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Nirsevimab Effectiveness Against Intensive Care Unit Admission for Respiratory Syncytial Virus in Infants — 24 States, December 2024–April 2025

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Abstract

Respiratory syncytial virus (RSV) is a leading cause of intensive care unit (ICU) admission and respiratory failure among infants (children aged <1 year) in the United States. In August 2023, CDC's Advisory Committee on Immunization Practices recommended nirsevimab, a long-acting monoclonal antibody, to protect against RSV-associated lower respiratory tract infection among all infants aged <8 months born during or entering their first RSV season. Following licensure, nirsevimab effectiveness has been demonstrated against RSV-associated infant hospitalization, but evidence regarding effectiveness against RSV-associated critical illness is limited. In a 27-hospital case-control investigation, nirsevimab effectiveness against both RSV-associated infant ICU admission and acute respiratory failure (illness requiring continuous positive airway pressure, bilevel positive airway pressure, or invasive mechanical ventilation) after hospital admission was evaluated during December 1, 2024–April 15, 2025. Among 457 case-patients who received a positive RSV test result and 302 control patients who received a negative RSV test result admitted to an ICU with respiratory symptoms, 14% and 45%, respectively, had received nirsevimab ≥7 days before symptom onset. Nirsevimab was 80% effective (95% CI = 70%–86%) against RSV-associated ICU admission and 83% effective (95% CI = 74%–90%) against acute respiratory failure when received a median of 52 days (IQR = 32–89 days) and 50 days (IQR = 32–86 days) before onset for each respective endpoint. These estimates support the recommendation for use of nirsevimab as a prevention strategy to protect infants against severe outcomes from RSV infection.

Introduction

Respiratory syncytial virus (RSV) is a leading cause of intensive care unit (ICU) admission and acute respiratory failure in U.S. infants (*1*,*2*). Pooled, prelicensure, placebo-controlled clinical trials of nirsevimab, a long-acting anti-RSV monoclonal antibody, indicated high efficacy against RSV lower respiratory tract infection resulting in hospitalization and ICU admission (*3*). In August 2023, the Advisory Committee on Immunization Practices (ACIP) recommended nirsevimab for all infants aged <8 months born during or entering their first RSV season whose mothers had not received maternal RSV vaccine >14 days before delivery (*3*). Postlicensure, effectiveness

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of nirsevimab in preventing RSV-associated hospitalization among young infants has been demonstrated to be high (*4*), but real-world effectiveness in preventing RSV-associated ICU admission and acute respiratory failure has not been rigorously assessed using large U.S. multicenter patient networks. In this analysis of data from a large, multicenter surveillance network, the effectiveness of 1 dose of nirsevimab against both RSV-associated ICU admission and acute respiratory failure among hospitalized infants aged <1 year was estimated.

Methods

Participants

This case-control investigation relied on the Overcoming RSV Network, an extension of the CDC-funded Overcoming COVID-19 Network to conduct RSV surveillance, to collect data from 27 pediatric hospitals in 24 states that actively enrolled patients and documented information on their demographic and clinical characteristics and RSV immunization status. Infants (children aged <1 year) who were admitted to an ICU with respiratory symptoms[§] that began ≤14 days before hospital admission were prospectively enrolled. Case-patients were infants born during April 1, 2024–March 31, 2025, who were admitted to an ICU during hospitalization for laboratory-confirmed[¶] RSV-associated disease during December 1, 2024–April 15, 2025. Control patients were born during the same period but received a negative RSV test result[**] ≤1 day before or during hospitalization. Case-patients and control patients were enrolled and matched in a targeted 1:1 ratio by site, date of hospital admission (within 30 days), and age group (<1 month, 1–2 months, 3–5 months, and 6–11 months). Control patients were admitted to an ICU during November 1, 2024–April 15, 2025, to account for matching within 30 days of hospitalization to a case-patient. Nirsevimab receipt was defined as having received 1 dose ≥7 days before hospitalization, to account for the time to peak antibody concentration.[††] Infants were a priori excluded[§§]

[§] Respiratory symptoms sufficient for inclusion included one or more of the following: cough, shortness of breath, wheezing, apnea, use of new or elevated oxygen support for the acute illness, or new pulmonary findings on chest imaging. Symptom onset date was determined by caregiver report if caregiver interview was conducted and onset date was known; if not known, symptom onset date was estimated by subtracting date of hospital admission from the median days between symptom onset and admission date in records with complete data.

[¶] Clinically obtained test from a respiratory sample that is positive for RSV by polymerase chain reaction (PCR) or other nucleic acid amplification test (NAAT), or antigen testing during hospitalization or in a health care setting before hospitalization.

[**] Clinically obtained test from a respiratory sample that is negative by PCR or other NAAT for RSV performed during hospitalization or in a health care setting within 1 calendar day before admission to the site hospital.

[††] In clinical trials, peak neutralizing antibody concentration levels were reached in adults by day 6 after intramuscular administration.

[§§] In addition to listed exclusion criteria, infants were not eligible for inclusion in the primary analysis if 1) they were never discharged from their birth hospitalization, 2) they had previously been enrolled in the RSV nirsevimab effectiveness investigation since December 1, 2024, and 3) the infant's home state immunization information system could not be accessed.

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from the analysis if 1) verification of RSV immunization product receipt was unsuccessful,¶¶ 2) nirsevimab was received <7 days before illness onset or before October 1, 2024, or >1 nirsevimab dose was received, 3) palivizumab (a monoclonal antibody indicated for children aged <2 years at high risk for severe RSV infection) was received,*** 4) the birth mother received maternal RSV vaccine during pregnancy, 5) illness onset occurred >14 days before hospitalization, 6) the first positive RSV test result was received >3 days after admission, or 7) the infant was aged <7 days at symptom onset.

Statistical Analysis and Product Effectiveness Estimation

The primary analysis assessed nirsevimab effectiveness against RSV-related ICU admission using all eligible ICU-admitted case-patients and control patients. A secondary analysis assessed effectiveness against acute respiratory failure, defined as illness requiring respiratory support within an ICU (above the patient's baseline received at home preadmission)††† involving continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), or invasive mechanical ventilation (IMV). The secondary analysis included case-patients with acute respiratory failure and all control patients.

Balance of matching factors and potential covariates between case-patients and control patients was assessed to identify potential confounding using the absolute value of the standardized mean differences (SMD).§§§ Unconditional multivariable logistic regression was used to estimate odds ratios for the ICU admission and respiratory failure outcomes among the entire enrolled population, using generalized estimating equations to address within-hospital site correlation, and adjusting for infant age in months, biweekly date of hospital admission, U.S. Census Bureau region, the presence of one or more specified underlying medical conditions,¶¶¶ and social vulnerability index of infant's residential zip code.**** The primary analysis was stratified by interval from nirsevimab dose to symptom onset (7–59 days and ≥60 days) to account for the mean nirsevimab half-life from trial data of 59 days (*5*). Nirsevimab effectiveness was calculated as (1 – adjusted odds ratio) x 100%.

To account for potential differences in matching characteristics between case-patients and control patients in the overall sample, a post hoc analysis was performed using conditional multivariable logistic regression, incorporating only matched 1:1 case-patients and control patient pairs. SAS software (version 9.4; SAS Institute) was used to conduct all analyses. This activity was reviewed by CDC, deemed not research, and conducted consistent with applicable federal law and CDC policy.††††

Results

Characteristics of Enrolled Population

A total of 917 infants admitted to an ICU were enrolled, including 548 (60%) case-patients and 369 (40%) control patients. After the exclusion of 91 (17%) case-patients

¶¶ Immunization product receipt was considered verified if the infant's immunization status was identified through either their state's immunization information system or in their electronic medical record. Plausible self-report from caregiver interview data was considered a source for verification if the caregiver provided both a date and location where immunization was received.

*** Palivizumab was considered to have been potentially received if documentation review during product verification indicated that an anti-RSV monoclonal antibody was received, but type was not specified. The American Academy of Pediatrics publishes recommendations for palivizumab (Respiratory Syncytial Virus | Red Book: 2024–2027 Report of the Committee on Infectious Diseases | Red Book Online | American Academy of Pediatrics). Effective December 31, 2025, palivizumab will no longer be available in the United States in the context of current recommendations for nirsevimab and clesrovimab.

††† Receipt of respiratory support that was higher than that required at baseline was evaluated. Analyses of highest level of respiratory support received excluded one case-patient and one control patient who were receiving invasive mechanical ventilation at baseline and one control patient who was receiving CPAP at baseline with no increased level of respiratory support during the hospitalization.

§§§ SMDs measure the magnitude of difference between group means and proportions. An SMD with an absolute value of the difference ≥0.2 indicated nonnegligible differences in variable distribution.

¶¶¶ Specified underlying medical conditions in the case report form included respiratory disorders (chronic lung disease, bronchopulmonary dysplasia, cystic fibrosis, assistance required for secretion clearance, reactive airway disease, obstructive sleep apnea, tracheomalacia/laryngomalacia, and congenital airway disorders), cardiac disorders (congenital heart disease, history of cardiac repair [surgery or interventional catheterization], pulmonary hypertension, and congestive heart failure), immune or oncologic disorders (primary immunodeficiency, HIV, and acquired immune deficiency, and includes receipt of high-dose corticosteroid therapy for any rheumatologic, oncologic, or autoinflammatory disorder), neurologic or neuromuscular disorders (muscular dystrophy, static encephalopathy, spastic quadriplegia, seizure disorder, neuromuscular weakness, and hydrocephalus), endocrine disorders (including diabetes), and metabolic or confirmed genetic disorders (trisomy 21 or any other chromosomal disorder, mitochondrial disorder, or fatty acid deficit).

**** 2022 Social Vulnerability Index (SVI) scores (SVI | Place and Health - Geospatial Research, Analysis, and Services Program (GRASP) | ATSDR) were linked to patients by the first four digits of their zip code, extrapolated to U.S. Census Bureau tract using the U.S. Postal Service tract-to-zip code crosswalk file from the U.S. Department of Housing and Urban Development (HUD USPS ZIP Code Crosswalk Files | HUD USER). Where a zip code matched to multiple U.S. Census Bureau tracts, a weighted average for SVI was computed using tract-based population estimates derived from the American Community Survey (2018–2022) estimates, embedded within the SVI data set.

†††† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

and 67 (18%) control patients,[§§§§] 457 case-patients and 302 control patients remained. Distributions of sex, race and ethnicity, and hospital U.S. Census Bureau region[¶¶¶¶] were similar among case-patients and control patients (Table 1). Compared with control patients, case-patients less commonly had a history of one or more underlying medical conditions (11% versus 34%, SMD = 0.59). Among the 62 (14%) case-patients and 136 (45%) control patients who received nirsevimab, the median interval from administration of the nirsevimab dose to symptom onset was 64 days among case-patients (IQR = 45–109 days) and 46 days among control patients (IQR = 29–83 days) (SMD = 0.39).

Among case-patients and control patients, 237 (52%) and 165 (55%), respectively, met criteria for acute respiratory failure. Among control patients, the highest level of respiratory support received above the patient's preadmission baseline (11% CPAP, 17% BiPAP, and 27% IMV) was similar to or higher than that received by case-patients (14% CPAP, 25% BiPAP, and 14% IMV). Median length of hospital and ICU stay was 6 days (IQR = 4–9 days) and 4 days (IQR = 3–6 days), respectively, for case-patients and 6 days (IQR = 4–11 days) and 4 days (IQR = 2–7 days) for control patients. Two case-patients and two control patients required extracorporeal membrane oxygenation; and one case-patient and four control patients died during their hospitalization.

Nirsevimab Effectiveness

Overall, 62 (14%) of 457 case-patients and 136 (45%) of 302 control patients had received nirsevimab ≥7 days before illness onset (Table 2). Nirsevimab effectiveness against RSV-associated ICU admission among infants in their first RSV season was 80% (95% CI % = 70%–86%); the median interval from nirsevimab receipt to symptom onset was 52 days (IQR = 32–89 days). Effectiveness against acute respiratory failure among all enrolled ICU-admitted patients was 83% (95% CI = 74%–90%); the median interval from nirsevimab receipt to symptom onset was 50 days (IQR = 32–86 days). When stratified by interval from receipt of nirsevimab to symptom onset, nirsevimab effectiveness against RSV-associated ICU admission was 86% (95% CI = 77%–92%) at 7–59 days after the dose and 66% (95% CI = 47%–79%) at 60–183 days. Including only 226 matched pairs, overall effectiveness against ICU admission was 76% (95% CI = 59%–86%).

Discussion

In this multisite analysis of 759 U.S. infants admitted to an ICU for acute respiratory infection during their first RSV season, nirsevimab was 80% effective against RSV-associated ICU admission a median of 52 days from receipt to symptom onset and 83% effective against RSV-associated acute respiratory failure. CDC recommends nirsevimab to prevent severe illness among infants and young children (*3*) and recently added clesrovimab as a second infant monoclonal antibody option in June 2025 (*6*). This investigation demonstrated effectiveness of nirsevimab against severe RSV-related outcomes in a population of infants who received it up to 6 months before onset of respiratory symptoms.

Strengths of this analysis include a large and geographically heterogeneous sample and systematic methods for verifying nirsevimab receipt through electronic health records or state immunization information systems. Few studies have been adequately powered to assess nirsevimab effectiveness against RSV-associated illness resulting in ICU admission or acute respiratory failure in infants during their first RSV season. Previously, the only postlicensure U.S. analysis demonstrated 85% effectiveness against ICU admission; however, these results were from a single regional health system lacking nationwide generalizability (*7*). That U.S. analysis was included in a meta-analysis that included studies from France and Spain, indicating a pooled estimate of nirsevimab effectiveness against RSV-related ICU admission of 81% (*8*). In this investigation, most (89%) infants admitted to an ICU for RSV-associated illness were otherwise healthy, and 71% were born at term, aligning with previous descriptions of infants with severe RSV (*9,10*).

Limitations

The findings in this report are subject to at least five limitations. First, clinical RSV testing was used to identify case-patients and control patients, but expanded clinical respiratory viral testing was not conducted consistently across sites; therefore, the possible contribution of other respiratory viruses, particularly among case-patients, could not be assessed. Second, a matched control patient was not identified for each case-patient; however, a post hoc analysis limited to matched case-patients and control patient pairs, conducted to assess the impact of matching imbalance on results, yielded similar results compared with the primary analysis. Third, although

[§§§§] A total of 917 (548 case-patients and 369 control patients) were initially enrolled. Infants excluded from the analysis included 91 (17%) case-patients and 67 (18%) control patients who 1) received palivizumab or an unknown monoclonal antibody (one case-patient and 1 control patient); 2) were born to mothers who received maternal RSV vaccine during pregnancy (54 case-patients and 46 control patients); 3) received >1 dose of nirsevimab (one control patient); 4) had onset of symptoms <7 days after nirsevimab receipt (eight case-patients and nine control patients); 5) received nirsevimab outside of the nirsevimab season, April 1–September 30, 2024 (three case-patients and five control patients); 7) had illness onset >14 days before hospitalization (four case-patients and three control patients); 8) received a first positive RSV test result (by PCR, NAAT, or antigen testing) ≥3 days after hospital admission (11 case-patients); or 9) were aged <7 days on the date of hospitalization (10 case-patients and two control patients).

[¶¶¶¶] U.S. Census Bureau Regions and Divisions of the United States

TABLE 1. Characteristics of case-patients and control patients* born during or entering their first respiratory syncytial virus season who were admitted to an intensive care unit with respiratory symptoms — the Overcoming Respiratory Syncytial Virus Network, United States December 1, 2024–April 15, 2025

Characteristics	No. (column %) Case-patients with positive RSV test results* n = 457	Control patients with negative RSV test results* n = 302	SMD†
Age group (at admission)			
7 days to <1 mo	71 (16)	36 (12)	0.10
1–2 mos	171 (37)	99 (33)	
3–5 mos	119 (26)	87 (29)	
6–11 mos	96 (21)	80 (26)	
Month of ICU admission			
Nov 2024	0 (—)	9 (3)	0.14
Dec 2024	185 (40)	89 (29)	
Jan 2025	122 (27)	71 (24)	
Feb 2025	94 (21)	61 (20)	
Mar 2025	43 (9)	46 (15)	
Apr 2025	13 (3)	26 (9)	
Sex			
Female	182 (40)	117 (39)	0.02
Male	275 (60)	185 (61)	
Race and ethnicity			
American Indian or Alaska Native, non-Hispanic	4 (1)	6 (2)	0.11
Asian, non-Hispanic	11 (2)	8 (3)	
Black, non-Hispanic	72 (16)	57 (19)	
Hispanic or Latino	84 (18)	68 (23)	
White, non-Hispanic	217 (47)	120 (40)	
Multiple/Other	20 (4)	14 (5)	
Unknown	49 (11)	29 (10)	
Social Vulnerability Index, median (IQR)	45 (29–62)	49 (32–65)	0.10
U.S. Census Bureau region			
Northeast	64 (14)	36 (12)	0.06
Midwest	112 (25)	65 (22)	
South	159 (35)	119 (39)	
West	122 (27)	82 (27)	
Gestational age			
Term (≥37 wks)	323 (71)	190 (63)	0.17
Preterm (<37 wks)	134 (29)	112 (37)	
Underlying medical condition			
None of the specified conditions§	409 (89)	199 (66)	0.59
One or more specified underlying condition§	48 (11)	103 (34)	
Respiratory¶	24 (5)	48 (16)	0.36
Cardiac**	25 (5)	50 (17)	0.37
Immune or oncologic disorder††	1 (0.2)	3 (1)	0.11
Neurologic or neuromuscular disease§§	3 (1)	25 (8)	0.42
Endocrine	2 (0.4)	4 (1)	0.10
Metabolic or confirmed genetic disorder¶¶	14 (3)	34 (11)	0.33
Nirsevimab received	62 (14)	136 (45)	0.72
Days from nirsevimab receipt to symptom onset, median (IQR)* **	64 (45–109)	46 (29–83)	0.39
Clinical course			
Highest level of respiratory support†††			
No oxygen support	8 (2)	10 (3)	0.22
Low-flow nasal cannula	19 (4)	30 (10)	
High-flow nasal cannula	192 (42)	95 (32)	
CPAP	63 (14)	32 (11)	
BiPAP	112 (25)	52 (17)	
IMV	62 (14)	81 (27)	
Respiratory support at baseline (received at home preadmission among patients requiring CPAP, BiPAP, or IMV during hospitalization)§§§			
None	213 (89)	143 (86)	0.12
Yes	25 (11)	24 (14)	

See table footnotes on the next page.

TABLE 1. (*Continued*) Characteristics of case-patients and control patients* born during or entering their first respiratory syncytial virus season who were admitted to an intensive care unit with respiratory symptoms— the Overcoming Respiratory Syncytial Virus Network, United States December 1, 2024–April 15, 2025

Characteristics	No. (column %) Case-patients with positive RSV test results* n = 457	Control patients with negative RSV test results* n = 302	SMD†
Level of support during hospitalization above baseline	24 (10)	22 (13)	0.10
Level of support during hospitalization not above baseline	1 (0)	2 (1)	0.09
ECMO	2 (0)	2 (1)	0.03
Death during hospitalization	1 (0.2)	4 (1.3)	0.14
Hospital length of stay, median (IQR)¶¶¶	6 (4–9)	6 (4–11)	0.16
ICU length of stay, median (IQR)****	4 (3–6)	4 (2–7)	0.24

Abbreviations: BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; NAAT = nucleic acid amplification test; PCR = polymerase chain reaction; RSV = respiratory syncytial virus; SMD = standardized mean difference.

* Case-patients received a positive RSV test result by PCR, NAAT, or antigen testing during hospitalization or in a health care setting before hospitalization. Control patients received a negative RSV test result by PCR or NAAT during hospitalization or in a health care setting within 1 calendar day of admission to the site hospital. For inclusion, all patients were required to have one or more of the following respiratory symptoms or examination findings present at hospital admission and onset within 14 days of hospital admission: cough, shortness of breath, wheezing, retractions, apnea, use of new or elevated oxygen support for the acute illness, or new pulmonary findings on chest imaging consistent with pneumonia.

† SMD ≥0.20 indicates a nonnegligible difference in variable distributions between case-patients and control patients. When calculating SMDs for differences in characteristics across multiple strata, the SMD was calculated as the weighted average of the absolute value of the SMD for each pairwise comparison between case-patients and control patients.

§ Specified underlying conditions included any of the specified respiratory conditions; cardiac conditions; immune or oncologic disorders; neurologic conditions; metabolic, genetic, or endocrine disorders; or sickle cell disease.

¶ Includes chronic lung disease, bronchopulmonary dysplasia, cystic fibrosis, assistance required for secretion clearance, reactive airway disease, obstructive sleep apnea, tracheomalacia/laryngomalacia, and congenital airway disorders.

** Includes congenital heart disease, history of cardiac repair (surgery or interventional catheterization), pulmonary hypertension, and congestive heart failure.

†† Data collected on immunosuppressive disorders included primary immunodeficiency (e.g., X-linked agammaglobulinemia, common variable immune deficiency, Wiskott-Aldrich syndrome, hyper immunoglobulin E/Job syndrome, DiGeorge syndrome (22q11 deletion), HIV infection, acquired immune deficiency (e.g., inflammatory bowel disease, juvenile idiopathic arthritis, systemic lupus erythematosus, dermatomyositis, and aplastic anemia or other disorders of bone marrow failure), including receipt of high-dose corticosteroid therapy for any rheumatologic, oncologic, or autoinflammatory disorder.

§§ Includes muscular dystrophy, static encephalopathy, spastic quadriplegia, seizure disorder, neuromuscular weakness, and hydrocephalus.

¶¶ Includes trisomy 21 or or any other chromosomal disorder, mitochondrial disorder, or fatty acid deficit.

*** Date of symptom onset was determined by the onset date reported by the caregiver in the caregiver interview; if caregiver-reported symptom onset date was missing, the median number of days from the date of symptom onset to hospitalization for nonmissing records was subtracted from the date of hospitalization.

††† Analyses of highest level of respiratory support included 756 infants after excluding one case-patient and one control patient who were receiving IMV at baseline and one control patient who was receiving CPAP at baseline with no increased level of respiratory support during their hospitalization.

§§§ A total of 405 patients who required CPAP, BiPAP, or IMV during hospitalization were included in this analysis, including 238 case-patients and 167 control patients. Patients who had received preadmission respiratory support at home who required elevated levels of support after admission included 24 case-patients (five CPAP, three BiPAP, and 16 IMV during hospitalization) and 22 control patients (two CPAP, four BiPAP, and 16 IMV during hospitalization).

¶¶¶ Hospital length of stay was calculable for 755 infants.

**** ICU length of stay was calculable for 758 infants.

nirsevimab receipt was verified through examination of infant immunization records, ascertainment of maternal RSV vaccine receipt might have been incomplete. This could have resulted in misclassification of infants who were protected against RSV as unprotected, and biased the results toward the null, thereby diluting the observed effectiveness of the intervention relative to the true value (if differential misclassification did not occur). Fourth, although timing from dose receipt to symptom onset might impact effectiveness, this investigation was not sufficiently powered to precisely assess duration of protection from nirsevimab. Finally, as an observational investigation, this study is likely subject to residual confounding by unmeasured factors and variables, although the study's effectiveness estimates align with those of previous studies and meta-analyses.

Implications for Public Health Practice

In this large case-control investigation, nirsevimab was protective against RSV-associated ICU admission and acute respiratory failure during the 2024–25 U.S. RSV season. Most children admitted to an ICU for RSV were previously healthy. ACIP recommends that infants be protected against severe RSV through either infant receipt of a long-acting RSV monoclonal antibody (nirsevimab or clesrovimab) or maternal RSV vaccination during pregnancy. These findings add to growing evidence supporting the effectiveness of monoclonal antibody immunization against severe outcomes from RSV infection in infants during their first RSV season and can be used by clinicians and parents to guide use of this prevention product.

TABLE 2. Nirsevimab product effectiveness against respiratory syncytial virus–associated intensive care unit admission and acute respiratory failure — the Overcoming Respiratory Syncytial Virus Network, United States, December 1, 2024–April 15, 2025

Clinical endpoint	Days from nirsevimab dose to symptom onset, median (IQR)	No. who received nirsevimab/Total (%)		Nirsevimab effectiveness, % (95% CI)	
		Case-patients	Control patients	Crude	Adjusted
ICU admission*	52 (32–89)	**62/457 (14)**	**136/302 (45)**	81 (73–87)	80 (70–86)¶
Acute respiratory failure†	50 (32–86)	**30/237 (13)**	**136/302 (45)**	82 (72–89)	83 (74–90)¶
ICU admission, by time from dose to symptom onset					
7–59 days	36 (20–46)	**30/425 (7)**	**84/250 (34)**	85 (76–91)	86 (77–92)**
60–183 days	98 (79–120)	**32/427 (7)**	**52/218 (24)**	74 (58–84)	66 (47–79)**
ICU admission, matched pairs only§	51 (33–86)	**39/226 (17)**	**101/226 (45)**	77 (61–86)	76 (59–86)††

Abbreviations: ICU = intensive care unit; RSV = respiratory syncytial virus.

* The primary analysis included case-patients and control patients who were admitted to an ICU and assessed the relative odds of previous receipt of nirsevimab in RSV-positive case-patients compared with control patients.

† Respiratory failure was defined as requiring treatment with continuous positive airway pressure, bilevel positive airway pressure, or invasive mechanical ventilation, when level of respiratory support received during hospitalization exceeded respiratory support received at baseline. This analysis included case-patients with respiratory failure and all ICU-admitted control patients to reflect the source population of ICU-admitted patients from which acute respiratory failure may arise.

§ This analysis included only case-patients and control patients who were matched on hospital site, age group, date of hospital admission (within 30 days) and excluded any unmatched patients.

¶ This reflects an unconditional multivariable logistic regression model adjusted for age (continuous, in months), biweekly date of hospital admission, the presence of one or more underlying medical condition, social vulnerability index, and U.S. Census Bureau regions. Hospital site was included as a repeated measure.

** Because of the high correlation ($\rho = 0.68$; $p<0.001$) between age (in months) and time (in days) between receipt of nirsevimab dose to symptom onset, age (in months) was removed from these stratified adjusted models.

†† Using conditional multivariable logistic regression, matched analyses were performed on 226 matched pairs to compare results to the primary analysis, to account for potential imbalance on matching variables when including all eligible enrolled infants.

Summary

What is already known about this topic?

Respiratory syncytial virus (RSV) is a leading cause of infant hospitalization and intensive care unit (ICU) admission in the United States. Effectiveness of nirsevimab, a long-acting monoclonal antibody, has been established against RSV-associated lower respiratory tract infection and hospitalization among infants; nirsevimab is currently recommended by CDC to prevent severe RSV-related disease. Data are more limited regarding its effectiveness against RSV infection resulting in ICU admission and respiratory failure.

What is added by this report?

In this multicenter case-control investigation, nirsevimab was 80% effective at preventing RSV-associated ICU admission and 83% effective at preventing acute respiratory failure among infants admitted to an ICU with respiratory symptoms during their first RSV season.

What are the implications for public health practice?

These data support recommendations to use nirsevimab as a prevention strategy to protect infants from severe outcomes from RSV infection.

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Notes from the Field

Expanding Birthing Hospital Enrollment in the Vaccines for Children Program to Increase Infant Immunization Against Respiratory Syncytial Virus — United States, October 2023–March 2025

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Respiratory syncytial virus (RSV), the leading cause of hospitalization among U.S. infants, results in 50,000–80,000 associated hospitalizations and 100–300 deaths among children aged <5 years each year (*1*). In 2023, the Advisory Committee on Immunization Practices (ACIP) recommended two options for preventing severe RSV in infants: maternal RSV vaccination during pregnancy (*2*) or administration of nirsevimab, a long-acting monoclonal antibody to infants (*1*). Nirsevimab is recommended for infants aged <8 months during their first RSV season (October–March in most of the United States); ideally, it should be administered during the birth hospitalization or within the first week of life. In September 2023, ACIP passed a resolution to add nirsevimab to the Vaccines for Children (VFC) Program, a public-private partnership that provides CDC-purchased vaccines to VFC-eligible children (those who are uninsured or underinsured, insured through Medicaid, or who are American Indian or Alaska Native) at no cost. Approximately one half (52.2%) of U.S. children aged 19–35 months are VFC-eligible, and among those, 93.4% are insured by Medicaid (*3*). Medicaid-insured infants have a higher incidence of severe RSV infection than do privately insured infants (*4*). Providers enrolled in the VFC program are able to administer nirsevimab at no cost to eligible children. Enrollment of birthing hospitals in VFC thus has the potential to expand infant immunization against RSV. This report describes enrollment of U.S. birthing hospitals (those with more than one birth during the previous year or at least one registered maternity bed) in the VFC program since the introduction of nirsevimab.

Investigation and Findings

Enrollment of Birthing Hospitals in VFC

Birthing hospitals are well positioned to provide timely access to nirsevimab, perhaps especially to Medicaid-insured infants who are less likely to receive a pediatric checkup within the first week of life than privately insured infants (*5*) and who therefore might miss the recommended window for receiving nirsevimab if it is not administered during the birth hospitalization. Enrolling as a VFC provider allows birthing hospitals to offset the high cost of nirsevimab.*

In 2023, CDC undertook efforts to facilitate birthing hospital enrollment in the VFC program. In April 2023, CDC held focus groups with 11 U.S. jurisdictions on facilitators and barriers to enrolling birthing hospitals in VFC. Many jurisdictions reported challenges in developing relationships with birthing hospitals, a need for capacity building within jurisdictions, and a need for flexible VFC policies. In response, to streamline administrative processes for providers, CDC updated VFC policies to facilitate nirsevimab ordering and inventory management by VFC providers and encouraged birthing hospitals to implement VFC policies reducing the required number of stocked immunization products to only those recommended within 1 week of birth (i.e., hepatitis B vaccine and nirsevimab), rather than all recommended childhood immunizations.

Beginning in August 2023, CDC partnered with professional organizations and health departments† to support birthing hospital enrollment in VFC through development and dissemination of educational and training resources and establishment of learning collaboratives that included facilitated discussions for sharing lessons learned and promising practices. U.S. birthing hospital enrollment in VFC and doses of nirsevimab purchased by these facilities were estimated across the two RSV seasons following the recommendation for nirsevimab for infants (October 1, 2023–March 31, 2024 [2023–24] and October 1, 2024–March 31, 2025 [2024–25]).

Identification of Birthing Hospitals Enrolled in VFC

A list of U.S. birthing hospitals was created using the 2022 American Hospital Association Annual Survey and the 2024 Maternity Practices in Infant Nutrition and Care survey to match birthing hospitals to enrolled VFC

* Before 2023, hepatitis B vaccine, a low-cost immunization, was the only immunization recommended at birth; thus, birthing hospitals had less financial incentive to enroll in VFC. Whereas hepatitis B vaccine costs approximately $15 per dose, nirsevimab costs approximately $415 per dose in the VFC program (CDC Vaccine Price List as of April 1, 2025). Clesrovimab, a new RSV monoclonal antibody product, was recommended by ACIP in June 2025; VFC pricing information is not yet available.

† American Hospital Association, Association of Immunization Managers, America's Health Insurance Plans, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, American College of Nurse-Midwives, Centers for Medicare & Medicaid Services, and Perinatal Quality Collaboratives.

Summary

What is already known about this topic?

Nirsevimab, a long-acting monoclonal antibody that protects infants against respiratory syncytial virus (RSV), should be administered within 1 week after birth to infants not protected by maternal RSV vaccination. The Vaccines for Children (VFC) program provides CDC-purchased immunizations, including nirsevimab, to eligible children at no cost.

What is added by this report?

A CDC effort with professional organizations and health departments to enroll birthing hospitals in VFC was associated with an increase in enrolled birthing hospitals from 763 (27.1% of 2,817 facilities) at the beginning of the 2023–24 RSV season to 1,021 (36.2%) by the end of the 2024–25 RSV season. The number of nirsevimab doses ordered approximately doubled.

What are the implications for public health practice?

Continued efforts to increase birthing hospital VFC enrollment can support expanded access to RSV immunization.

hospitals[§]; jurisdictions[¶] reviewed data for accuracy. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[**]

Birthing Hospital Enrollment During the 2023–24 and 2024–25 RSV Seasons

Among all 2,817 U.S. birthing hospitals, the number enrolled in VFC increased from 763 (27.1%) at the beginning of the 2023–24 RSV season to 1,021 (36.2%) by the end of the 2024–25 season (Table), covering approximately 41.8% of U.S. births in hospitals. The largest increase occurred among jurisdictions in the U.S. Census Bureau Northeast Region, from 158 (44.4%) birthing hospitals to 266 (74.5%). During the 2023–24 season, birthing hospitals ordered 46,738 VFC doses of nirsevimab; during the 2024–25 season, the number of doses ordered more than doubled, to 102,057.

[§] String matching (i.e., searching for a smaller text string within a larger string) using Python (version 3.12; Python Software Foundation) connected birthing hospitals to enrolled VFC providers using hospital names, contact information, and locations. VFC providers were matched to the same list of birthing hospitals at both time points; the total number of birthing hospitals did not change meaningfully from the beginning of the 2023–24 RSV season to the end of the 2024–25 RSV season.

[¶] Birthing hospital VFC enrollment is counted by the 61 jurisdictions with VFC funding: all 50 states, the District of Columbia, five U.S. cities (Chicago, Houston, New York City, Philadelphia, and San Antonio), and five U.S. territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands). VFC is updating its data system to better capture services offered and birthing hospital status.

[**] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

TABLE. Summary of change in birthing hospital enrollment in the Vaccines for Children program across two respiratory syncytial virus seasons — United States, October 1, 2023–March 31, 2024, and October 1, 2024–March 31, 2025

Jurisdiction	Birthing hospitals*		
	Total no. at the end of the 2024–25 RSV season	No. (% of total) enrolled in VFC	
		Beginning of the 2023–24 RSV season	End of the 2024–25 RSV season
United States	**2,817**	**763 (27.1)**	**1,021 (36.2)**
State or city			
Alabama	**49**	7 (14.3)	10 (20.4)
Alaska	**19**	10 (52.6)	11 (57.9)
Arizona	**48**	24 (50.0)	24 (50.0)
Arkansas	**35**	18 (50.0)	20 (57.1)
California	**226**	34 (15.0)	54 (23.9)
Colorado	**63**	6 (9.5)	22 (34.9)
Connecticut	**23**	18 (78.3)	23 (100.0)
Delaware[†]	**7**	2 (28.6)	2 (28.6)
District of Columbia	**6**	0 (—)	1 (16.7)
Florida	**119**	8 (6.7)	13 (10.9)
Georgia	**77**	5 (6.4)	4 (5.2)
Hawaii	**12**	11 (91.7)	10 (83.3)
Idaho	**31**	20 (64.5)	23 (74.2)
Illinois	**74**	2 (2.7)	6 (8.1)
Chicago	**15**	2 (13.3)	4 (26.7)
Indiana	**72**	16 (22.2)	27 (37.5)
Iowa	**53**	21 (39.6)	23 (43.4)
Kansas[†]	**64**	0 (—)	1 (1.6)
Kentucky	**49**	32 (65.3)	34 (69.4)
Louisiana	**52**	14 (26.9)	17 (32.7)
Maine	**19**	9 (45.0)	19 (100.0)
Maryland	**33**	2 (6.1)	6 (18.2)
Massachusetts	**40**	19 (47.5)	31 (77.5)
Michigan	**76**	58 (76.3)	64 (84.2)
Minnesota	**89**	10 (11.2)	11 (12.4)
Mississippi	**46**	17 (37.0)	19 (41.3)
Missouri	**63**	4 (6.3)	5 (7.9)
Montana	**25**	24 (96.0)	23 (92.0)
Nebraska	**55**	0 (—)	0 (—)
Nevada	**20**	8 (38.1)	8 (40.0)
New Hampshire	**15**	7 (46.7)	8 (53.3)
New Jersey	**50**	5 (10.0)	14 (28.0)
New Mexico	**29**	11 (37.9)	11 (37.9)
New York	**78**	2 (2.6)	54 (69.2)
New York City	**38**	26 (68.4)	38 (100.0)
North Carolina	**83**	41 (49.4)	44 (53.0)
North Dakota	**13**	12 (92.3)	5 (38.5)
Ohio	**91**	1 (1.1)	1 (1.1)
Oklahoma	**45**	14 (31.1)	17 (37.8)
Oregon	**47**	2 (4.3)	1 (2.1)
Pennsylvania	**72**	63 (84.0)	60 (83.3)
Philadelphia	**6**	0 (—)	5 (83.3)
Rhode Island	**5**	5 (100.0)	5 (100.0)
South Carolina	**45**	13 (28.9)	14 (31.1)
South Dakota	**23**	13 (54.2)	12 (52.2)
Tennessee	**64**	7 (10.9)	7 (10.9)
Texas	**211**	53 (25.1)	65 (30.8)
Houston	**13**	1 (7.7)	7 (53.8)
San Antonio	**7**	4 (57.1)	4 (57.1)
Utah	**46**	5 (10.9)	24 (52.2)

See table footnotes on the next page.

TABLE. (*Continued*) Summary of change in birthing hospital enrollment in the Vaccines for Children program across two respiratory syncytial virus seasons — United States, October 1, 2023–March 31, 2024, and October 1, 2024–March 31, 2025

Jurisdiction	Birthing hospitals*		
	Total no. at the end of the 2024–25 RSV season	No. (% of total) enrolled in VFC	
		Beginning of the 2023–24 RSV season	End of the 2024–25 RSV season
Vermont	**11**	4 (36.4)	9 (81.8)
Virginia	**58**	7 (11.9)	14 (24.1)
Washington	**54**	23 (42.6)	39 (72.2)
West Virginia	**21**	2 (9.5)	3 (14.3)
Wisconsin	**81**	15 (18.5)	19 (23.5)
Wyoming	**17**	2 (11.1)	1 (5.9)
U.S. Census Bureau region§			
Northeast	**357**	158 (44.3)	266 (74.5)
Midwest	**769**	154 (20.0)	178 (23.1)
South	**1,020**	247 (24.2)	301 (29.5)
West	**637**	180 (28.3)	251 (39.4)
Territory			
American Samoa	**1**	1 (100.0)	1 (100.0)
Guam	**2**	0 (—)	0 (—)
Northern Mariana Islands	**1**	0 (—)	0 (—)
Puerto Rico	**28**	21 (65.6)	22 (78.6)
U.S. Virgin Islands	**2**	2 (100.0)	2 (100.0)

Abbreviations: RSV = respiratory syncytial virus; VFC = Vaccines for Children.
* The total number of known birthing hospitals on March 31, 2025, was used as the denominator for both time points. The denominator did not change meaningfully between seasons.
† Jurisdiction did not provide additional feedback on its birthing hospital enrollment data.
§ U.S. Census Bureau regions and divisions of the United States excludes U.S. territories.

Preliminary Conclusions and Actions

Efforts to enroll birthing hospitals in VFC depend on jurisdiction staff members who administer the VFC program and understand its requirements. Starting July 1, 2025, as a condition of funding support for VFC, CDC requires that each jurisdiction enroll ≥30% of its birthing hospitals in VFC; as of March 31, 2025, 39 of 61 (63.9%) jurisdictions have met this target. Clesrovimab, a new RSV monoclonal antibody, was recommended by ACIP in June 2025 and will be available as an alternative to nirsevimab through the VFC program. CDC continues to partner with jurisdictions and professional organizations to address barriers to VFC enrollment for birthing hospitals and share best practices. Birthing hospital VFC enrollment can support expanded access to RSV immunization among infants at highest risk for severe disease.

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