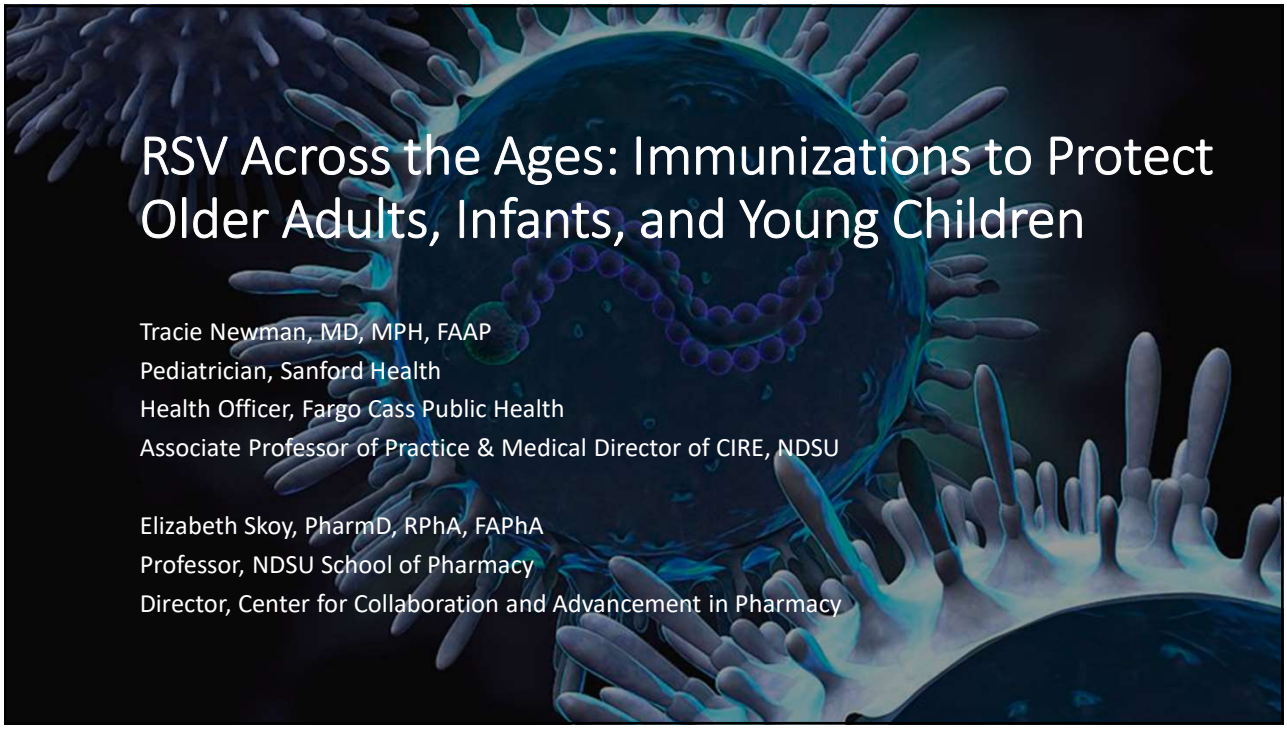

RSV Across the Ages: Immunizations to Protect Older Adults, Infants, and Young Children

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Disclosures

- Tracie Newman has no relevant financial relationships with ineligible companies to disclose.
- Elizabeth Skoy has no relevant financial relationships with ineligible companies to disclose.
- The off-label use of medications will not be discussed during this presentation.

Disclosure:
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Financial Support:
This project was supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $5,755,820 with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government. Additionally, the contents do not necessarily represent the official views of, nor an endorsement, by the North Dakota Department of Health and Human Services.

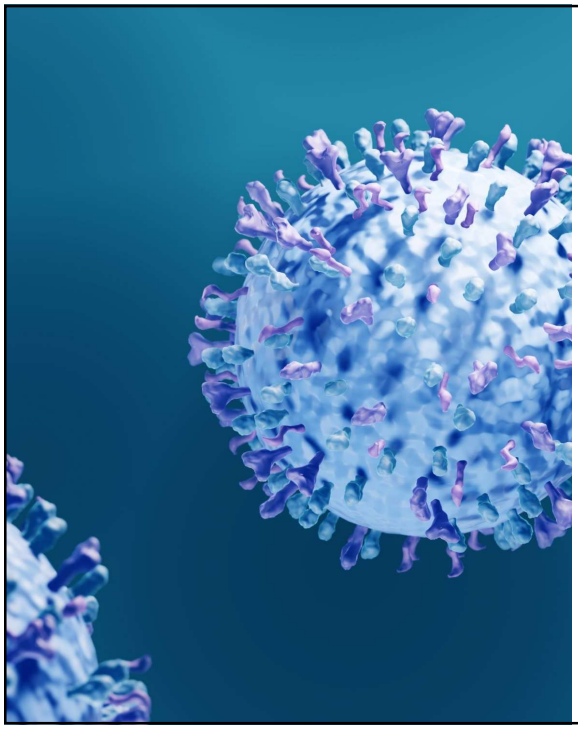
NDSU CENTER FOR IMMUNIZATION RESEARCH AND EDUCATION

MINNESOTA MEDICAL ASSOCIATION

Learning Objectives

Upon completion of this activity, the participant will be able to:

Summarize	Summarize the epidemiologic burden of RSV in infants, children, pregnant women, and adults.
Describe	Describe morbidity, mortality, and comparative epidemiology of RSV to influenza and covid-19 in the pediatric population.
Outline	Outline available evidence of prevention and treatment measures for RSV including recommended current immunization schedules.
Differentiate	Differentiate between available products used to prevent RSV.



Respiratory Syncytial Virus (RSV)

- Single stranded RNA virus, *Pneumoviridae* family
- Almost all children infected by age 2 years; reinfection common
- Causes acute respiratory tract illness in all ages
  - Symptoms vary with age, health, status, and primary vs secondary infection
- Supportive care → hospitalization → ICU

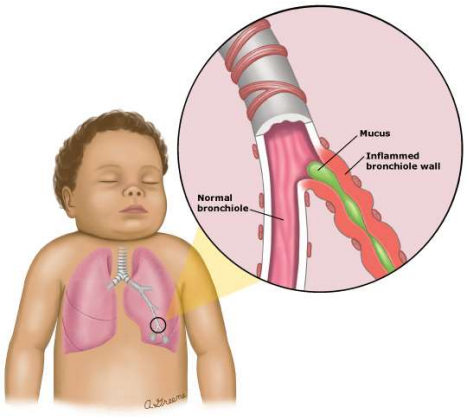
RSV Transmission

- Coughing or sneezing
- Virus droplets enter eyes, nose, mouth
- Direct contact
- Touching surface with virus, then touching face
  - RSV can survive hours on hard surfaces (tables, crib rails); shorter period on soft surfaces (hands, tissues)

RSV Symptoms in Babies

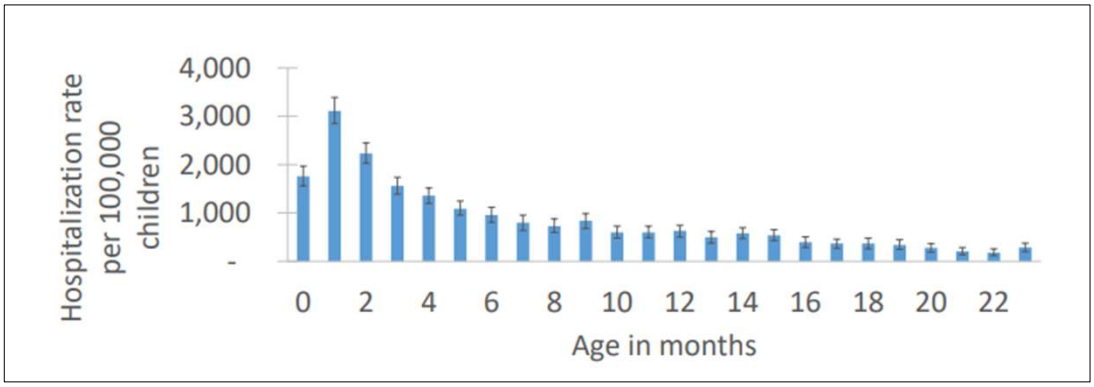
- Cold symptoms; can be bronchiolitis or pneumonia
- Symptoms peak days 3-5, last 7-14 days

Cold: Upper Respiratory Tract Infection	Bronchiolitis: Lower Respiratory Tract Infection
Cold symptoms may include: • Fever (temperature of 100.4 or higher) • Cough (dry or wet sounding) • Congestion • Runny nose • Sneezing • Fussiness • Poor feeding	May include **cold symptoms, plus:** • Fast breathing • Flaring of the nostrils & head bobbing with breathing • Rhythmic grunting during breathing *(see sound clip clip, below)* • Belly breathing, tugging between the ribs and/or the lower neck • Wheezing

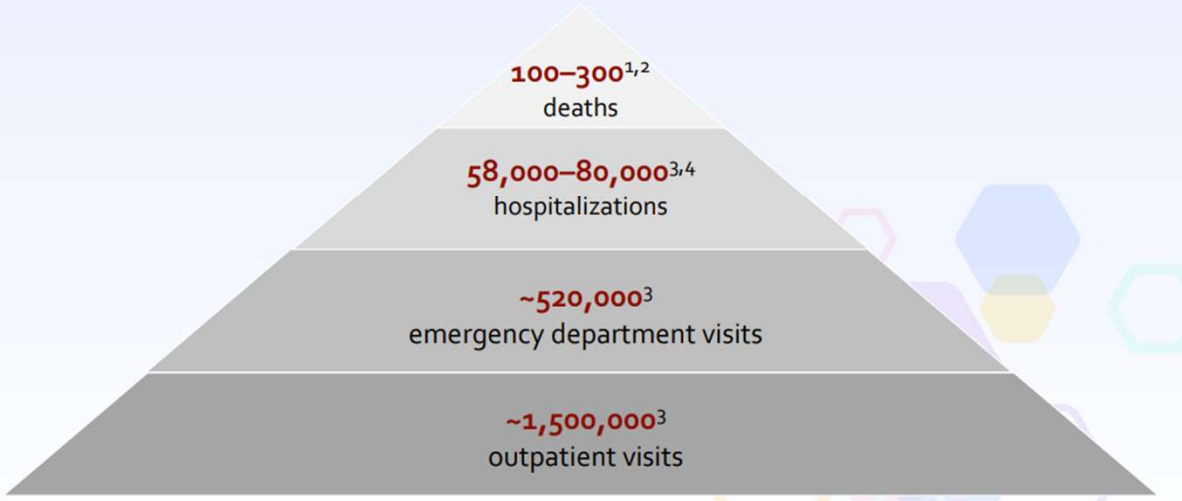


RSV Epidemiology

- Most infants (68%) infected during the 1st year of life; nearly all (97%) by age 2
- Most common cause of hospitalization in U.S. infants (2-3% of young infants)
  - Prematurity / chronic disease increases risk, but most (79%) are in healthy, term infants
  - Risk of hospitalization higher in younger infants



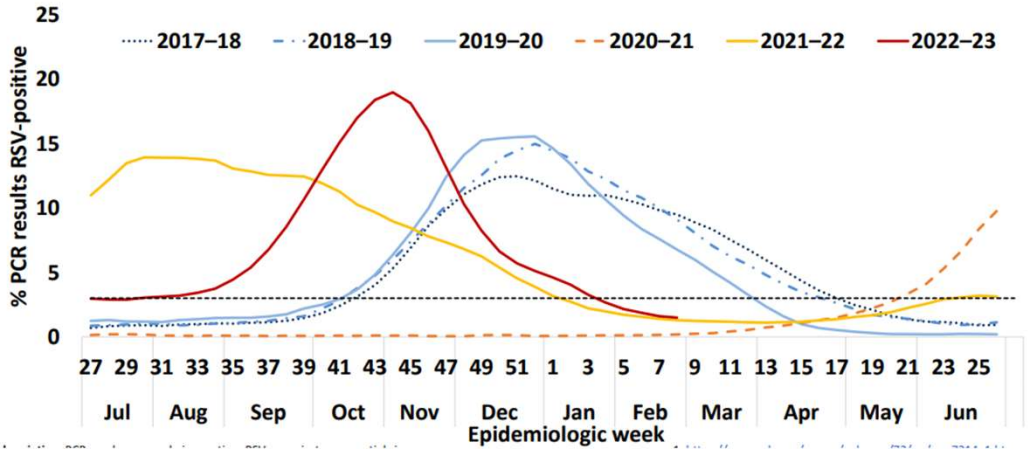
Each year in U.S. children aged less than 5 years, RSV is associated with…



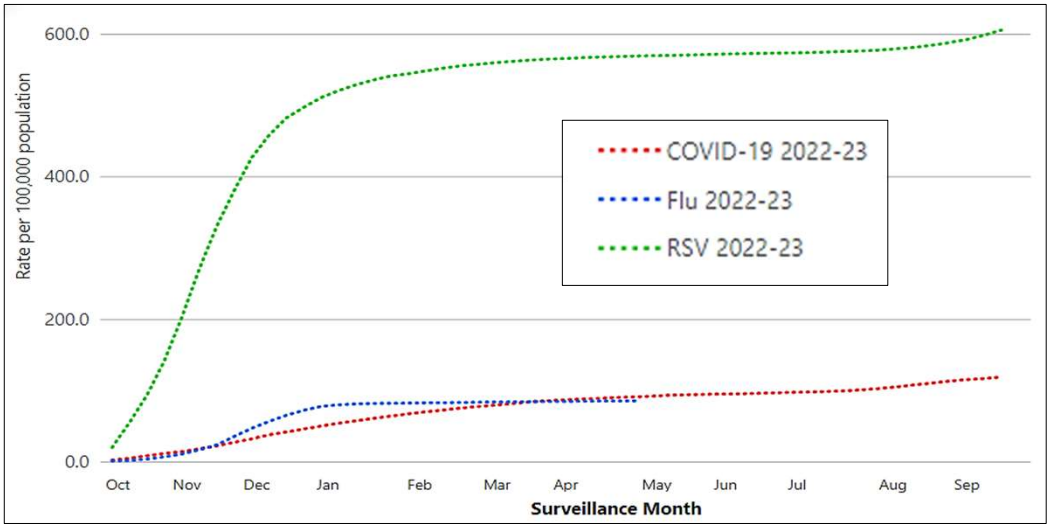
[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022 (*estimate 80,000 hospitalizations in infants

RSV Seasonality

Changes in seasonality of RSV transmission following SARS-CoV2 introduction— NREVSS[1], 2017–2023



Cumulative Risk of Hospitalization from Resp Viruses in Children 0-4 yrs, 2022-2023

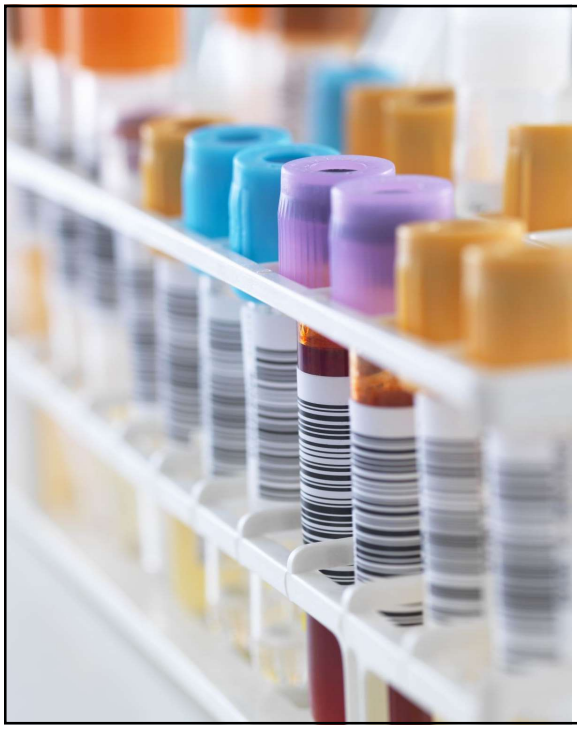


Pediatric Hospitalization Rates Higher for RSV than Omicron or Flu

Table 2. Age-Stratified Hospital Admission Rates in the Cohorts With SARS-CoV-2 Omicron, Influenza A/B, or RSV Infection[a]

	Hospital admissions, No./total No. (%)		
Age, y	Omicron (n = 648)	Influenza (n = 81)	RSV (n = 990)
1			
7			
5			
2-4	34/81 (42.0)	17/80 (21.2)	181/236 (76.7)
1	31/79 (39.2)	6/17 (35.3)	118/156 (75.6)
0	172/569 (30.2)	28/64 (43.8)	707/834 (84.8)
Overall	282/896 (31.5)	118/426 (27.7)	1041/1274 (81.7)

Odds of infant hospitalization for RSV ~11 x higher than Omicron



Nirsevimab = Long-acting Monoclonal Antibody

- Active immunization results from infection or vaccination → triggers an immune response
- Passive immunization is when a person receives antibodies from an external source
  - Transplacental
  - Breastmilk
  - IVIG
  - Monoclonal antibodies

Palivizumab

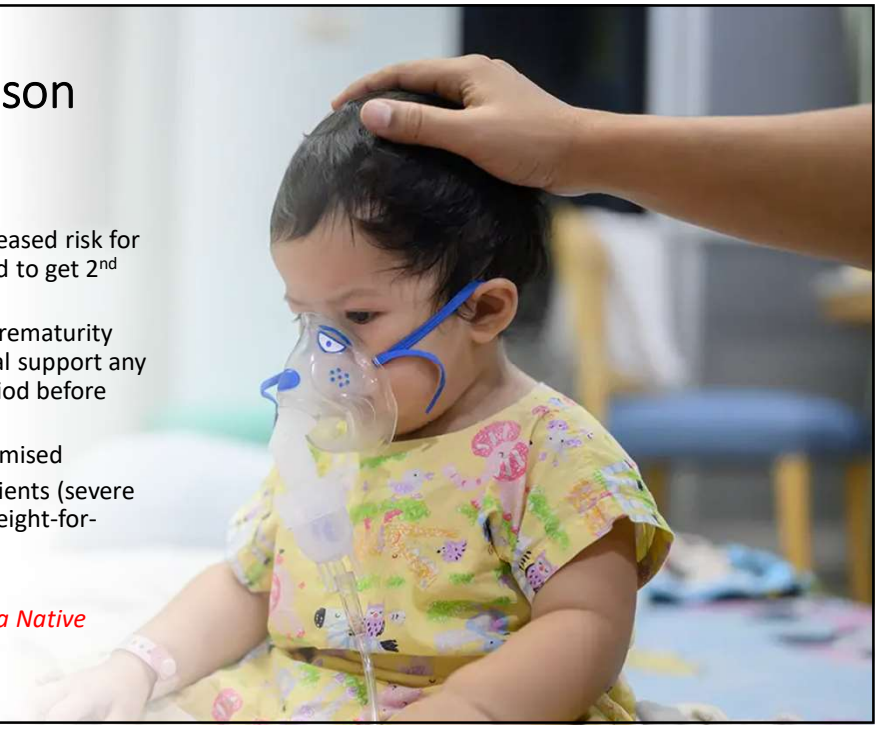
- Monoclonal antibody providing passive RSV immunity
- Limited use; indicated only for:
  - Premature infants (≤ 35 week) 6 months or younger
  - ≤ 24 months with BPD requiring medical treatment within last 6 months
  - ≤ 24 months with hemodynamically significant congenital heart disease
- Costly
- Requires monthly injections
- Palivizumab and Nirsevimab have only been compared regarding safety (no efficacy trials)

Nirsevimab

- ACIP recommends nirsevimab for prevention of RSV in *all* infants
- Single dose for:
  - All infants < 8 months born during or entering 1st RSV season
  - Infants and children 8-19 months at increased risk of severe RSV entering 2nd RSV season
- Simultaneous administration with age-appropriate vaccines recommended
- Included in childhood immunization schedule and eligible for Vaccines for Children Program
- Storage, handling, and administration similar to other routine vaccines for children

Second RSV Season Guidelines

- Babies 8-19 months with increased risk for severe disease (recommended to get 2nd dose during 2nd RSV season):
  - Chronic lung disease of prematurity patients requiring medical support any time during 6-month period before start of 2nd RSV season
  - Severely immunocompromised
  - Certain cystic fibrosis patients (severe lung disease or <10th% weight-for-length)
  - *American Indian or Alaska Native children*



Nirsevimab – pre-licensure studies

Efficacy

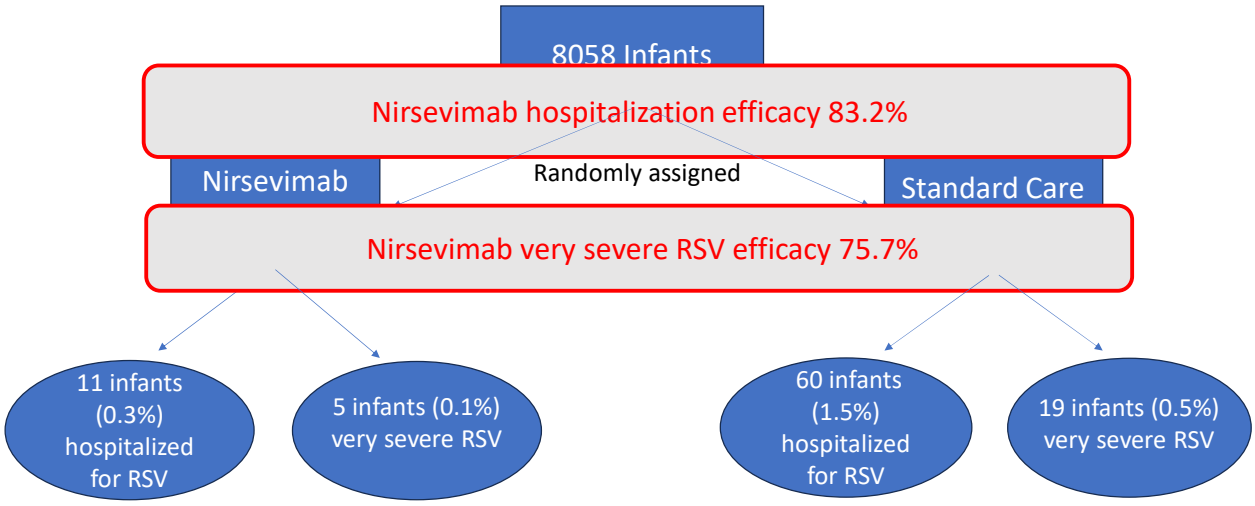
79% against medically attended RSV

80.6% against RSV hospitalization

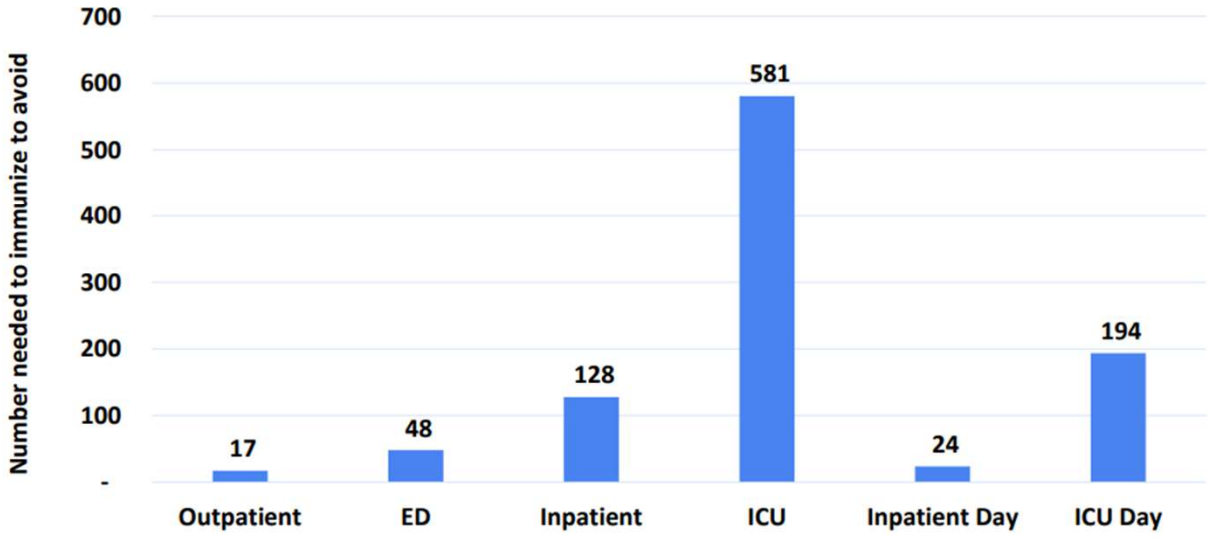
90% against RSV ICU admission

No safety concerns in pre-licensure trials

Nirsevimab Reduces Infant RSV Hospitalizations, Randomized Trial

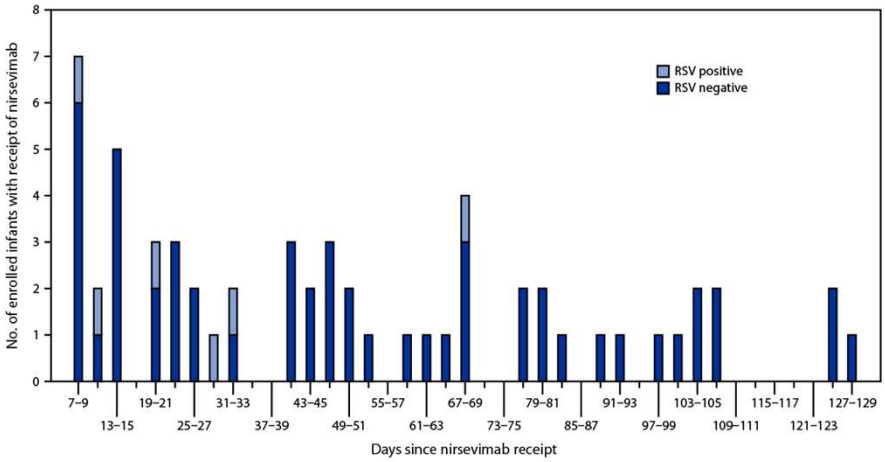


Number needed to immunize with nirsevimab to prevent one health outcome



CDC estimates nirsevimab 90% effective at preventing hospitalizations

FIGURE. Time from receipt of nirsevimab* to symptom onset among infants born during or entering their first respiratory syncytial virus season who were hospitalized with acute respiratory illness, by respiratory syncytial virus test result — New Vaccine Surveillance Network, October 2023–February 2024



Nirsevimab 70% Effective at preventing infant hospitalizations in Spain

Effectiveness of nirsevimab against hospitalisation in infants by the screening method and test-negative design, three regions in Spain, October 2023–January 2024 (n = 166 admissions)

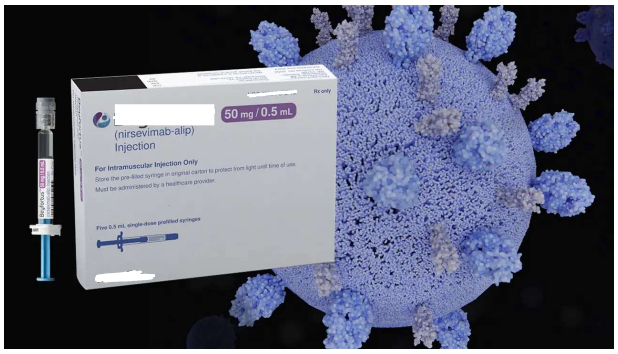
Method	RSV-LRTI (n = 95)		Negative RSV-LRTI (n = 71)	
	(1−OR) x 100	95% CI	(1−OR) x 100	95% CI
Screening				
Murcia	86.9	77.1 to 92.9	27.5	−47.3 to 66.2
Valencia	69.3	36.4 to 86.2	19.6	−180.8 to 82.3
Valladolid	97.0	87.7 to 99.6	NA	
Pooled data	84.4	76.8 to 90.0	32.4	−27.5 to 63.4[a]
Test-negative design				
Pooled data	70.2	38.3 to 88.5[a]	NA	

Nirsevimab 80% effective against hospitalization in France

TABLE 2. Estimated effectiveness of nirsevimab against cases of RSV bronchiolitis hospitalised in PICU, France, September 2023–January 2024.

Analysis	Controls not treated by nirsevimab	Controls treated by nirsevimab	Cases not treated by nirsevimab	Cases treated by nirsevimab	Unadjusted effectiveness (95% CI)	Adjusted effectiveness (95% CI) [a]
Main analysis (*N* = 288)	29	21	201	37	74.4% (50.5–86.8)	75.9% (48.5–88.7)
Sensitivity analysis 1 (*N* = 312)	29	35	201	47	80.5% (65.0–89.1)	80.6% (61.6–90.3)
Sensitivity analysis 2 (*N* = 319)	29	38	201	51	80.5% (65.4–89.0)	80.4% (61.7–89.9)

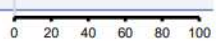
Nirsevimab effective against RSV hospitalization, PICU admission, mechanical ventilation in France



- In infants < 12 months, nirsevimab was:
  - 83% effective in preventing RSV hospitalization
  - 70% effective against PICU admission for RSV
  - 67% effective against RSV illness requiring ventilatory support

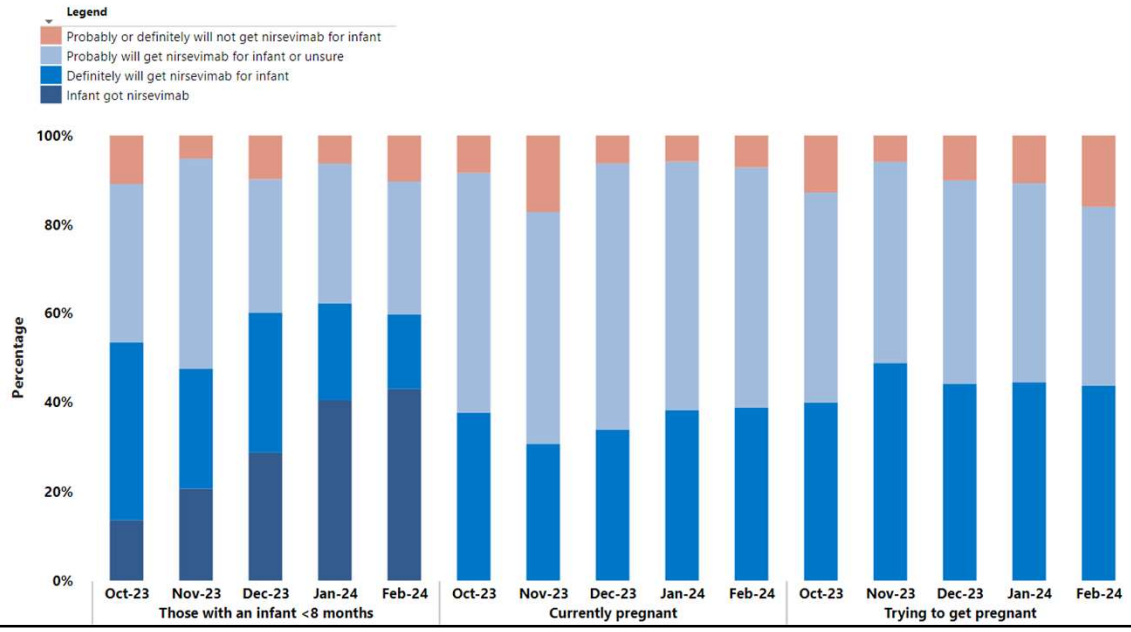
First season nirsevimab product effectiveness (PE) against RSV-associated ED encounters and hospitalization – VISION, October 8, 2023 – March 31, 2024

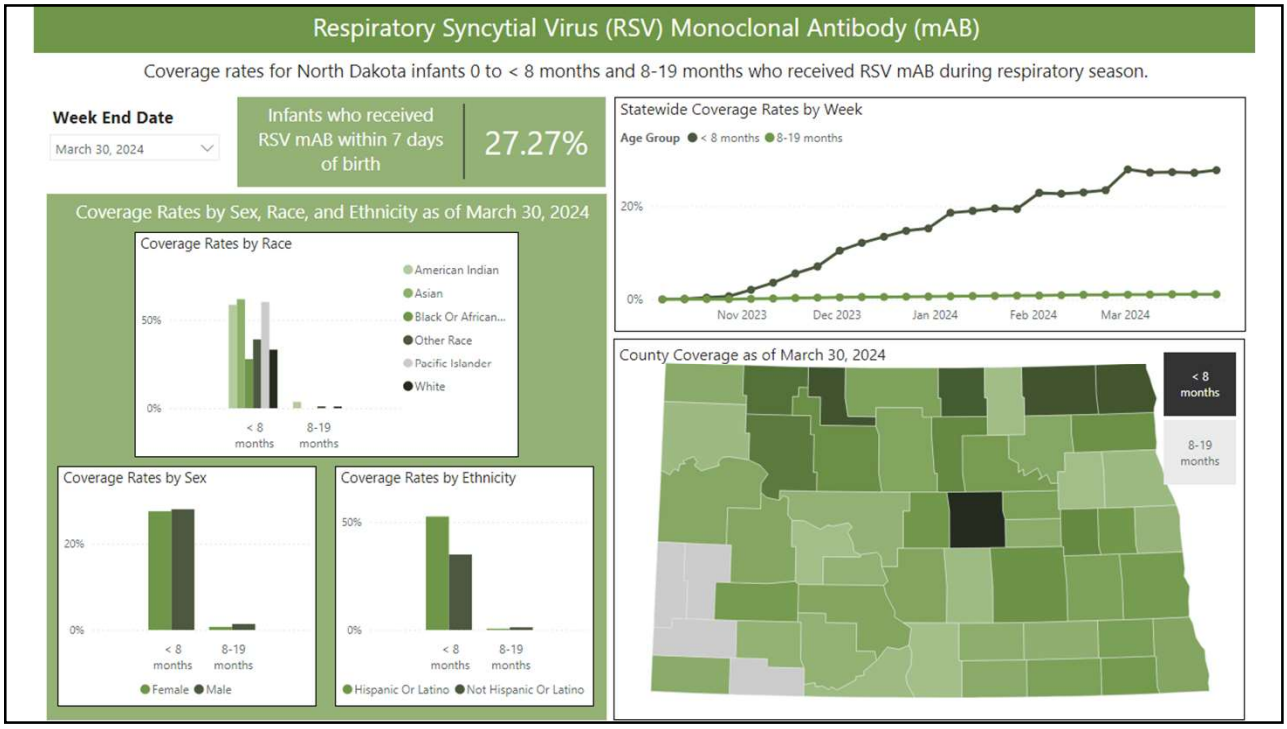
Outcome | Nirsevimab dosage pattern	Total encounters	RSV-positive encounters N (Row %)	Median days since dose (IQR)	Adjusted PE (95% CI)*
RSV-associated ED encounter				
No nirsevimab doses	4,610	1,988 (43)	N/A	ref
Nirsevimab, ≥7 days prior	442	63 (14)	53 (27-84)	77 (69-83)
RSV-associated hospitalization				
No nirsevimab doses	927	601 (65)	N/A	ref
Nirsevimab, ≥7 days prior	93	4 (4)	48 (25-84)	98 (95-99)



Nirsevimab was effective against RSV-associated ED encounters and hospitalization among infants in their first RSV season.

Figure 6. Monthly Nirsevimab Receipt and Intent Among Females Aged 18-49 Years Who Have an Infant<8 Months, Are Currently Pregnant, or Are Trying to Get Pregnant, United States*,†
Data Source: National Immunization Survey–Adult COVID Module





Nirsevimab administration algorithm for children aged <8 months on the day of administration

Meet all 3 following criteria? (yes/no)

1. Either mother did not receive RSV vaccine during pregnancy ≥14 days prior to birth or maternal RSV vaccine status unknown [1]
2. Day of nirsevimab administration during October through March [2]
3. Never previously received dose of nirsevimab [3]

No
Any criteria not met

→ Nirsevimab not needed

Yes
All 3 criteria met

→ Nirsevimab recommended

14

Nirsevimab Administration Visual Guide

American Academy of Pediatrics
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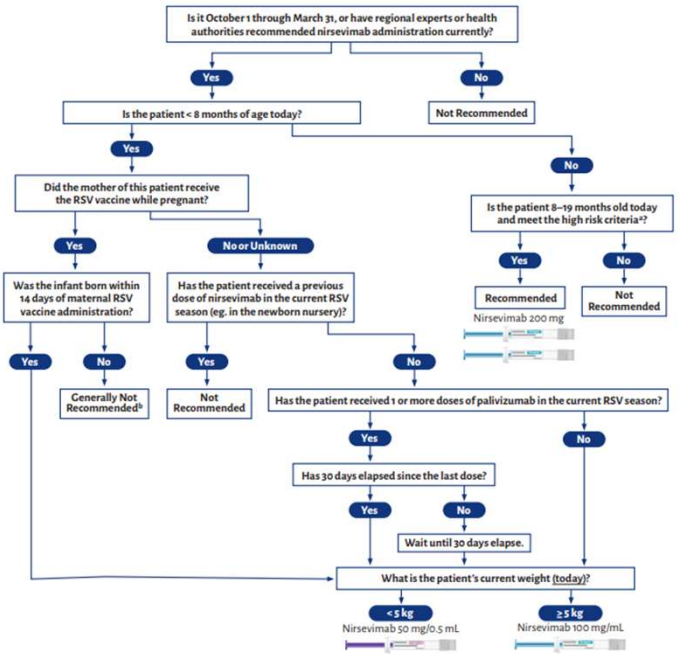
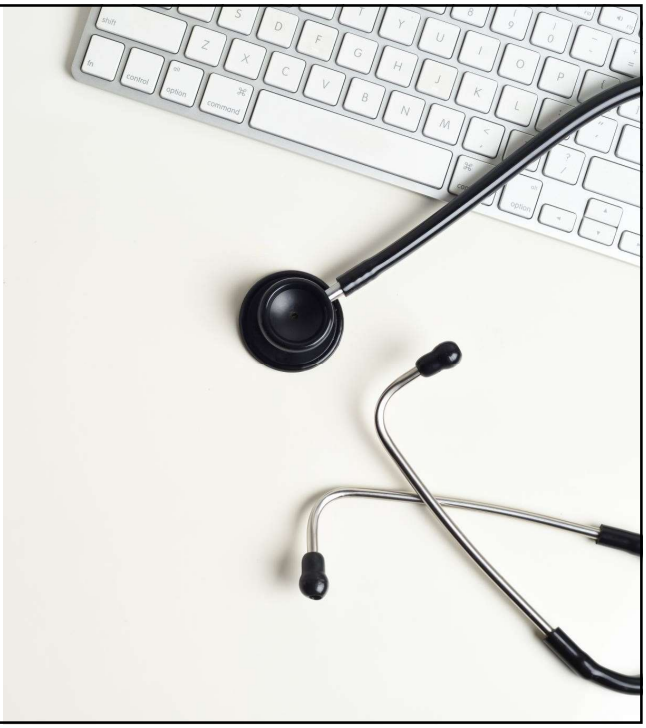


Maternal RSV Vaccine

- Abrysvo: 1st RSV vaccine for pregnancy to prevent RSV in infants birth – 6 months
- FDA approved for use at 32 – 36 weeks gestation
- Safety and effectiveness evaluation ongoing in randomized, placebo-controlled international clinic trials
- Prelim data:
  - Reduced risk of severe LRTD by 81.8% within 90 days of birth; 69.4% within 180 days after birth

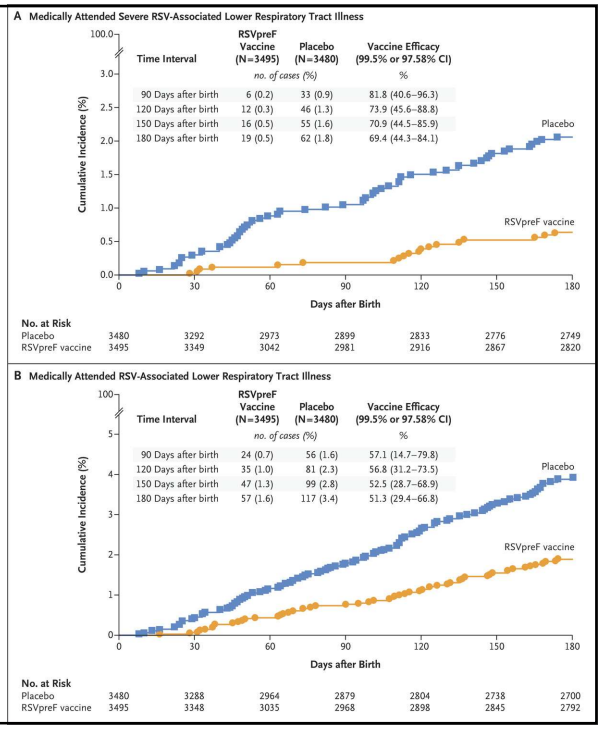
2023-2024 Recommendations

- ACIP recommends maternal RSV for pregnant people during 32 – 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants
  - September - January in most of continental U.S.
  - In jurisdictions where seasonality differs (Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration



Maternal RSV Vaccine Efficacy

- Within 3 months after birth, maternal RSV vaccine reduced the risk of infant hospitalization for RSV by 68% and having a healthcare visit for RSV by 57%
- Within 6 months after birth, maternal RSV vaccine reduced the risk of infant hospitalization for RSV by 57% and having a healthcare visit for RSV by 51%



Maternal RSV Vaccine Safety

- Most common side effects: pain at injection site, HA, myalgia, nausea
- Preterm birth
  - Pre-licensure trial initially included pregnant persons at weeks 24-36 gestation
  - More preterm births were seen in vaccine recipients vs placebo (not statistically significant)
  - In pregnant women 32-36 weeks gestation who received vaccine, 4.2% had preterm birth compared to 3.7% placebo
  - ***Available data insufficient to establish or exclude causal relationship***

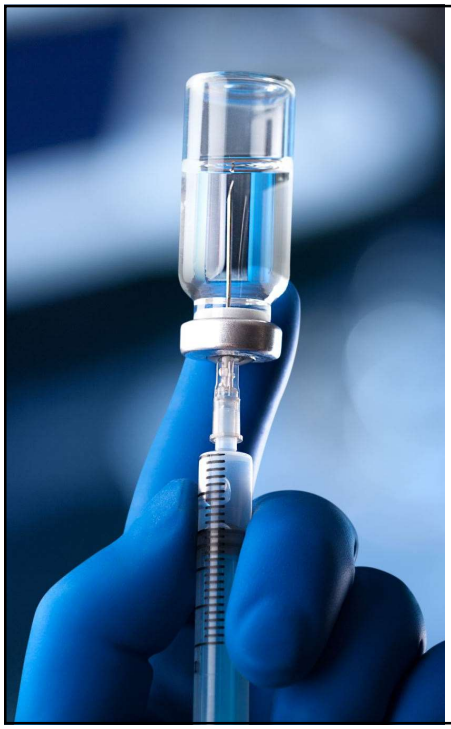
Maternal RSV Vaccination Showed No Significant Differences in Pre-term Births

Table 2. Pregnancy Outcomes Between Patients Who Had RSV Vaccination During Pregnancy Documented in Their Electronic Health Record vs Those Who Did Not

Pregnancy outcome	Patients, No. (%)		OR (95% CI)	aOR (95% CI)[a]	HR (95% CI)[b]
	RSV vaccine (n = 1011)	No RSV vaccine (n = 1962)			
Primary outcome					
Preterm birth <37 weeks' gestation	60 (5.9)	131 (6.7)	0.88 (0.64-1.20)	0.87 (0.62-1.20)	0.93 (0.64-1.34)
Secondary outcomes					
Hypertensive disorders of pregnancy	203 (20.1)	355 (18.1)	1.14 (0.94-1.38)	1.10 (0.90-1.35)	1.43 (1.16-1.77)
Gestational hypertension[c]	153 (15.1)	273 (13.9)	NA	NA	NA
Preeclampsia	67 (6.6)	130 (6.6)	NA	NA	NA
Eclampsia	1 (0.1)	1 (0.1)	NA	NA	NA
HELLP syndrome	2 (0.2)	2 (0.1)	NA	NA	NA
Small-for-gestational age birth weight[d]	107 (10.6)	178 (9.1)	1.19 (0.92-1.52)	1.16 (0.89-1.50)	1.31 (0.97-1.77)
Stillbirth	2 (0.2)	3 (0.2)	1.29 (0.17-7.82)	NA	NA

prenatal RSV vaccine trial halted

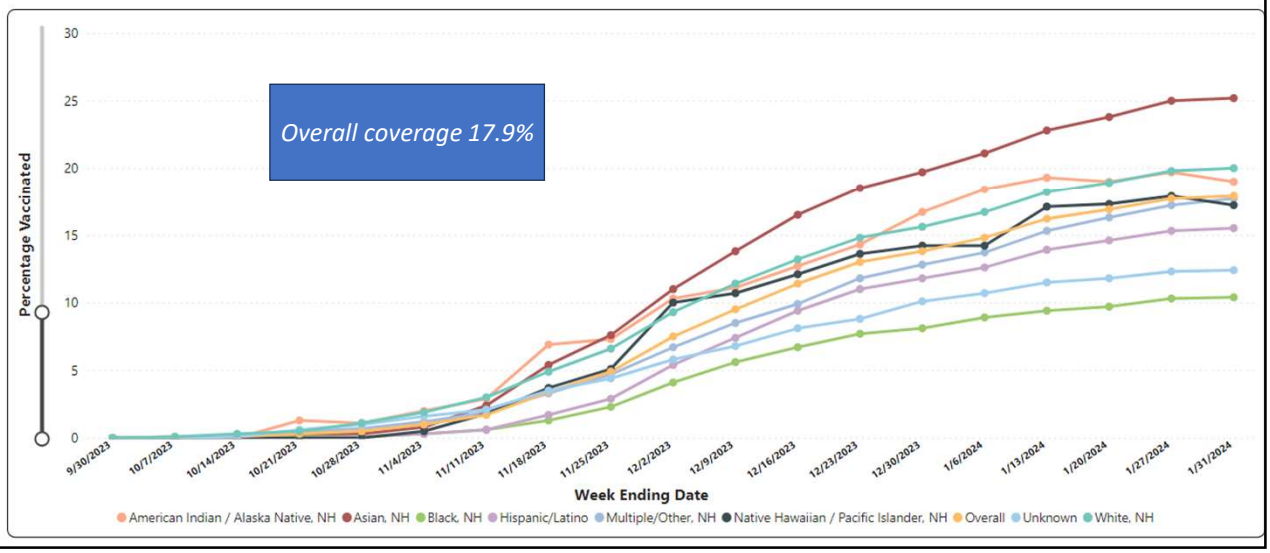
- Preterm births in vaccine group > than placebo (6.8% vs 4.9%)
- Of preterm births, 5.5% in vaccine group were very (<32 weeks) or extremely (<28 weeks) preterm vs 2.3% in placebo group
- Neonatal death risk higher in vaccine group (due to extreme prematurity)



Other Vaccine Safety Outcomes

- Overall uncommon, but hypertensive disorders of pregnancy occurred in 1.8% of maternal vaccine recipients vs 1.4% placebo
- The following conditions (often associated with preterm birth) occurred more frequently in infants born to mothers who received the RSV vaccine compared to placebo:
  - Pre-eclampsia
  - Low birth weight (< 5.5 lbs)
  - Jaundice

Figure 5. Percent of pregnant persons ages 18–49 years vaccinated† with RSV vaccine overall and by race and ethnicity — Vaccine Safety Datalink



ND RSV Vaccination Data

NORTH Dakota | Health & Human Services
Be Legendary.

- NDHHS has internal dashboard that tracks additional RSV immunization data
- During the 2023-24 season, 1,369 Abrysvo doses were administered to women <50 years (it is likely these were pregnant women)

RSV Vaccination Intention Among People Who Are or Plan to Become Pregnant

Predicted proportions	Overall	With child at home	Without child at home
Currently pregnant			
Yes, currently pregnant	54%	57%	46%
No, planning to get pregnant	57%	58%	55%
Heard of RSV			
In 2022	54%	58%	50%
In 2021	51%	51%	55%
In 2020 or earlier	58%	60%	53%
Never	55%	58%	50%
Vaccines during past pregnancies			
Yes, received some or all vaccines	62%	62%	
No, did not receive past pregnancy vaccines	33%	33%	
No previous pregnancy	52%		52%
Seriousness and likelihood of RSV			
Serious and likely	63%	63%	63%
Serious and not likely	55%	59%	49%
Not serious (likely or not likely)	35%	37%	32%
Race and ethnicity			
American Indian/ Alaskan Native	70%	72%	56%
Asian	55%	49%	60%
Black, non-Hispanic	58%	53%	64%
Native Hawaiian/ Pacific Islander	47%	46%	48%
Hispanic	59%	63%	53%
Multirace/Other	54%	59%	44%
White, non-Hispanic	53%	57%	48%
Insurance type			
Commerical	52%	55%	46%
Public	60%	61%	60%
No Insurance	46%	58%	30%
Maternal age			
18–24 y	53%	52%	51%
25–29 y	56%	61%	51%
30–34 y	58%	61%	52%
35–39 y	52%	53%	54%
40–45 y	60%	63%	52%
Census region			
Northeast	54%	58%	48%
South	55%	56%	53%
Midwest	55%	57%	52%
West	58%	60%	54%

Legend: Low — High

Pediatrics. Published online April 25, 2024. doi:10.1542/peds.2023-065140

Relative risks and benefits of maternal vaccination and nirsevimab

Both products are safe and effective in preventing RSV lower respiratory infection in infants

Maternal RSV vaccine	Nirsevimab
Benefits • Provides protection immediately after birth • May be more resistant to virus mutation • Avoids injection of infant **Risks** • Protection reduced if fewer antibodies produced or are transferred from mother to baby (e.g., mother immunocompromised or infant born soon after vaccination) • Potential risk of preterm birth	**Benefits** • Studies of antibody levels suggest that protection might wane more slowly • Can provide antibodies directly if infant receives less antibodies from mother • No risk of adverse pregnancy outcomes **Risks** • Potentially limited availability during 2023-2024 RSV season

11

Timing of RSV vaccine and nirsevimab

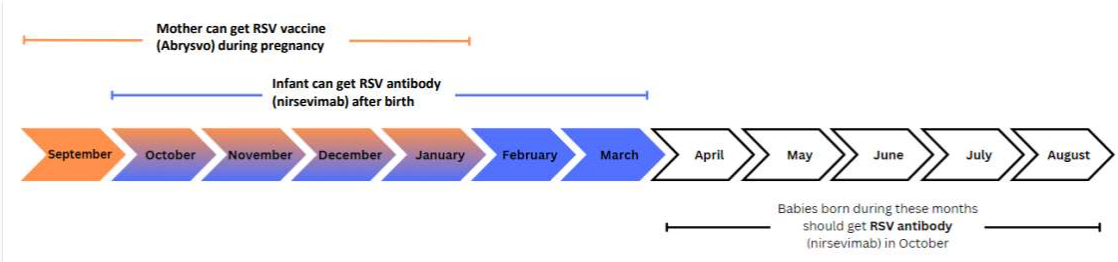


Figure represents recommended timing of immunization product deployment for most of the continental U.S. In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration

Knowledge Check

What is the nirsevimab recommendation for a baby born in May, given the mother did NOT receive Abrysvo?

a. The infant should not receive nirsevimab.
b. The infant should receive nirsevimab within one week of birth.
c. The infant should receive nirsevimab around October, or the start of RSV season.
d. The infant should only receive nirsevimab if at increased risk for severe RSV.

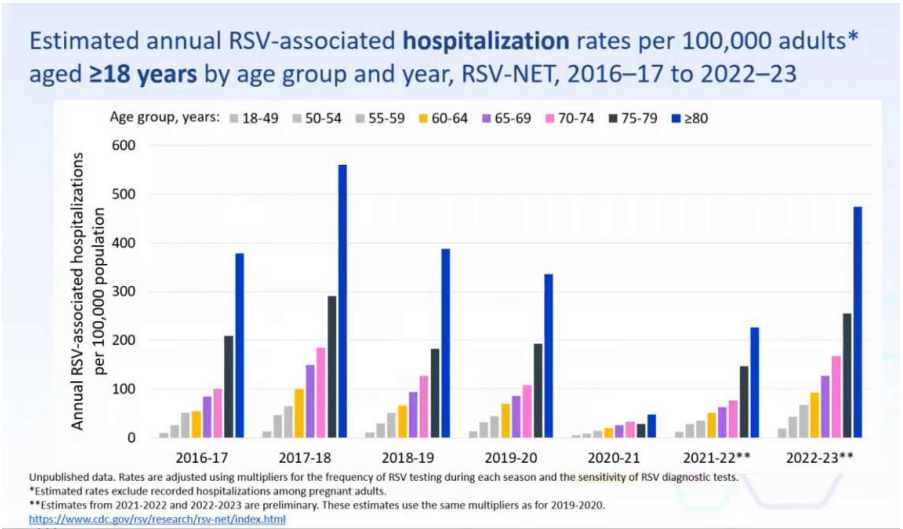
RSV Vaccination in Adults

RSV Burden of Disease: Adults

- Hospitalizations
  - 60,000 to 160,000 annually
- Deaths
  - 6,000-10,000 annually
- High risk
  - Diabetes
  - Lung disease
  - Kidney disease
  - Cardiovascular disease
  - Immunocompromised*
  - Frail/nursing homes

www.cdc.gov, www.nfid.org

RSV Burden of Disease: Adults



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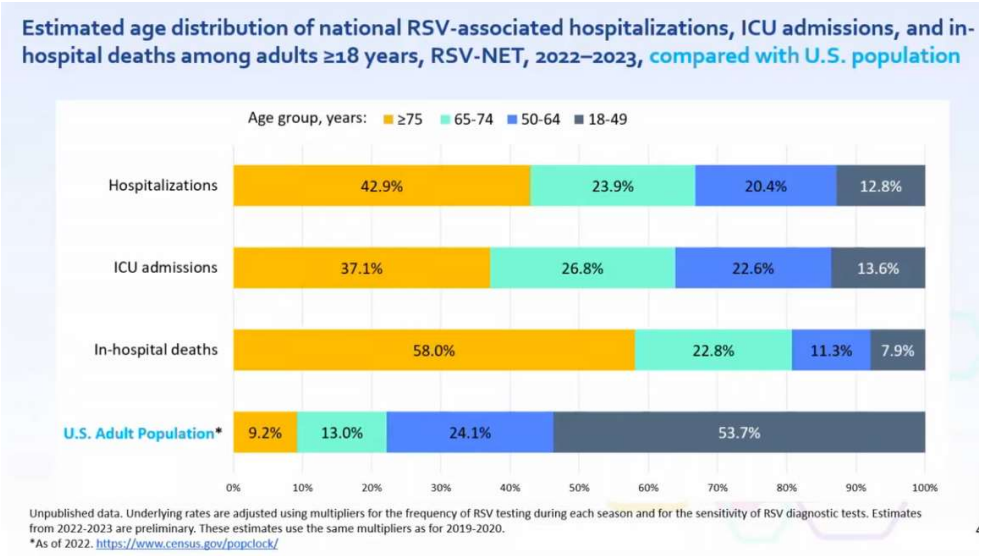
RSV Burden of Disease: Adults



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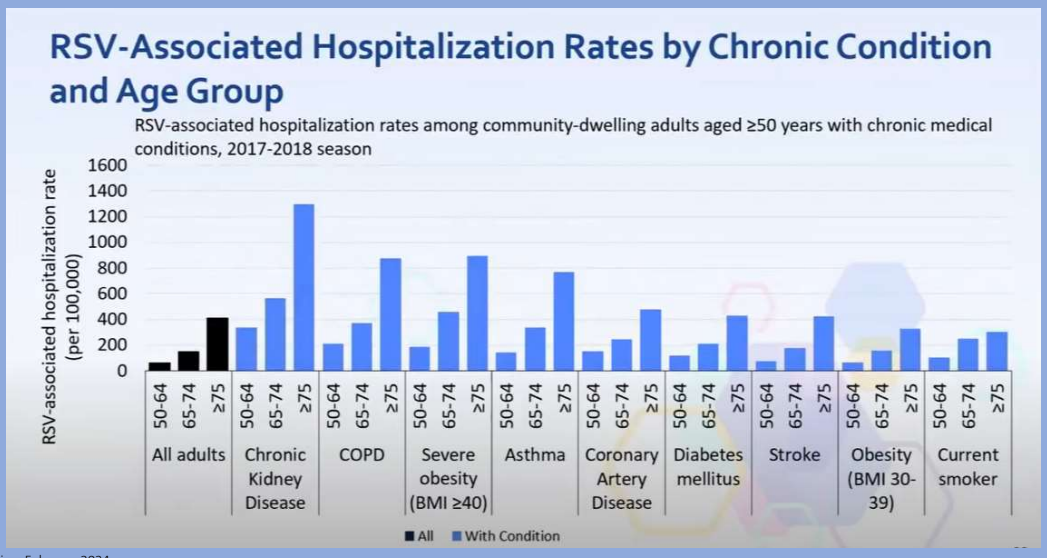
RSV Burden of Disease: Adults



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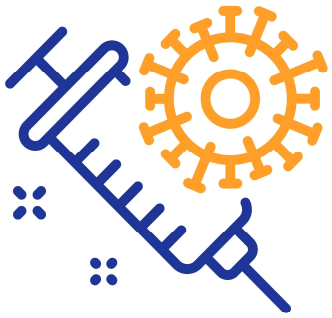
Vaccine Overview

- Available vaccines
  - Viral subunit vaccines: Abrysvo and Arexvy
  - mRNA vaccine (mRESVIA)
- Approved for adults 60 years and older
  - Abrysvo
  - Arexvy
  - mRESVIA
- FDA approved for adults 50 years and older at risk*
  - Arexvy
- Approved for pregnant women
  - Abrysvo
- Vaccine with an adjuvant
  - Arexvy
- Insurance
  - Medicare Part D
  - Private Insurance/Medicaid



Vaccine Overview

	Arexvy	Abrysvo	mRESVIA
Storage	Refrigerated	Refrigerated	Frozen Refrigerator up to 30 days
Reconstitution	Yes (with adjuvant)	Yes (vial adapter)	No
How supplied	Single dose vials	Single dose vials	Prefilled syringes
CDC recommendation	All adults 75 and older Adults 60-74 with increased risk	All adults 75 and older Adults 60-74 with increased risk Pregnant persons 32-36 weeks gestational age	All adults 75 and older Adults 60-74 with increased risk
Dose/route	0.5 mL /IM	0.5 mL /IM	0.5 mL /IM
Vaccine type	Viral subunit	Viral subunit	mRNA

Abrysvo: Efficacy

Efficacy evaluation period	Vaccine efficacy against outcome, % (95% CI)*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	88.9 (53.6–98.7)	84.6 (32.0–98.3)
Season 2 (interim)**	78.6 (23.2–96.1)	—††
Combined seasons 1 and 2 (interim)§§	84.4 (59.6–95.2)	81.0 (43.5–95.2)

MMWR *Weekly* / July 21, 2023 / 72(29);793–801

Abrysvo: Safety

Safety event	Risk for event		
	RSVpreF recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Serious AE**	792/18619 (4.3%)	749/18334 (4.1%)	1.04 (0.94–1.15)
Severe reactogenicity events††	36/3673 (1.0%)	24/3491 (0.7%)	1.43 (0.85–2.39)
Inflammatory neurologic events§§	3/18622 (—)¶¶	0/18335 (—)	—¶¶

MMWR *Weekly* / July 21, 2023 / 72(29);793–801

Arexvy: Efficacy

Efficacy evaluation period	Vaccine efficacy against outcome*	
	RSV-associated LRTD†	RSV-associated medically attended LRTD§
Season 1¶	82.6 (57.9–94.1)**	87.5 (58.9–97.6)††
Season 2§§	56.1 (28.2–74.4)††	—¶¶
Combined seasons 1 and 2 (interim)***	74.5 (60.0–84.5)†††	77.5 (57.9–89.0)††

MMWR *Weekly* / July 21, 2023 / 72(29);793–801

Arexvy: Safety

Safety event	Risk for event		
	RSVPreF3 recipients no./No. (%)†	Placebo recipients no./No. (%)§	Relative risk (95% CI)¶
Serious AE**	549/12,570 (4.4)	540/12,604 (4.3)	1.02 (0.91–1.15)
Severe reactogenicity events††	37/979 (3.8)	9/976 (0.9)	4.10 (1.99–8.45)
Inflammatory neurologic events§§	3 events in trials without placebo recipients¶¶	—¶¶	—¶¶

MMWR *Weekly* / July 21, 2023 / 72(29);793–801

mResvia: Efficacy

Efficacy to Prevent First Episode of RSV-LRTD With 2 or More Signs/Symptoms (8.6 Months Median Follow-up)

Subgroup	MRESVIA Cases, n/N†	Placebo Cases, n/N†	VE*, % (95% CI)
Overall (≥60 years)	48/18,074	127/18,010	62.5 (47.7, 73.1)
60 to 69 years	32/11,193	77/11,146	58.8 (37.8, 72.7)
70 to 79 years	10/5,455	45/5,431	78.0 (56.3, 88.9)
≥80 years	6/1,426	5/1,433	-20.0 (-293.3, 63.4)‡
≥60 years with ≥1 comorbidity§	17/5,365	51/5,244	67.4 (43.6, 81.2)

Fda.gov (mResvia package insert)

mResvia: Safety

Adverse Event	mRESVIA (N=18,154-18,156) %	Placebo (N=18,093-18,084) %
Injection-site pain	55.9	13.8
Fatigue	30.8	20.0
Headache	26.7	18.8
Myalgia	25.6	14.4
Arthralgia	21.7	14.0
Axillary (underarm) swelling/tenderness	15.2	6.1
Chills	11.6	6.8

Fda.gov (mResvia package insert)

Knowledge Check

Which of the following RSV Vaccines are approved for use in older adults and pregnant persons?

a. Abrysvo

b. Arexvy

c. mResvia

d. All of the above

ACIP Recommendation: Adults

All adults 75 years of age and older should receive a single dose of RSV vaccine.

Adults 60-74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.

Chronic medical conditions and risk factors for a risk-based recommendation for RSV vaccination in adults aged 60–74 years

- **Chronic cardiovascular disease** (e.g., heart failure, coronary artery disease, congenital heart disease; *excluding isolated hypertension*)
- **Chronic lung disease** (e.g., chronic obstructive pulmonary disease [COPD], emphysema, asthma, interstitial lung disease, cystic fibrosis)
- **Chronic kidney disease, advanced** (e.g., stages 4–5, dependence on hemodialysis or other renal replacement therapy)
- **Diabetes mellitus with end-organ damage** (e.g., diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease)
- **Severe obesity** (body mass index ≥40 kg/m²)
- **Decreased immune function** from disease or drugs (i.e., **immunocompromising conditions***)
- **Neurologic or neuromuscular conditions** (e.g., neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness; *excluding history of stroke without impaired airway clearance*)
- **Liver disorders** (e.g., cirrhosis)
- **Hematologic conditions** (e.g., sickle cell disease, thalassemia)
- **Frailty**
- **Residence in a nursing home or other long-term care facility**
- **Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to respiratory infection**

* List of immunocompromising conditions would match the existing list from the COVID-19 vaccination Interim Clinical Considerations.

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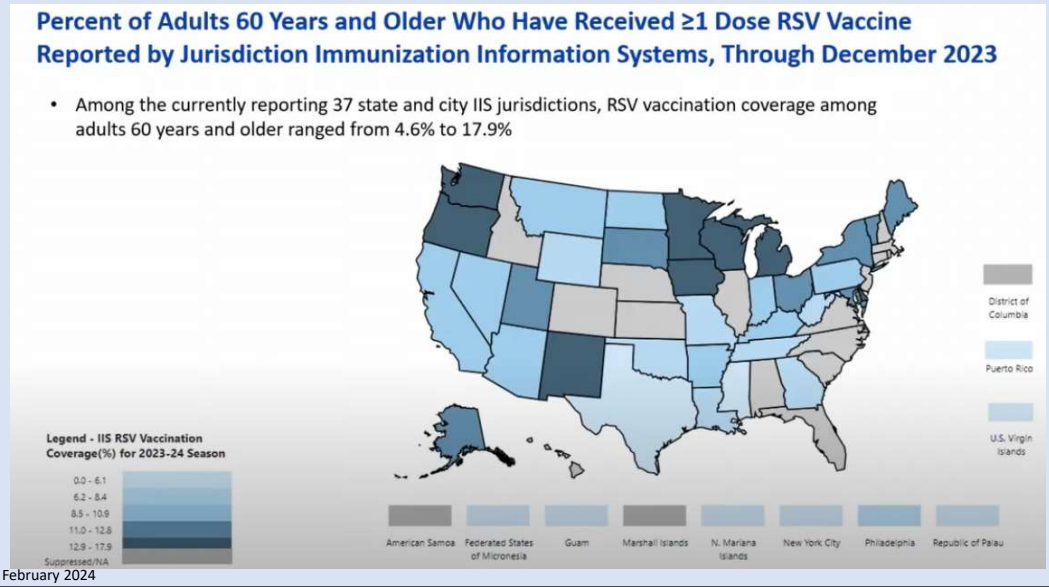
RSV Vaccination in the US: Adults 60 and Older

Percent of Adults 60 Years and Older Who Have Received ≥1 Dose RSV Vaccine Reported by Jurisdiction Immunization Information Systems, Through December 2023

- Among the currently reporting 37 state and city IIS jurisdictions, RSV vaccination coverage among adults 60 years and older ranged from 4.6% to 17.9%



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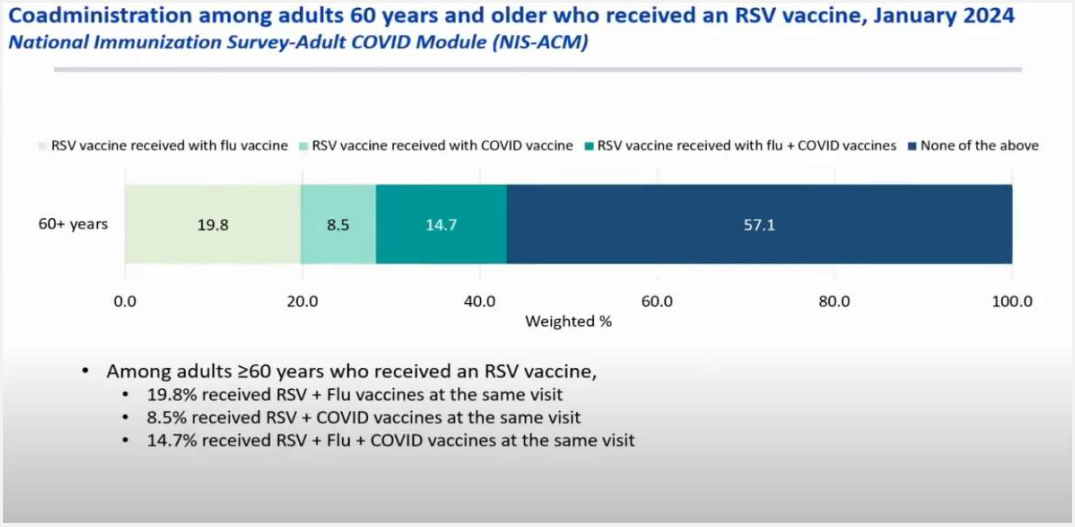
RSV Vaccination in the US: Adults 60 and Older



- Among adults ≥60 years who received an RSV vaccine,
  - 19.8% received RSV + Flu vaccines at the same visit
  - 8.5% received RSV + COVID vaccines at the same visit
  - 14.7% received RSV + Flu + COVID vaccines at the same visit

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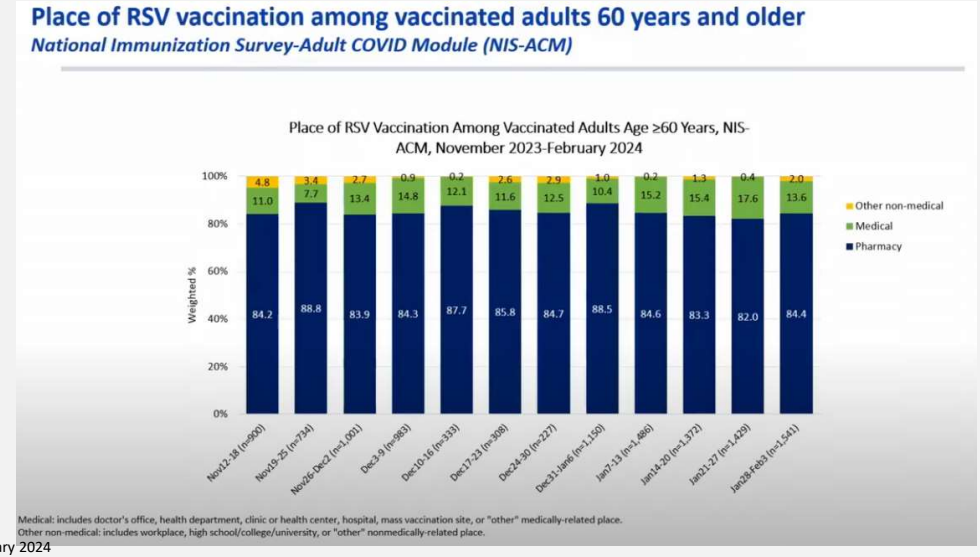
RSV Vaccination in the US: Adults 60 and Older



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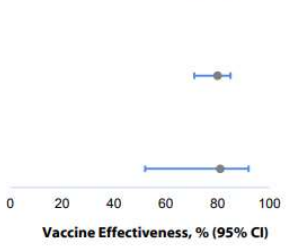
Ongoing Observation

- CDC guidance on implementing high risk categories 60-74 years
- Revaccination
- Age expansion
- Serious side effects
  - GBS
  - Immune thrombocytopenia (ITP)
- Effectiveness

VE against RSV-associated *ED visits*, *hospitalization*, and *critical illness* among immunocompetent adults aged ≥60 years, *October 1, 2023–March 31, 2024*

	Total	RSV-Positive, N (row %)	Median interval since last dose, days (IQR)	Vaccine Effectiveness*, % (95% CI)
RSV-associated *ED visits*				
≥60 years				
Unvaccinated (Ref)	33,491	2,645 (8)	NA	Ref
Vaccinated	3,030	57 (2)	67 (40–101)	**77 (70–83)**
RSV-associated *hospitalization*				
≥60 years				
Unvaccinated (Ref)	25,816	1567 (6)	NA	Ref
Vaccinated	2,455	35 (1)	74 (44–109)	**80 (71–85)**
RSV-associated *critical illness*†				
≥60 years				
Unvaccinated (Ref)	24,506	257 (1)	NA	Ref
Vaccinated	2,425	5 (<1)	74 (44–109)	**81 (52–92)**



VE was high against RSV-associated ED visits, hospitalization, and critical illness

*Odds ratios used to calculate VE estimates were adjusted for age, race/ethnicity, sex, underlying medical conditions, social vulnerability index, site, calendar time, and geographic region. VE was calculated as (1-adjusted odds ratio)*100%.
† Critical illness was defined as intensive care unit admission and/or death

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