National Center for Immunization and Respiratory Diseases



Effectiveness and impact of RSV prevention products in infants during the 2024–2025 RSV season

Coronavirus and Other Respiratory Viruses Division

June 25, 2025



Agenda

Product Effectiveness (PE)

- Summary of CDC systems used to evaluate PE
- Effectiveness of nirsevimab and maternal RSV vaccine during the 2024–2025 RSV season in the U.S.

RSV Hospitalization Rates and Product Impact

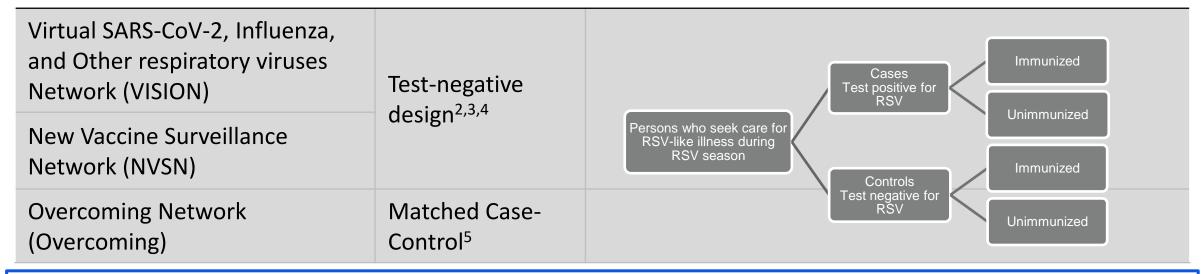
- Summary of CDC systems used for monitoring RSV hospitalization rates
- Impact of nirsevimab and maternal RSV vaccine during the 2024–2025 RSV season in the U.S.





Study designs for observational PE studies

Observational VE studies Methods¹



Effectiveness = 1 – (odds ratio) x 100% Odds ratio = $\frac{Odds \ of \ immunization_{cases}}{Odds \ of \ immunization_{controls}}$

References for study design methods with relevant examples

¹Roper L, et. al. A framework for monitoring RSV prevention product effectiveness in the United States. *Vaccine* 2025;45:126633

² Chua H, et. al. The Use of Test-negative Controls to Monitor Vaccine Effectiveness: A Systematic Review of Methodology. *Epidemiology* 2020;31:43–64.

³ Moline HL, et al. Respiratory Syncytial Virus Disease Burden and Nirsevimab Effectiveness in Young Children From 2023-2024. JAMA Pediatr 2025;179:179-187.

⁴ Payne AB, et. al. Respiratory syncytial virus (RSV) vaccine effectiveness against RSV-associated hospitalisations and emergency department encounters among adults aged 60 years and older in the USA, October, 2023, to March, 2024: a test-negative design analysis. *Lancet* 2024;404:1547-1559.

⁵ Zambrano LD, et. al. Durability of Original Monovalent mRNA Vaccine Effectiveness Against COVID-19 Omicron-Associated Hospitalization in Children and Adolescents - United States, 2021-2023. MMWR 2024;73:330-338

CDC networks used to assess RSV product effectiveness in infants and children

VISION



Multi-site network of electronic health records (EHRs)

160 emergency department (ED) and 131 hospitals in 6 states

Children visiting a participating ED or hospital with RSV-like illness are eligible for inclusion

NVSN



Active surveillance for acute respiratory illness (ARI) in children

7 academic pediatric health systems in 7 states

Children hospitalized or visiting the ED for ARI are eligible for enrollment

Overcoming



Active surveillance for pediatric RSV with case-control design

26 pediatric intensive care units (ICUs) in 23 states

Children in a participating ICU with ARI are eligible for inclusion.

Summary of CDC networks used to assess RSV product effectiveness in children

	VISION	NVSN	Overcoming
Infant and maternal immunization data	Electronic health records, state and city registries, and claims data (subset of sites)	Electronic health records, state registries, out-of-network provider records, parent report	Electronic health records, state registries, provider records, parent report
Analytic study period	October 2024–March 2025	October 2024–March 2025	December 2024–April 2025
Cases	RSV-like illness (RLI) with clinical positive RSV antigen or nucleic acid amplification test (NAAT)	Acute respiratory illness (ARI) with RSV detected on systematic NAAT testing	ARI with clinical positive RSV antigen or NAAT
Controls	RSV-like illness with negative RSV NAAT	Acute respiratory illness (ARI) with no RSV detected on systematic NAAT testing	ARI with negative NAAT; Case-matched on site, age, and date of hospitalization

Summary of VISION, NVSN, and Overcoming analytic methods used to assess product effectiveness in children

	VISION	NVSN	Overcoming			
Nirsevimab analytic population	Infants <8 months as of October 1, 2024, or born after October 1, 2024 with no maternal RSV vaccination receipt					
Maternal vaccine analytic population	Infants born on or after September 14, 2024 who did not receive nirsevimab	Infants <6 months of age during the study period who did not receive nirsevimab	Not assessed			
Analysis	Multivariable logistic regression models, adjusting for site, age in months, calendar date, race and ethnicity, and sex. Models adjusting for underlying medical conditions did not meaningfully change estimates.	Multivariable logistic regression models, adjusting for site, age in months, and month of enrollment. Nirsevimab analysis adjusted for presence of ≥1 high-risk medical condition for severe RSV disease; maternal RSV analysis adjusted for race/ethnicity and insurance status.	Multivariable logistic regression models, adjusting for site, age in months, timing of enrollment, presence of ≥1 underlying medical condition, and social vulnerability index.			
Outcomes assessed	Hospitalization, emergency department (ED) visit, intensive care unit (ICU) admission	Hospitalization, ED visit, ICU admission	ICU admission			

Nirsevimab effectiveness during the 2024-2025 RSV season in the United States



Nirsevimab product effectiveness (PE) against RSV-associated emergency department (ED) visits among infants in their first RSV season, VISION & NVSN, 2024–2025

SYSTEM Nirsevimab Status	RSV-positive encounters N (Col %)	RSV-negative encounters N (Col %)	Median days since dose (IQR)		djusted (95% CI)	
VISION	1225	2833				
No nirsevimab doses	966 (79)	1799 (64)	Not Applicable	Reference		
Nirsevimab, ≥7 days prior*	259 (21)	1034 (36)	68 (37-102)	63 (56-69)†		
NVSN	107	381				
No nirsevimab doses	92 (86)	214 (56)	Not Applicable	Reference		
Nirsevimab, ≥7 days prior [‡]	15 (14)	167 (44)	68 (41-103)	76 (55-87)§	-	•
				C) 50 Product Effectiveness (%)	10

Nirsevimab was effective against RSV-associated ED visits.

IQR: Interquartile Range | CI: Confidence Interval

^{*}VISION analysis included children who received nirsevimab ≥7 days prior to encounter.

[†]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, calendar date, race and ethnicity, and sex.

[‡]NVSN analysis included children who received nirsevimab ≥7 days prior to symptom onset.

[§]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, month of enrollment, and presence of >1 high-risk medical condition for severe RSV disease.

Nirsevimab product effectiveness (PE) against RSV-associated <u>hospitalization</u> among infants in their first RSV season, VISION & NVSN, 2024–2025

SYSTEM Nirsevimab Status	RSV-positive encounters N (Col %)	RSV-negative encounters N (Col %)	Median days since dose (IQR)		Adjusted E (95% (
VISION	286	318							
No nirsevimab doses	233 (81)	174 (55)	Not Applicable	Reference					
Nirsevimab, ≥7 days prior*	53 (19)	144 (45)	61 (27-102)	79 (67-87)†			-	•••	
NVSN	294	378							
No nirsevimab doses	263 (89)	229 (61)	Not Applicable	Reference					
Nirsevimab, ≥7 days prior [‡]	31 (11)	149 (39)	52 (27-87)	82 (71-88)§					
					0 20 Pro	40 duct Eff	60 ectivene	80 ss (%)	10

Nirsevimab was effective against RSV-associated hospitalization.

^{*}VISION analysis included children who received nirsevimab ≥7 days prior to encounter.

[†]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, calendar date, race and ethnicity, and sex.

[‡]NVSN analysis included children who received nirsevimab ≥7 days prior to symptom onset.

[§]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, month of enrollment, and presence of >1 high-risk medical condition for severe RSV disease.

Nirsevimab product effectiveness (PE) against RSV-associated intensive care unit (ICU) admission among infants in their first RSV season, VISION, NVSN & **Overcoming, 2024–2025**

SYSTEM Nirsevimab Status	RSV-positive encounters N (Col %)	RSV-negative encounters N (Col %)	Median days since dose (IQR)		Adjusted E (95% C	I)		
VISION	56	318	, ,					
No nirsevimab doses	48 (86)	174 (55)	Not Applicable	Reference	1			
Nirsevimab, ≥7 days prior*	8 (14)	144 (45)	56 (25-97)	82 (57-93)†	1 1 1	_	-	-
NVSN	73	71						
No nirsevimab doses	67 (92)	40 (56)	Not Applicable	Reference	1			
Nirsevimab, ≥7 days prior [‡]	6 (8)	31 (44)	52 (24-84)	88 (63-96)§		-		—
Overcoming	409	263						
No nirsevimab doses	354 (87)	146 (56)	Not Applicable	Reference	I I			
Nirsevimab, ≥7 days prior*	55 (13) [°]	117 (44)	50 (32-86)	80 (73-85)¶			1-0-1	
						40 60 uct Effectivene	80 ess (%)	10

Nirsevimab was effective against RSV-associated ICU admission.

¶Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for age in months, timing of admission, census region, presence of ≥1 underlying medical condition, and social vulnerability index. Hospital site included as a repeated measure. The analysis was not limited to matched pairs. 11

^{*}Analysis included children who received nirsevimab ≥7 days prior to encounter.

[†]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, calendar date, race and ethnicity, and sex. RSV-negative encounters were those among children hospitalized for RSV-like illness and not limited to children admitted to the ICU.

[‡]NVSN analysis included children who received nirsevimab ≥7 days prior to symptom onset.

[§]Product effectiveness (PE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, month of enrollment, and presence of >1 high-risk medical condition for severe RSV disease.



Maternal vaccine effectiveness (VE) against RSV-associated <u>emergency</u> <u>department (ED) visits</u> among infants in their first RSV season, VISION, 2024–2025

SYSTEM Nirsevimab Status	RSV- positive encounters N (Col %)	RSV-negative encounters N (Col %)	Median days since birth (IQR)	Median days since dose (IQR)		djusted (95% CI)	
VISION	333	660					
No maternal vaccine	262 (79)	428 (65)	Not Applicable	Not Applicable	Reference	-	
Maternal vaccine*	71 (21)	232 (35)	53 (31-90)	85 (65-110)	54 (35-67)†	20 40 60 Vaccine Effectiveness	80 10 s (%)

Maternal RSV vaccine was effective against RSV-associated ED visits in infants.

IQR: Interquartile Range | CI: Confidence Interval

^{*}VISION analysis included children who were born ≥14 days after maternal RSV vaccine dose.

[†]Vaccine effectiveness (VE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, calendar date, race and ethnicity, and sex.

Maternal vaccine effectiveness (VE) against RSV-associated <u>hospitalization</u> among infants in their first RSV season, VISION & NVSN, 2024–2025

SYSTEM Vaccination Status	RSV-positive encounters N (Col %)	RSV-negative encounters N (Col %)	Median days since birth (IQR)	Median days since dose (IQR)		justed 95% CI)
VISION	134	122				
No maternal vaccine	109 (81)	77 (63)	Not Applicable	Not Applicable	Reference	
Maternal vaccine*	25 (19)	45 (37)	35 (17-69)	73 (52-111)	79 (55-90)†	
NVSN	108	213				
No maternal vaccine	89 (82)	142 (67)	Not Applicable	Not Applicable	Reference	
Maternal vaccine‡	19 (18)	71 (33)	32 (17-58)	71 (50-103)	70 (28-88)§	-
					C	20 40 60 80 10 Vaccine Effectivness (%)

Maternal RSV vaccine was effective against RSV-associated hospitalization in infants.

^{*}VISION analysis included children who were born ≥14 days after maternal RSV vaccine dose.

[†]Vaccine effectiveness (VE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, calendar date, race and ethnicity, and sex. ‡NVSN analysis included children who born ≥14 days after maternal RSV vaccine dose

[§]Vaccine effectiveness (VE) calculated as (1-adjusted odds ratio)*100, with adjusted odds ratio estimated using multivariable logistic regression model, adjusting for site, age in months, month of enrollment, race/ethnicity, and health insurance status.

Limitations of product effectiveness analyses

- These surveillance systems have different enrollment methodologies and source populations and may not be directly comparable.
- Residual confounding was possible
- Misclassification of RSV immunization status was possible, although all systems used multiple sources to verify immunization status

VISION:

- Cases may have sought care for something other than RSV
- All RSV testing was clinician-directed
- EHR data may not fully capture all underlying medical conditions, which may be associated with likelihood of immunization and risk of severe RSV disease

NVSN:

- May not be nationally representative
- Cases may have sought care for something other than RSV

Overcoming Network:

- Enrollment began after the RSV season started
- All RSV testing was clinician-directed



Summary of RSV prevention product effectiveness (PE) among infants in their first RSV season, 2024–2025

Outcome	Product	CDC Network	Product Ef	ficacy*/Effectiveness (95% CI)
		VISION	63 (56-69)	⊢
RSV-associated <u>ED visit</u>	Nirsevimab	NVSN	76 (55-87)	———
		Clinical Trial	Not Applicable	
	Maternal Vaccine	VISION	54 (35-67)	———
	Maternal vaccine	Clinical Trial	Not Applicable	
		VISION	79 (67-87)	⊢
	Nirsevimab*	NVSN	82 (71-88)	
		Clinical Trial	81 (62-90)	
RSV-associated <u>hospitalization</u>		VISION	79 (55-90)	⊢
	Maternal Vaccine†	NVSN	70 (28-88)	———
		Clinical Trial	57 (15-80)	· · · · · · · · · · · · · · · · · · ·
RSV-associated <u>Intensive Care</u> <u>Unit (ICU) admission</u>		VISION	82 (57-93)	· • • • • • • • • • • • • • • • • • • •
	NP or a facility	NVSN	88 (63-96)	· •
	Nirsevimab*	Overcoming	80 (73-85)	⊢
		Clinical Trial	90 (16-99)	•

^{*}Jones et al. MMWR 2023. Available: https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm †Kampmann et al. NEJM 2023. Available: https://www.nejm.org/doi/full/10.1056/NEJMoa2216480

Product Effectiveness Conclusions

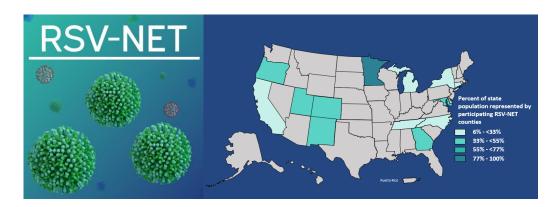
- Nirsevimab was effective against RSV-associated emergency department (ED) encounters, hospitalization, and critical illness among infants in their first RSV season during the 2024–2025 RSV season in the United States.
- Maternal vaccination was effective against RSVassociated ED encounters and hospitalization during the 2024–2025 RSV season in the United States.
- Ongoing monitoring of post-licensure nirsevimab and maternal RSV vaccine effectiveness will be necessary to assess additional outcomes.





Analyzed data from two active, population-based U.S. surveillance systems that monitor laboratory-confirmed RSV-associated hospitalizations

RSV-NET



RESP-NET: Respiratory Virus Hospitalization Surveillance Network

- RSV-NET, FluSurv-NET, COVID-NET
- Patients of any age from >300 hospitals, 161 counties in 13 states
- https://www.cdc.gov/rsv/php/surveillance/rsv-net.html

NVSN



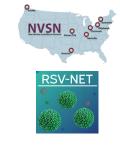
NVSN: New Vaccine Surveillance Network

- Children <18 years old hospitalized with acute respiratory illness at 7 academic pediatric health systems in 7 states
- https://www.cdc.gov/nvsn/php/about/index.html

- Ecological analysis that compared RSV-associated hospitalizations and rates between RSV seasons before and after RSV prevention product introduction
 - Pre-pandemic, before product introduction
 - RSV-NET: 2018–19, 2019–20
 - NVSN: 2017–19, 2018–19, 2019–20
 - After product introduction
 - 2024–25, 2nd year of product availability
- Excluded RSV seasons
 - 2020-21, 2021-22, and 2022-23 seasons impacted by COVID-19 pandemic
 - 2023-24, 1st year of product availability
 - Low product availability and uptake



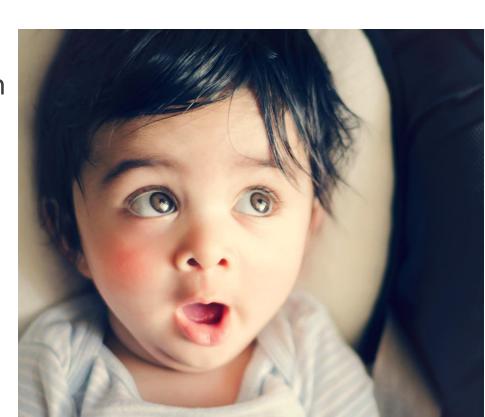
- Compared adjusted RSV-associated hospitalization and ICU admission rates*
 before and after RSV prevention product introduction
 - Weekly (RSV-NET) and monthly (NVSN) hospitalization rates during 2024–25 versus same periods in prior seasons
 - Cumulative 2024–25 hospitalization rates compared to pooled rates from prior seasons
 - Hospitalization rates (RSV-NET and NVSN)
 - ICU admission rates (RSV-NET)
 - Estimated rate ratios (RR) comparing cumulative rates
 - Estimated relative rate reductions (RRR): (1-RR) x 100



 Assessed changes in rates before and after RSV prevention product introduction for three age groups with different RSV prevention options

NVSN O

- Assessed changes in rates before and after RSV prevention product introduction for three age groups with different RSV prevention options
 - Infants aged 0–7 months
 - Eligible for nirsevimab
 - Potentially protected by maternal RSV vaccination



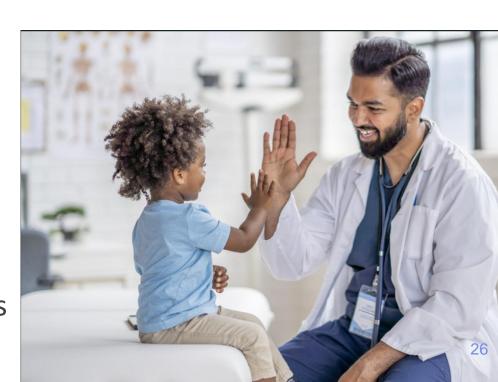
NVSN ... Q

- Assessed changes in rates before and after RSV prevention product introduction for three age groups with different RSV prevention options
 - Infants aged 0–7 months
 - Eligible for nirsevimab
 - Potentially protected by maternal RSV vaccine
 - Children aged 8–19 months
 - Small number may have been eligible for nirsevimab based on risk conditions



NVSN PORT

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 - Children aged 20–59 months
 - Age group ineligible for RSV prevention products





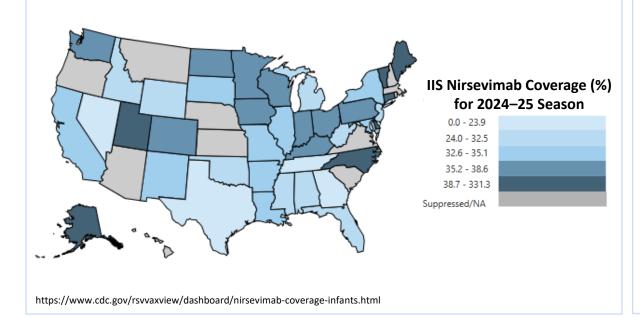
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 - Children aged 8–19 months
 - Small number may have been eligible for nirsevimab based on risk conditions
 - Children aged 20–59 months
 - Age group ineligible for RSV prevention products

Comparison populations
mostly ineligible for RSV
prevention products.
Included to detect
hospitalization rate
changes unrelated to
RSV product uptake.

During 2024–25, RSV prevention products were available before RSV season onset in most states, with product coverage that increased over time.

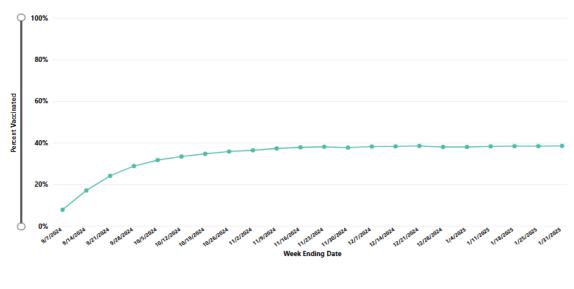
Nirsevimab

 21% to 48% coverage among infants aged 0–7 months across 36 reporting jurisdictions as of March 2025



Maternal RSV Vaccine

 39% of eligible* pregnant women aged 18–49 years received RSV vaccine as of January 2025



*includes pregnant women who reached at least 32 weeks' gestation as of September 1, 2024 https://www.cdc.gov/rsvvaxview/dashboard/pregnant-women-coverage.html

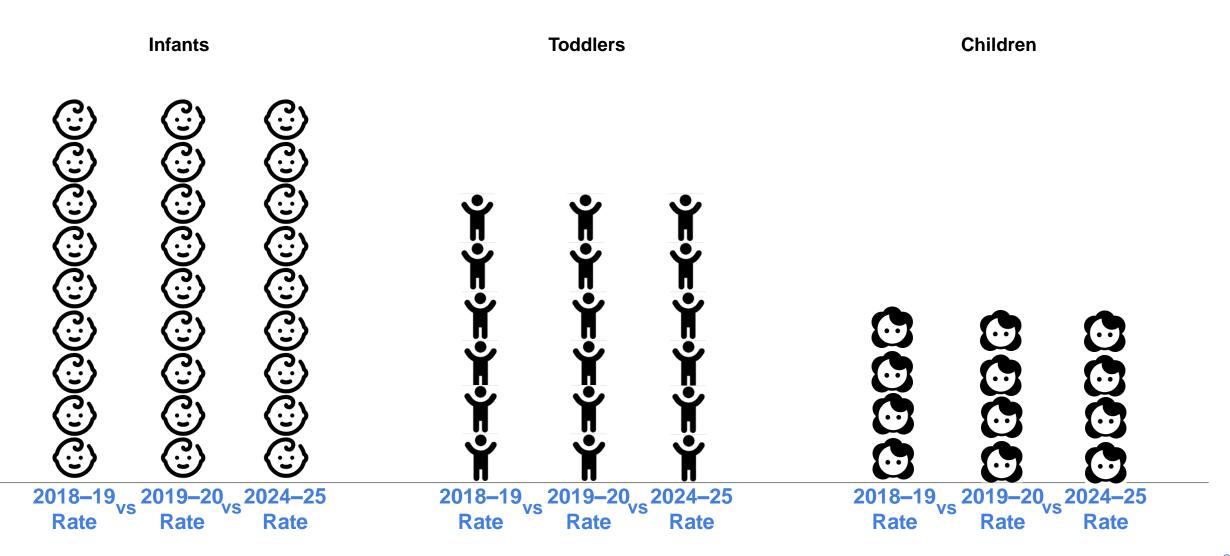
For an ecological analysis, RSV-associated hospitalization rates can be assessed in three age groups across different RSV seasons



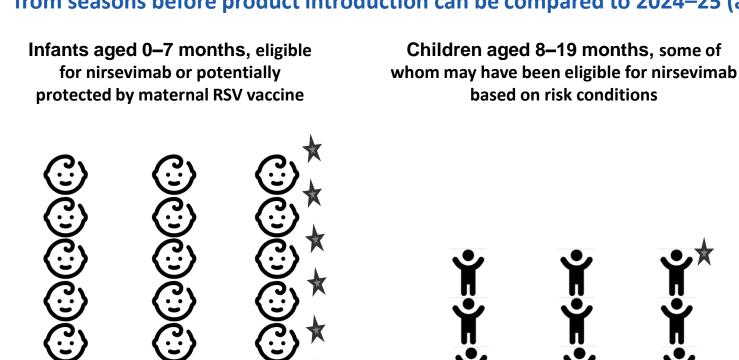




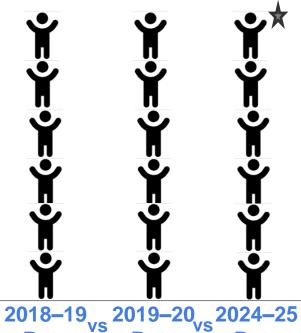
In the absence of new RSV prevention products, RSV-associated hospitalization rates would be expected to vary by age group, but remain consistent within each age group across seasons.



Because new RSV prevention products are only recommended for some children, RSV-associated hospitalization rates from seasons before product introduction can be compared to 2024–25 (after product introduction), by age group



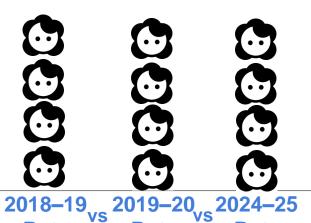
Children aged 20–59 months, age group ineligible for RSV prevention products



Rate

Rate

Rate



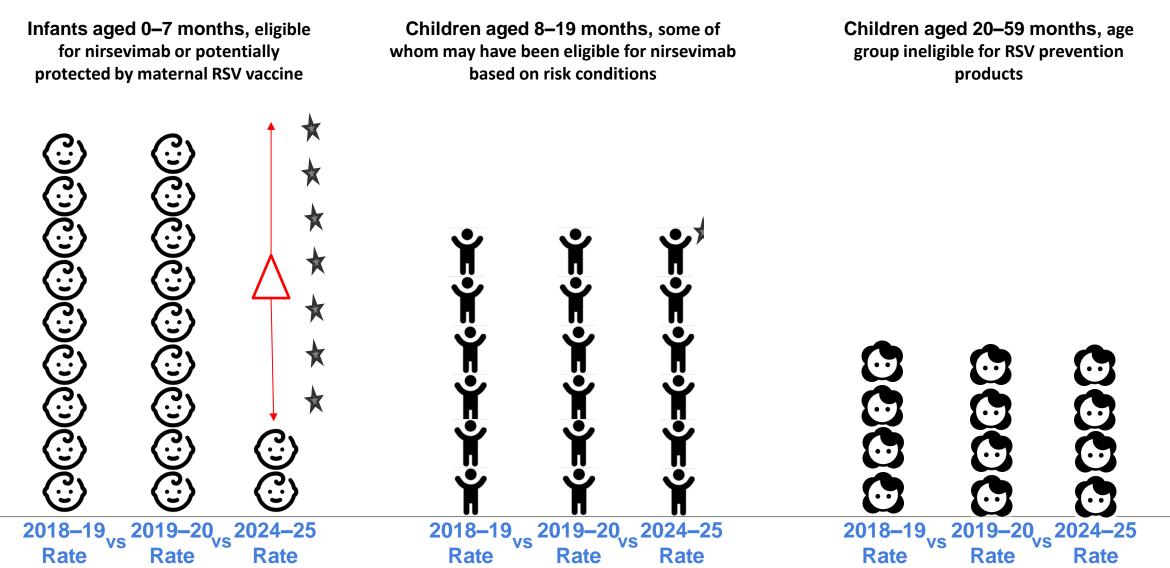
Rate

Rate

31

Rate

The analysis can assess whether RSV-associated hospitalization rates in 2024–25 compared to prior seasons changed more for infants aged 0–7 months than for children aged 8–19 and 20–59 months





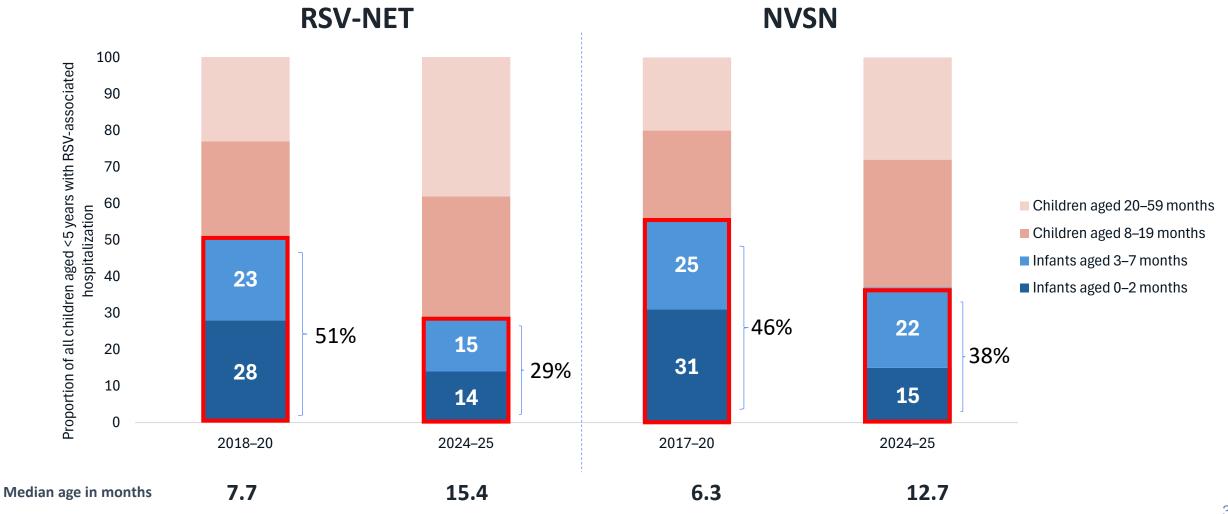


Combined, RSV-NET and NVSN identified >20,000 children aged <5 years with RSV-associated hospitalizations

	RSV-NET		NV		
	2018–20	2024–25	2017–20	2024–25	Total*
Hospitalizations	9,717	7,003	3,119	1,001	20,840
Intensive Care Unit (ICU) Admissions	2,332	251	671	200	3,454

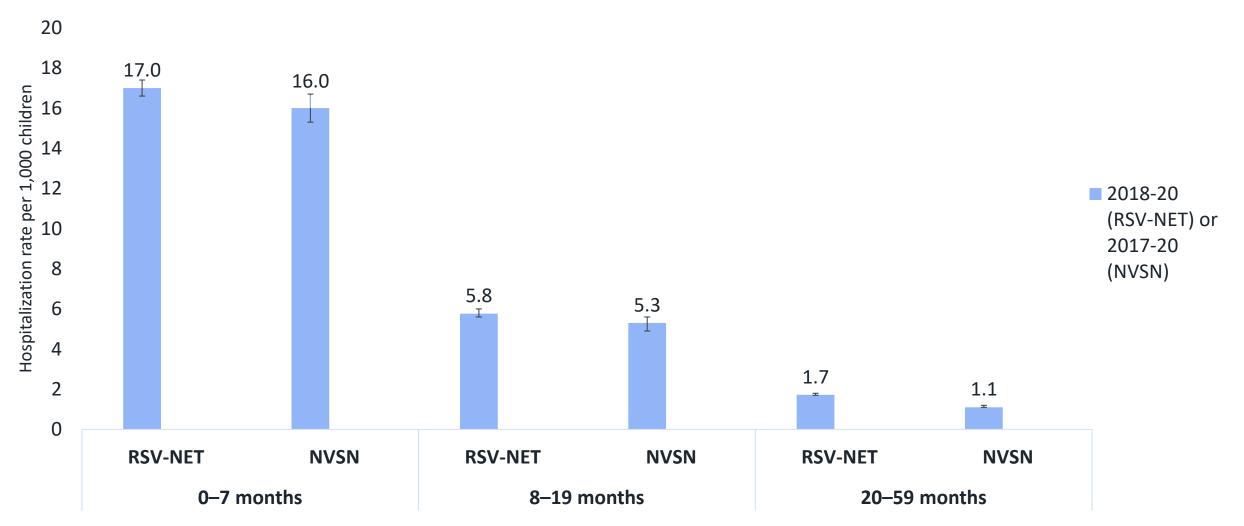
^{*}Children at two surveillance sites for NVSN and RSV-NET could be documented in both systems. In 2018–20, 252 hospitalized children were enrolled in both systems, with 54 also having an ICU admission. During 2024–25, 76 children were enrolled in both systems with 25 having an ICU admission.

Proportions of children aged <5 years with an RSV-associated hospitalization who were aged 0–7 months decreased, and median age increased, in 2024–25 compared to seasons before product introduction



Cumulative adjusted RSV-associated hospitalization rates in 2024–25 were compared to seasons before product introduction by age group

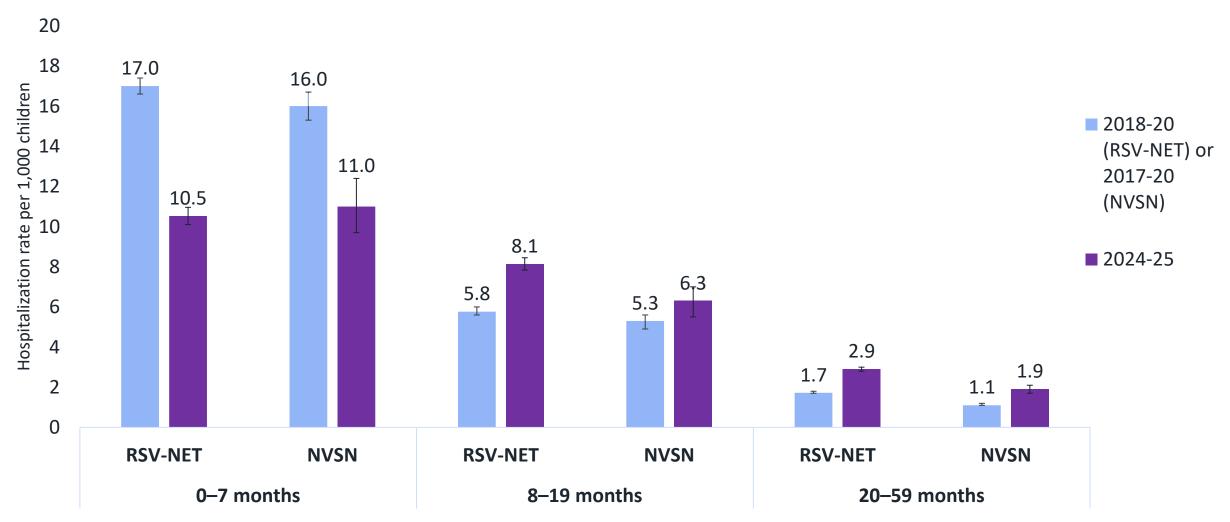




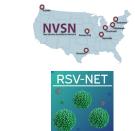
Bar labels indicate cumulative laboratory-confirmed RSV-associated hospitalizations per 1,000 children as of April 30 (RSV-NET) or March 31 (NVSN) each season. Rates use U.S. population denominators. RSV-NET rates are adjusted to account for RSV underdetection because of testing practices and test sensitivity. NVSN rates are adjusted to account for weeks with <7 days of surveillance, the proportion of eligible children not enrolled, sensitivity of respiratory syncytial virus reverse-transcription polymerase chain reaction testing compared to serology, and each site's estimated market share of acute respiratory illness hospitalizations by age. Error bars denote 95% confidence intervals (95% CI).

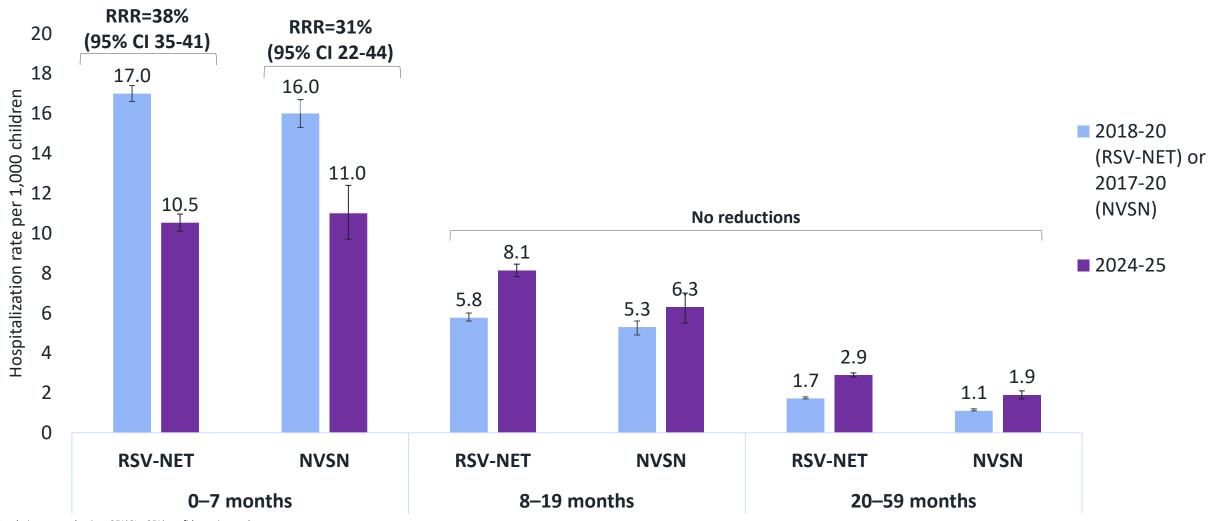
Cumulative adjusted RSV-associated hospitalization rates in 2024–25 were compared to seasons before product introduction by age group





Among infants aged <u>0–7 months</u> (eligible for protection by nirsevimab or maternal vaccine) RSV-associated hospitalization rates were <u>reduced by 38% and 31%</u> in 2024–25 compared to seasons before product introduction

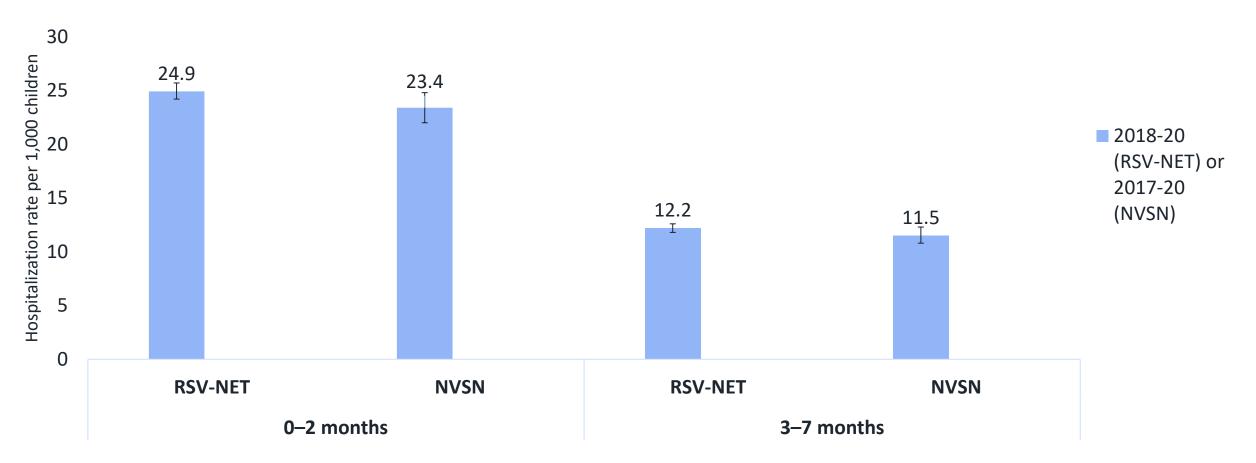




RRR=relative rate reduction, 95%CI = 95% confidence interval

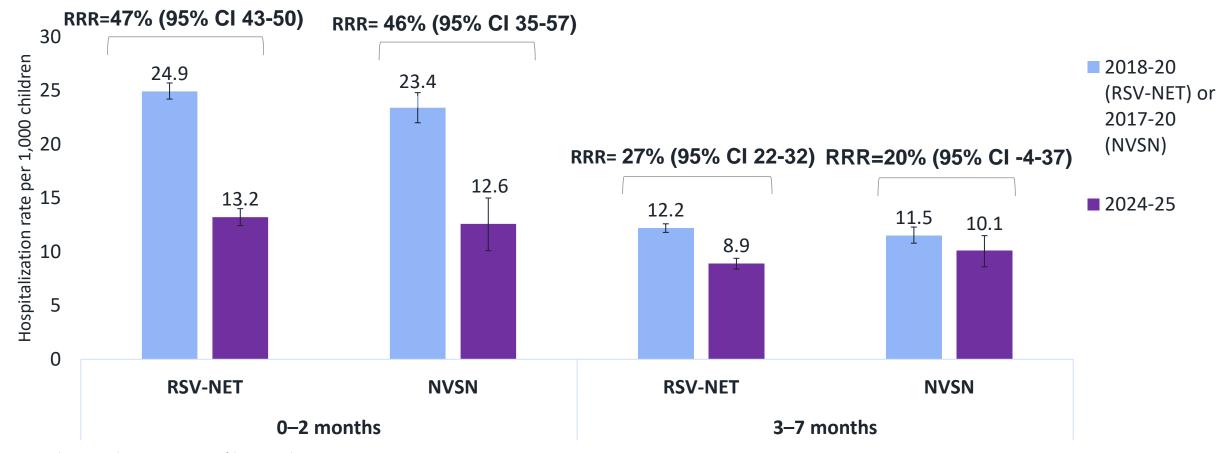
Cumulative adjusted RSV-associated hospitalization rates in 2024–25 were compared to prior seasons among subgroups of infants aged 0–2 and 3–7 months





RSV-associated hospitalization rates were reduced by 47% in RSV-NET and 46% in NVSN among infants aged 0–2 months in 2024–25 compared to seasons before product introduction





RRR=relative rate reduction, 95%CI = 95% confidence interval



RSV Prevention Product Impact Conclusions

- Two U.S. population-based surveillance networks demonstrated reductions in RSVassociated hospitalization rates during 2024–25 among infants eligible for RSV prevention product protection
 - 38% (RSV-NET) and 31% (NVSN) reductions in
 2024–25 compared to RSV seasons before product introduction among infants aged 0–7 months



Conclusions

- Reductions in RSV-associated hospitalization were greatest among infants aged 0–2 months born just before or during the RSV season
 - 47% (RSV-NET) and 46% (NVSN) reductions in 2024–25
 - Group at highest risk of hospitalization
 - Underscores importance of protection through maternal vaccination during pregnancy or nirsevimab in first week of life
- Ongoing monitoring of RSV disease trends—including severity and age distribution—is critical to assess sustained impact of RSV prevention products



Acknowledgements

- CDC National Center for Immunizations and Respiratory Diseases (NCIRD)
- CDC-funded partners
 - VISION
 - New Vaccine Surveillance Network (NVSN)
 - Overcoming Network
 - RSV-NET

For more information, contact CDC 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

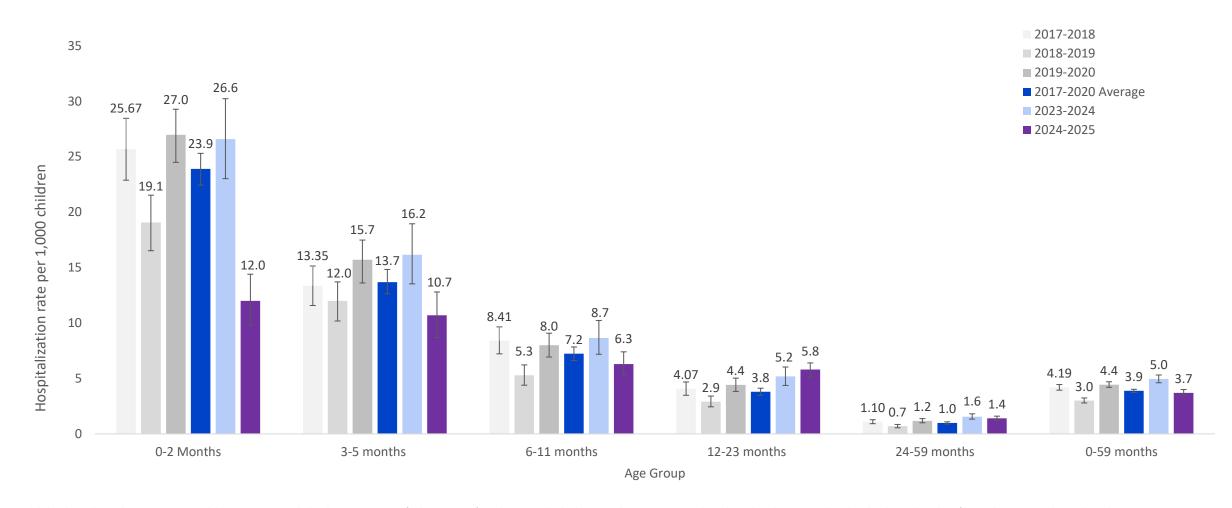
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NVSN .

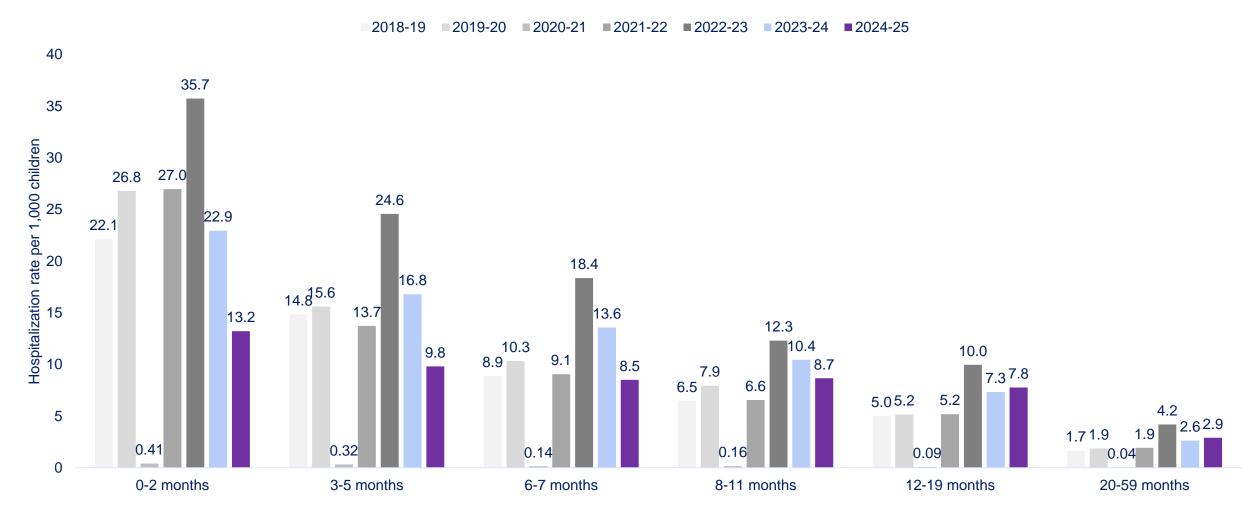
RSV-associated hospitalization rates among children <5 years of age, by season, New Vaccine Surveillance Network, 2017-2025



Bar labels indicate the incidence rate per 1,000 children. Rates were calculated using county-specific denominators from the 2020 US bridged-race population estimates, and population-based numerators based on the observed number of hospitalizations at each site adjusted to account for weeks with <7 days of surveillance, the proportion of eligible children not enrolled, sensitivity of respiratory syncytial virus reverse-transcription polymerase chain reaction testing compared to serology, and each site's estimated market share of ARI hospitalizations by age. Error bars denote 95% confidence intervals determined based on 1000 bootstrap samples for each rate.

RSV-NET

RSV-associated hospitalization rates among children <5 years of age, by season, RSV-NET, 2018–2025



Bar labels indicate the incidence rate per 1,000 children. Rates were calculated using county-specific denominators from the 2020 US bridged-race population estimates, and population-based numerators based on the observed number of hospitalizations at each site adjusted to account for weeks with <7 days of surveillance, the proportion of eligible children not enrolled, sensitivity of respiratory syncytial virus reverse-transcription polymerase chain reaction testing compared to serology, and each site's estimated market share of ARI hospitalizations by age. Error bars denote 95% confidence intervals determined based on 1000 bootstrap samples for each rate.

Weekly (RSV-NET) and monthly* (NVSN) adjusted RSV-associated hospitalization rates in 2024–25 were lower compared to prior seasons among infants aged 0-7 months and were the same or higher than prior seasons among children aged 20-59 months



Infants aged 0–7 months

Eligible for protection by nirsevimab or maternal vaccine

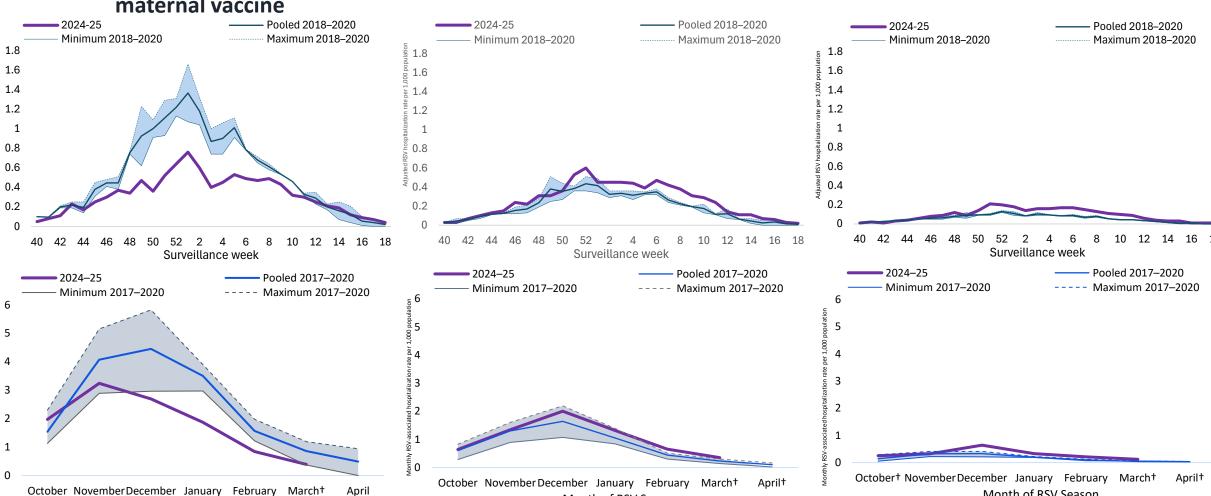
Month of RSV Season

RSV-NET

NSN

Children aged 8–19 months Small number eligible for nirsevimab





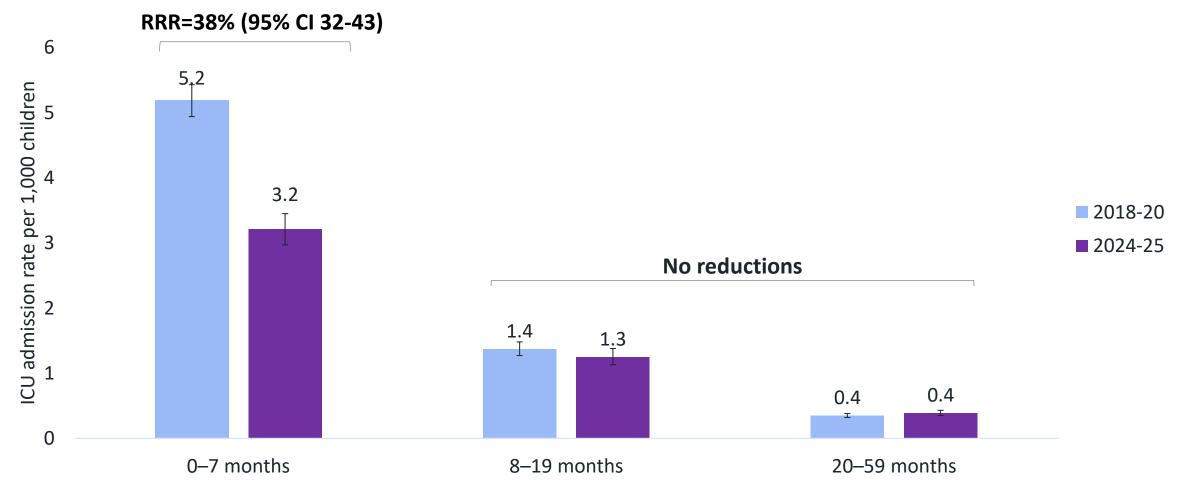
^{*2024-25} NVSN rates through March 31, 2025. †NVSN rates should be interpreted with caution as relative standard error ≥30 or n <5: 0-7 months March 2024-25, 8-19 months March 2017-20 max, 20-59 months October, March and April 2017-20 min and April 2017-20 pooled RSV-NET rates are adjusted to account for RSV underdetection because of testing practices and test sensitivity. NVSN rates are adjusted to account for weeks with <7 days of surveillance, the proportion of eligible children not enrolled, sensitivity of respiratory syncytial virus reverse-transcription polymerase chain reaction testing compared to serology, and each site's estimated market share of acute respiratory illness hospitalizations by age.

Month of RSV Season

Month of RSV Season

RSV-associated ICU admission rates in RSV-NET were <u>reduced by 38%</u> among infants <u>aged 0–7 months</u>; no reductions occurred among children aged 8–19 and 20–59 months

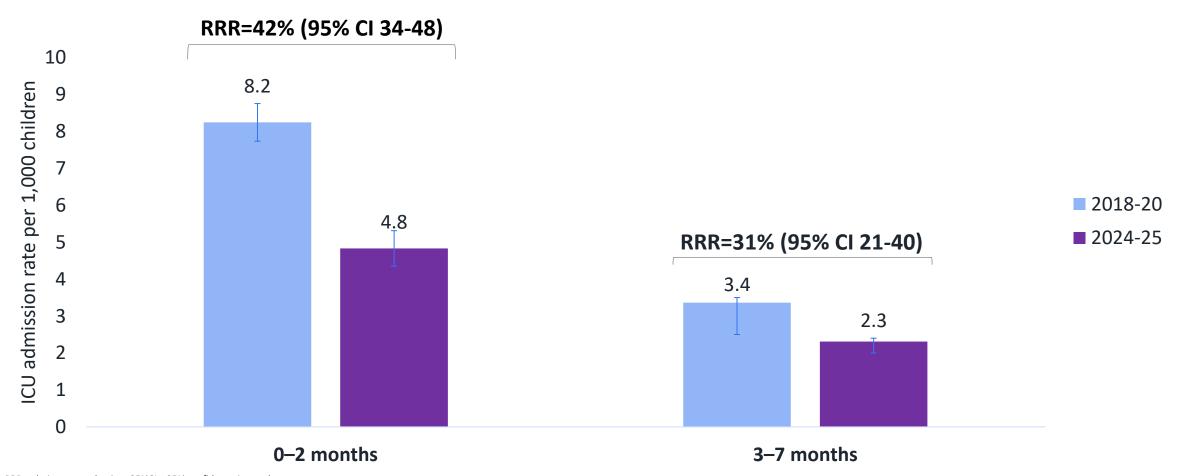




RRR=relative rate reduction, 95%CI = 95% confidence interval

RSV-NET

RSV-associated ICU admission rates in RSV-NET were reduced by 42% among infants aged 0–2 months and by 31% among infants aged 3–7 months

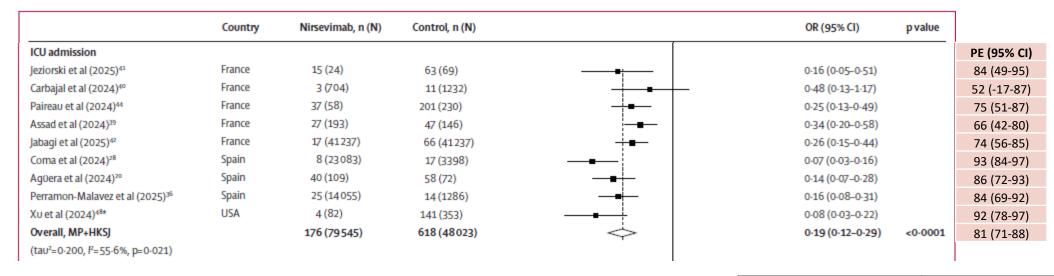


RRR=relative rate reduction, 95%CI = 95% confidence interval

Meta-analysis of nirsevimab effectiveness against RSV-associated hospitalization, 2023-2024 season

	Country	Nirsevimab, n (N)	Control, n (N)		OR (95% CI) p v	/alue
RSV-related hospitalisation						PE (95% CI)
Jeziorski et al (2025) ⁴¹	France	102 (230)	609 (766)	:=-	0-21 (0-15-0-28)	79 (72-85)
Carbajal et al (2024) ⁴⁰	France	22 (723)	170 (1391)	! •	0.23 (0.14-0.35)	77 (65-86)
Assad et al (2024) ³⁹	France	60 (690)	97 (345)	<u> </u>	0-24 (0-17-0-35)	76 (65-83)
Lenglart et al (2025) ⁴³	France	26 (62)	199 (241)	-	0-15 (0-08-0-28)	85 (72-92)
Jabagi et al (2025) ⁴²	France	342 (41237)	992 (41237)	-	0-34 (0-30-0-38)	66 (62-70)
Consolati et al (2024) ¹³	Italy	0 (369)	14 (168)	←	0-01 (0-00-0-24)	99 (76-100)
López-Lacort et al (2024) ³²	Spain	56 (115)	39 (51)	 -	0-29 (0-14-0-61)	71 (39-86)
Coma et al (2024) ²⁸	Spain	52 (23127)	76 (3398)		0.10 (0.07-0.14)	90 (86-93)
Ag0era et al (2024) ²⁰	Spain	40 (109)	54 (72)	- - -	0.19 (0.10-0.37)	81 (63-90)
Rodríguez-Fernández et al (2024)38	Spain	6 (14)	15 (18)		0-15 (0-03-0-77)	85 (23-97)
Andina Martínez et al (2024) ³⁴	Spain	150 (331)	246 (277)	- ■-{	0-10 (0-07-0-16)	90 (84-93)
Perramon-Malavez et al (2025) ³⁶	Spain	109 (14055)	34 (1286)	 -	0-29 (0-19-0-42)	71 (58-81)
Núñez et al (2025)35	Spain	603 (3973)	346 (733)	-	0-20 (0-17-0-24)	80 (76-83)
Moline et al (2025) ⁴⁶	USA	6 (59)	401 (640)		0-07 (0-03-0-16)	93 (84-97)
Moline et al (2024) ^g	USA	6 (73)	525 (802)		0-05 (0-02-0-11)	95 (89-98)
Xu et al (2024) ^{48*}	USA	5 (75)	161 (468)		0.14 (0.05-0.34)	86 (66-95)
Overall, MP+HKSJ		1585 (85242)	3978 (51893)		0.17 (0.12-0.23) <0	83 (77-88)
(tau ² =0·246, l ² =85·8%, p<0·001)						
				·	VISION	79 (67-87
					NVSN	82 (71-88

Meta-analysis of nirsevimab effectiveness against RSV-associated ICU admission, 2023-2024 season



VISION	82 (57-93)		
NVSN	88 (63-96)		
ОС	79 (62-89)		

Maternal RSV vaccine effectiveness estimates from Argentina and UK

Argentina

- Razzini et al.¹: VE against <u>RSV-associated hospitalization</u> was 81% (95% Cl 63–91) among infants under age 3 months
- Perez Marc et al.²: VE against <u>RSV-associated hospitalization</u> was <mark>79% (95% CI 62–88)</mark> among infants under age 3 months
- Gentile et al.³: VE against <u>RSV-associated hospitalization</u> was 79% (95% CI: 51–91) among infants under age 6 months

UK

- Williams et al.⁴: VE against <u>RSV-associated hospitalization</u> was <mark>72% (95% CI: 48–85)</mark> among infants under age 3 months

¹Razzini JL et al. Impact and Effectiveness of Universal Respiratory Syncytial Virus Vaccination During Pregnancy on Infant Hospitalizations in Buenos Aires: A Retrospective Cohort Study. *VeriXiv.* 2025 Pérez Marc G et al. Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalisation in infants during the 2024 RSV season in Argentina (BERNI study): a multicentre, retrospective, test-negative, case—control study. *The Lancet Infectious Diseases.* 2025

³Gentile A et al. Maternal Immunization With RSVpreF Vaccine: Effectiveness in Preventing Respiratory Syncytial Virus—associated Hospitalizations in Infants Under 6 Months in Argentina: Multicenter Case—control Study. *The Pediatric Infectious Disease Journal*. 2025

⁴Williams TC et al. Bivalent Prefusion F Vaccination in Pregnancy and Respiratory Syncytial Virus Hospitalisation in Infants: Results of a Prospective, Multi-Centre, Test-Negative Study. Available at SSRN: https://ssrn.com/abstract=5184994 or http://dx.doi.org/10.2139/ssrn.5184994

Product Effectiveness Analyses – Controlling for Confounding

	VISION	NVSN	Overcoming
Analysis	Multivariable logistic regression models, adjusting for site, age in months, calendar date, race and ethnicity, and sex. Models adjusting for underlying medical conditions did not meaningfully change estimates.	Multivariable logistic regression models, adjusting for site, age in months, and month of enrollment. Nirsevimab analysis adjusted for presence of ≥1 high-risk medical condition for severe RSV disease; maternal RSV analysis adjusted for race/ethnicity and insurance status.	Multivariable logistic regression models, adjusting for site, age in months, timing of enrollment, presence of ≥1 underlying medical condition, and social vulnerability index.

 Models did not adjust for healthcare utilization behavior or specific underlying characteristics between vaccinated and unvaccinated patients