

Maternal RSV Vaccine Effective in Reducing RSV Infections and Hospitalizations in Infants

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Key Findings:

- Babies born to mothers who receive the respiratory syncytial virus (RSV) vaccine during pregnancy are 61% less likely to have an RSV infection compared to babies whose mother did not receive the RSV vaccine.
- Babies born to mothers who receive the RSV vaccine during pregnancy are 78% less likely to be admitted to the hospital with RSV compared to babies whose mother did not receive the RSV vaccine.

In 2023, the U.S. Food and Drug Administration (FDA) approved a vaccine for respiratory syncytial virus (RSV) to be administered during pregnancy to prevent RSV in infants.¹ To evaluate the real-world effectiveness of this new vaccine, we identified 393,561 babies born to mothers between September 2023 and May 2024 with 7.7% of mothers having a documented RSV vaccine. We then matched vaccinated mothers to unvaccinated mothers in a ratio of 1:4 by birth month and gestational age of the infant at birth, resulting in a study population of 58,060 births. We adjusted for maternal age, maternal comorbidities, Social Vulnerability Index quintile, rural or urban status, census region, neonatal infection in first 30 days of life, and prematurity.

We found that babies born to mothers who received the RSV vaccine during pregnancy were 61% less likely to have an RSV infection compared to those whose mother did not receive the RSV vaccine, as seen in Figure 1. Similarly, babies born to mothers who received the RSV vaccine during pregnancy were 78% less likely to be admitted to the hospital with RSV compared to those born to mothers who did not receive the RSV vaccine.

Likelihood of Infant RSV Infection or Hospitalization by Maternal RSV Vaccination Status

■ 95% Confidence Interval

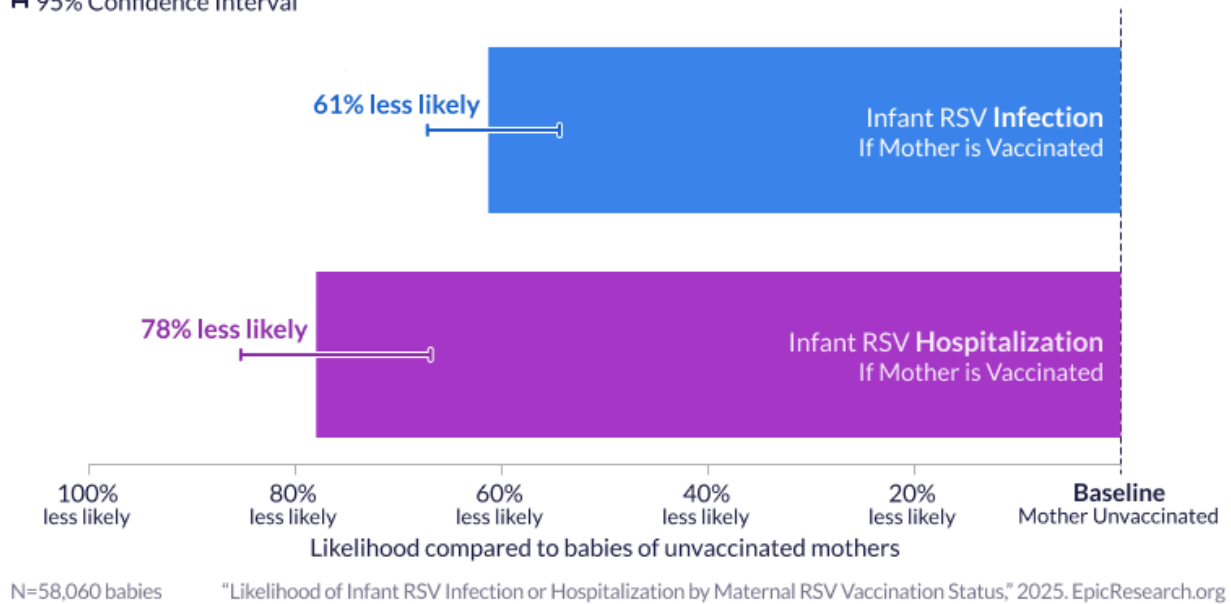


Figure 1. The likelihood of a baby having an RSV infection or hospital admission by whether their mother received the RSV vaccine during pregnancy.

These data come from Cosmos, a dataset created in collaboration with a community of Epic health systems representing more than 289 million patient records from 1,600 hospitals and more than 37,000 clinics from all 50 states, Lebanon, and Saudi Arabia. This study was completed by two teams that worked independently, each composed of a clinician and research scientists. The two teams came to similar conclusions. Graphics by Brian Olson.

References

1. FDA approves first vaccine for pregnant individuals to prevent RSV in infants. U.S. Food and Drug Administration. September 21, 2023. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants>. Accessed December 17, 2024.

Data Definitions

Term	Definition
Study period	Births between 9/1/2023 and 5/31/2024
Study population	<p>A birth that occurred in the United States during the study period with a link to a mother’s record in Cosmos.</p> <p>Inclusions:</p> <ul style="list-style-type: none"> • A newborn face-to-face visit after six months of age • A vaccine registry query on the mom’s chart two weeks before birth or later • A vaccine registry query on the baby’s chart after 6-months of age <p>Exclusions:</p>

	<ul style="list-style-type: none"> • Gestational age less than 32 weeks or greater than 44 weeks • Births to mothers younger than 18 • Babies who received any RSV vaccine with a CVX code of 303, 304, 305, 306, 307, 314, 315, or 326 in the first year after birth • Mothers who received an RSV vaccine not indicated for pregnancy with a CVX code of 303, 306, 307, 315, or 326
RSV vaccine	A vaccine with CVX code 304, 305, or 314 given to the mother during pregnancy
RSV	In the first six months after birth, a diagnosis with ICD-10-CM code J12.1*, J20.5*, J21.0*, or B97.4* or a lab with an abnormal result or value of "Detected" with LOINC code 14129-1, 17520-8, 55100-2, 88527-7, 91782-3, 91785-6, 101425-7, 77022-2, 88595-4, 91795-5, 101426-5, 77023-0, 88597-0, 91794-8, 101298-8, 76088-4, 76089-2, 82176-9, 85479-4, 91133-9, 92131-2, 92957-0, 30075-6, 101982-7, 41456-5, 80597-8, 88204-3, 80598-6, 88202-7, 30076-4, 40987-0, 88528-5, 60271-4, 40988-8, 31949-1, 31950-9, 32040-8, 33045-6, 50329-2, 5874-3, 5875-0, 5876-8, 5877-6, 68966-1, 72885-7, 77389-5, 77390-3, or 88909-7
Confounders	<p>RUCA: Metropolitan, Micropolitan, Small Town, Rural Census Region: West, South, Midwest, Northeast Social Vulnerability Index quintile Maternal age: 18-24, 25-34, 35+ Baby infection: A diagnosis with ICD-10-CM code P23.1, P39.1, P00.82, A32*, P37.2, P35.0, A50*, B58*, P37.1, or P35.4 in first 30 days after birth Maternal comorbidities:</p> <ul style="list-style-type: none"> • Autoimmune: A diagnosis with ICD-10-CM code M32.9, O99.891, R76.0, D68.61, M06.9, O99.11*, O99.12*, or L40.5* • Infection: A diagnosis with ICD-10-CM code O98*, O99.82*, N76.0, A56.0*, A56.8, B08.3, A54.0*, Z22.330, B16*, B18.0, B18.1, B17.1*, B19.1*, B18.2, B19.2*, B20, B97.7, A69.2*, B06*, A51*, A52*, A59*, or A92.5 • Hypertension: A diagnosis with ICD-10-CM code O10*-O13* • Diabetes: A diagnosis with ICD-10-CM code O24.1* or O24.4* <p>Prematurity: Gestational age before 37 weeks</p>
RUCA	Rural-Urban Commuting Area is a classification of geographic areas based on population density, urbanization, and daily commuting. It ranges from 1 to 10, with lower values indicating more urban areas and higher values indicating more rural areas.
Social Vulnerability Index	The social vulnerability quintile for the ZIP Code of the patient's most recent address.
Model specifications	<p>Births where the mother received the RSV vaccine were matched to unvaccinated mothers 1:4, matching on the calendar month of birth and gestational age in weeks.</p> <p>Vaccine effectiveness was calculated from the hazard ratio from a Cox proportional hazards regression.</p>

Table 1: Characteristics of Study Population

	Total	Total (%)	Unvax	Unvax (%)	Maternal RSV Only	Maternal RSV Only (%)
All	58,060	100.0%	46,448	80.0%	11,612	20.0%
Maternal Age 18 to 24	10,432	18.0%	9,228	19.9%	1,204	10.4%
Maternal Age 25 to 34	34,261	59.0%	27,411	59.0%	6,850	59.0%
Maternal Age 35 to 44	13,173	22.7%	9,662	20.8%	3,511	30.2%
Maternal Age 45 Plus	194	0.3%	147	0.3%	47	0.4%
Baby Infection	4,942	8.5%	4,005	8.6%	937	8.1%
Maternal Autoimmune	17,944	30.9%	14,277	30.7%	3,667	31.6%
Maternal Diabetes	7,435	12.8%	5,870	12.6%	1,565	13.5%
Maternal Hypertension	12,299	21.2%	9,741	21.0%	2,558	22.0%
Maternal Infection	17,528	30.2%	14,345	30.9%	3,183	27.4%
SVI_Q1	7,434	12.8%	5,284	11.4%	2,150	18.5%
SVI_Q2	9,937	17.1%	7,349	15.8%	2,588	22.3%
SVI_Q3	10,338	17.8%	8,037	17.3%	2,301	19.8%
SVI_Q4	13,345	23.0%	11,091	23.9%	2,254	19.4%
SVI_Q5	17,005	29.3%	14,687	31.6%	2,318	20.0%
RUCA Rural	1,619	2.8%	1,338	2.9%	281	2.4%
RUCA Small Town	2,475	4.3%	2,105	4.5%	370	3.2%
RUCA Micropolitan	5,172	8.9%	4,444	9.6%	728	6.3%
RUCA Metropolitan	48,794	84.0%	38,561	83.0%	10,233	88.1%
Census Region NE	6,860	11.8%	5,619	12.1%	1,241	10.7%
Census Region MW	27,708	47.7%	21,388	46.0%	6,320	54.4%
Census Region S	16,258	28.0%	14,457	31.1%	1,801	15.5%
Census Region W	7,234	12.5%	4,984	10.7%	2,250	19.4%
Outcome Baby RSV Infection	1,916	3.3%	1,757	3.8%	159	1.4%
Outcome Baby RSV Admission	477	0.8%	452	1.0%	25	0.2%
Premature	4,185	7.2%	3,348	7.2%	837	7.2%
Birth Month 2023-09-01	-	-	-	-	-	-
Birth Month 2023-10-01	250	0.4%	200	0.4%	50	0.4%
Birth Month 2023-11-01	3,135	5.4%	2,508	5.4%	627	5.4%
Birth Month 2023-12-01	12,940	22.3%	10,352	22.3%	2,588	22.3%
Birth Month 2024-01-01	12,520	21.6%	10,016	21.6%	2,504	21.6%
Birth Month2024-02-01	10,955	18.9%	8,764	18.9%	2,191	18.9%
Birth Month2024-03-01	11,685	20.1%	9,348	20.1%	2,337	20.1%
Birth Month 2024-04-01	6,085	10.5%	4,868	10.5%	1,217	10.5%
Birth Month2024-05-01	485	0.8%	388	0.8%	97	0.8%

Table 2: Likelihood of Infant RSV Infection or Hospitalization by Maternal RSV Vaccination Status – RSV Infection

Covariate	exp(coef)	exp(coef) lower 95%	exp(coef) upper 95%
RSV Vaccination	0.39	0.33	0.46
Maternal Age 18 to 24	1.11	1.00	1.24
Maternal Age 35 to 44	0.78	0.68	0.88
Maternal Age 45 Plus	1.24	0.62	2.49
Baby Infection	1.18	1.01	1.38
Maternal Autoimmune	1.29	1.17	1.42
Maternal Diabetes	0.95	0.82	1.09
Maternal Hypertension	1.01	0.90	1.12
Maternal Infection	1.08	0.97	1.19
SVI_Q2	1.05	0.87	1.27
SVI_Q3	1.20	1.00	1.43
SVI_Q4	1.22	1.03	1.45
SVI_Q5	1.15	0.97	1.36
RUCA Rural	1.39	1.09	1.77
RUCA Small Town	1.42	1.17	1.72
RUCA Micropolitan	1.49	1.30	1.70
Census Region MW	1.53	1.29	1.81
Census Region S	1.44	1.20	1.71
Census Region W	1.13	0.91	1.40
Premature	1.34	1.15	1.56

Table 3: Likelihood of Infant RSV Infection or Hospitalization by Maternal RSV Vaccination Status – RSV Admission

Covariate	exp(coef)	exp(coef) lower 95%	exp(coef) upper 95%
RSV Vaccination	0.22	0.15	0.33
Maternal Age 18 to 24	1.19	0.95	1.48
Maternal Age 35 to 44	0.72	0.55	0.93
Maternal Age 45 Plus	1.20	0.30	4.84
Baby Infection	1.38	1.02	1.86
Maternal Autoimmune	1.49	1.24	1.80
Maternal Diabetes	0.94	0.71	1.24
Maternal Hypertension	1.13	0.91	1.40
Maternal Infection	0.86	0.70	1.06
SVI_Q2	0.85	0.60	1.22
SVI_Q3	1.02	0.73	1.43
SVI_Q4	1.09	0.79	1.51
SVI_Q5	0.92	0.67	1.27
RUCA Rural	1.40	0.88	2.22
RUCA Small Town	1.48	1.02	2.14
RUCA Micropolitan	1.16	0.86	1.55
Census Region MW	1.59	1.14	2.24
Census Region S	1.21	0.84	1.74
Census Region W	1.66	1.10	2.50
Premature	1.84	1.40	2.42