by maternal vaccination or nirsevimab during peak RSV circulation in January-February 2025²



OBJECTIVE

- To estimate nirsevimab and maternal RSV vaccine effectiveness against medically attended RSV-associated ARI and the impact of these prevention products on RSV-associated hospitalizations during the 2024-2025 season



METHODS

STUDY DESIGN



Study design

- Test-negative, case-control study
- Cases and controls were infants with ARI who had PCR test results for RSV that were positive and negative, respectively



Population

Children <2 years of age who received care for ARI in an NVSN outpatient clinic, urgent care, ED, or hospital



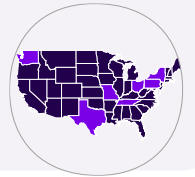
Data

Data collection: October 1, 2024, through April 30, 2025 (2024-2025 season); and children <2 years of age hospitalized with RSV on October 1-April 30 of the 2017-2020 RSV seasons (for impact analyses only)
Data source: NVSN



Location

NVSN:
7 academic medical centers in the US



PARTICIPANTS

- **Nirsevimab:** Infants <8 months of age born on or after October 1, 2024, and excluded those with maternal RSV vaccination, palivizumab receipt, or nirsevimab receipt <7 days before symptom onset
 - o Second-season analyses included infants 8-19 months of age, and excluded those who were recommended to receive or had received nirsevimab in the second season
- **Maternal RSV vaccination:** Infants <6 months of age at medical encounter and excluded those who received nirsevimab or whose mothers received an RSV vaccine <14 days before giving birth



OUTCOMES

Primary endpoint

- Effectiveness of nirsevimab and maternal RSV vaccine against MA (defined as clinical care provided in the inpatient, ED, urgent care, or outpatient settings) RSV-associated ARI and RSV hospitalization in infants

Additional endpoints

- Effectiveness of nirsevimab receipt in children's first RSV season against MA RSV-associated ARI and RSV hospitalization during their second season
- Combined public health impact of RSV prevention products on RSV hospitalization rates in infants and children <2 years of age



RESULTS

MA RSV-associated ARI and RSV-associated hospitalization (primary outcome)

Maternal immunization effectiveness (N=446)

- **19%** (27/139) of case patients and **35%** (106/307) of control patients had maternal RSV vaccination
- Maternal vaccination effectiveness (95% CI)
 - o **64%** (37%-79%) against MA RSV-associated ARI
 - o **70%** (37%-86%) against RSV hospitalization
- Median (IQR) age at ARI symptom onset was **49 days** (21-85)

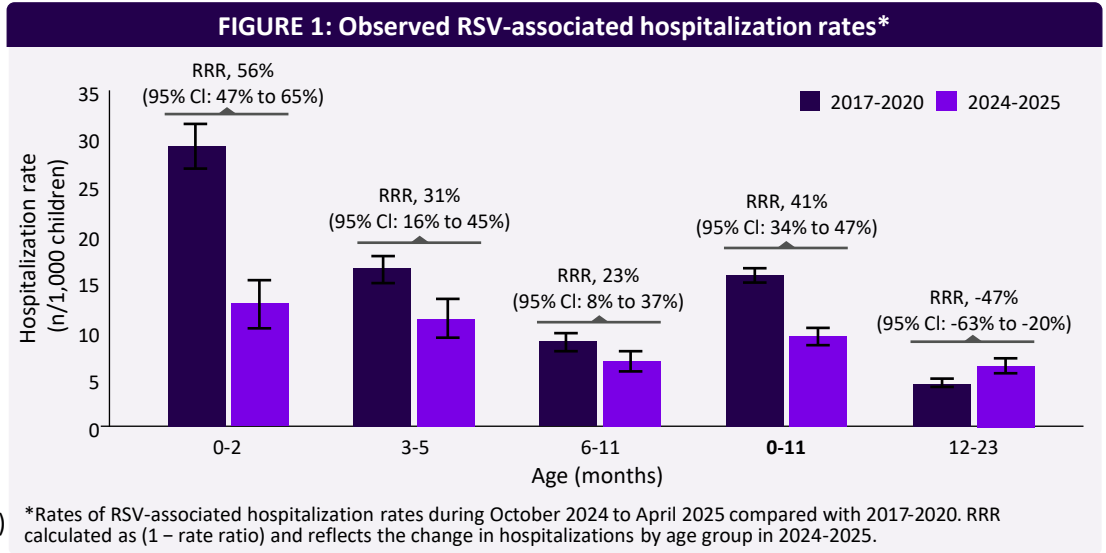
Nirsevimab effectiveness (N=1,765)

- **14%** (66/462) of case patients and **44%** (548/1,259) of control patients received nirsevimab
- Nirsevimab effectiveness (95% CI)
 - o **77%** (69%-83%) against MA RSV-associated ARI
 - o **81%** (71%-87%) against RSV hospitalization
 - o **90%** (68%-97%) against ICU admission
- Median (IQR) age at ARI symptom onset was **79 days** (38-120)
- In a separate analysis, prior-season receipt of nirsevimab was not effective against MA RSV-associated ARI or hospitalization (Data not shown, refer to full publication)



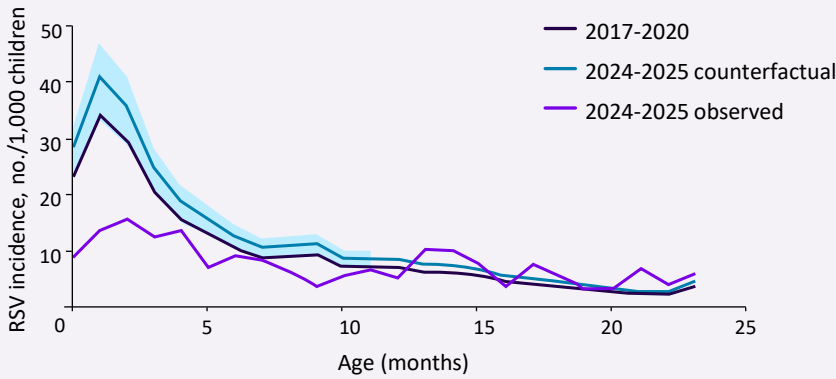
RSV-associated hospitalization rates

- Among the 2,659 infants and children <2 years of age included in the analysis, the RSV hospitalization rate during 2024-2025 was **7.8 per 1,000 children** (95% CI: 7.2-7.8)
- Among infants <11 months of age, estimated RRR in RSV hospitalizations ranged from 41% (observed rates comparison; **Figure 1**) to 51% (DID approach; **Figure 2**)
- RRR was greatest among newborns and infants 0-2 months of age (56%-63%) (**Figure 1, Table 1**)



NVSN effectiveness and impact

FIGURE 2: Observed and counterfactual RSV-associated hospitalization rates



- A DID analysis was used to compare observed hospitalization rates vs counterfactual rates during the 2024-2025 season
- The counterfactual line represents the expected 2024-2025 RSV hospitalization rate in the absence of pediatric RSV prevention products, based on the trend curve of RSV-associated hospitalization rates by month of age during 2017-2020

TABLE 1: Observed and counterfactual (expected) RSV-associated hospitalization rates per 1000 children by age group (n=2,659)

Age group, mo	Observed rate 2024-2025 (95% CI)	Counterfactual (expected) rate (95% CI)	2024-2025 observed vs counterfactual RRR* (95% CI)	NNI† (95% CI)
0-11	9.3 (8.4 to 10.3)	18.9 (17.4 to 19.4)	51% (43 to 55)	104.2 (95.9 to 131.5)
0-2	12.7 (10.2 to 15.2)	34.7 (30.4 to 37.2)	63% (54 to 70)	45.5 (39.8 to 59.1)

*RRR was calculated as (1 - rate ratio) and reflects the RRR in 2024-2025.

†NNI was calculated as (1/absolute risk reduction), where absolute risk reduction was the counterfactual (expected) rate during 2024-2025 minus the observed rate during 2024-2025. In this analysis, the number needed to immunize was calculated collectively for immunization with either maternal RSV vaccine or nirsevimab.

STRENGTHS

- Multisite population-based active surveillance
- Test-negative case-control design
- 2 complementary approaches used to estimate population-level impact
- Examined simultaneous use of dual RSV prevention strategies

LIMITATIONS

- Population from large academic medical centers may not be nationally representative
- Self-reported receipt of prevention products was used for some children lacking source documentation
- Analyses used cannot fully establish causality

KEY MESSAGES

1 With widespread and early uptake, both maternal RSV vaccine and nirsevimab were effective against RSV-associated hospitalizations in infants, with rates in infants 0-11 months of age reduced by 41% during the 2024-2025 season

2 Early and high immunization coverage in new birth cohorts each season will be required to achieve sustained reductions in severe RSV burden in infants

Glossary: ARI, acute respiratory infection; CI, confidence interval; DID, difference-in-differences; ED, emergency department; ICU, intensive care unit; IQR, interquartile range; MA, medically attended; mo, months; NNI, number needed to immunize; NVSN, New Vaccine Surveillance Network; PCR, polymerase chain reaction; RRR, relative rate reduction.

References: 1. Fleming-Dutra KE, et al. *MMWR Morb Mortal Wkly Rep.* 2023;72(41):1115-1122. 2. US Centers for Disease Control and Prevention. RSVVaxView. Accessed April 16, 2026. <https://www.cdc.gov/rsvvaxview/index.html>

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