Protecting the Most Vulnerable: Updates in RSV Prevention for Mothers and Infants

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Disclosures

- Dr. Charlotte Roy: None
- Dr. Janine Hutson
 - o SPEAKER FEES: Pfizer
- Erin Fleischer
 - o ADVISORY BOARD: Abbvie, AstraZeneca, Sanofi, MDBriefcase
 - o SPEAKER FEES: Sanofi

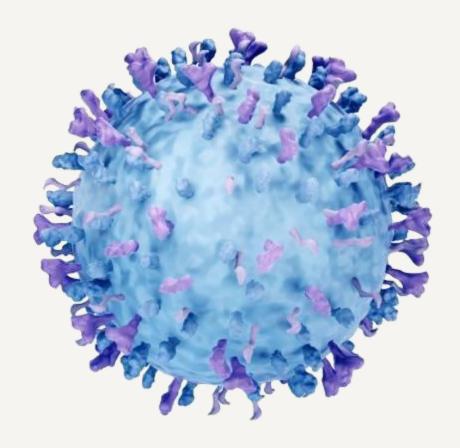
Objectives

- To review the current RSV prophylaxis options and literature to support the use of these
- To review our local 2024-25 RSV prophylaxis data and RSV admission rates
- To review the 2025-26 MOH guidelines and work being done to implement here at LHSC

9/15/2025

Review of RSV

- Single-stranded RNA virus
- Pathogen with highest disease burden in vulnerable populations such as children, elderly, immuno-compromised, or medically comorbid²
- Affects nearly all children <2 y.o.¹
- Can cause upper respiratory infection, bronchiolitis, lower respiratory infection, and even pneumonia, respiratory failure, or death



^{1.} Abrams, E. M., Doyon-Plourde, P. D., Davis, P., Brousseau, N., Irwin, A., Siu, W., & Killikelly, A. (2024). Burden of disease of respiratory syncytial virus in infants, young children and pregnant women and people. *Can Commun Dis Rep*, 50(1/2), 1-15. https://doi.org/10.14745/ccdr.v50i12a01

^{2.} Di Giallonardo, F., Kok, J., Fernandez, M., Carter, I., Geoghegan, J. L., Dwyer, D. E., Holmes, E. C., & Eden, J. (2018). Evolution of human respiratory syncytial virus (RSV) over multiple seasons in New South Wales, Australia. https://doi.org/10.20944/preprints201808.0318.v1



Burden of RSV in Tertiary Care Pediatric Hospitals

(IMPACT Network)

Data from 5 RSV seasons at 13 pediatric tertiary care centers (age 0 -16 years with laboratory-confirmed RSV infection)^{1*}

11 014 RSV associated hospitalization in children



0 - 5 months: 49.8 %

6 – 11 months: 11.3 %

23.6% Admitted to ICU



Of which 60.8% were children aged < 6 months

4 days (range 2 to 6) Median Hospital Stay

^{* 2017-2018} to 2021-2022.

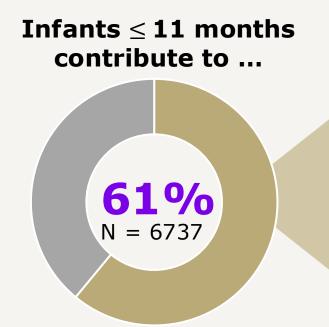
RSV=respiratory syncytial virus.

^{1.} Bourdeau, et al. JAMA Netw Open. 2023;6(10):e2336863. doi:10.1001/jamanetworkopen.2023.36863



Infants In the First Year Of Life Pose the Highest Hospitalization Burden From RSV Infection

Data from 5 RSV seasons at 13 pediatric tertiary care centers (age 0 - 16 years with laboratory-confirmed RSV infection, N=11014)^{1*}

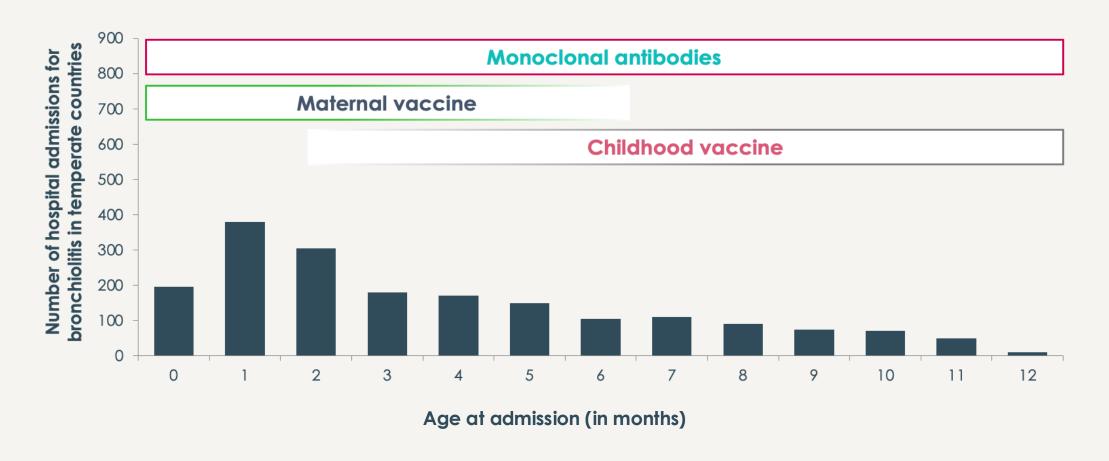


RSV Pediatric Hospitalizations



^{* 2017-2018} to 2021-2022.

Current Strategies for RSV Immunization Options



^{1.} Janet, S., Broad, J., & Snape, M. D. (2018). Respiratory syncytial virus seasonality and its implications on prevention strategies. *Human Vaccines & Immunotherapeutics*, *14*(1), 234-244. https://doi.org/10.1080/21645515.2017.1403707

9/15/2025

Current Strategies for RSV Immunization Options

Pregnancy:

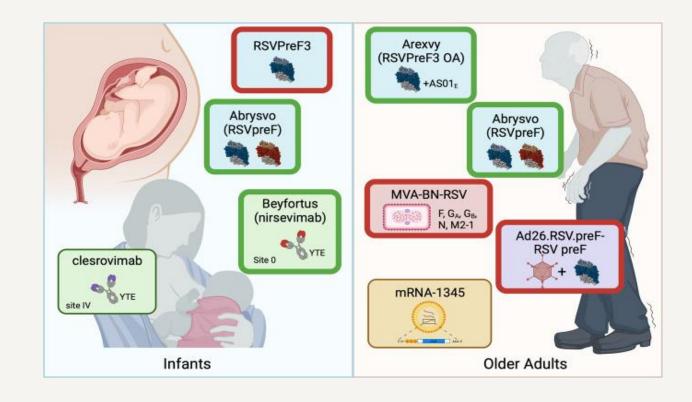
Abrysvo (RSVpreF)

Monoclonal Antibodies (Infants):

- Beyfortus (Nirsevimab)
- Synagis (Palivizumab)

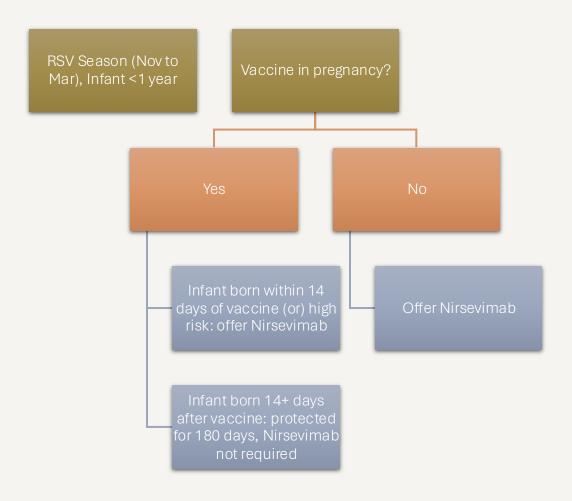
RSV Vaccines (Older Adults)

- Abrysvo (RSVpreF)
- Arexy (RSVpreF3)
- mRESVIA (mRNA-1345)



^{1.} Respiratory syncytial virus (RSV) vaccines: Canadian immunization guide. (2025, May 14). Canada.ca. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/respiratory-syncytial-virus.html#a2

2024 – 2025 LHSC Administration Plan



9/15/2025

2024 - 2025 Abrysvo Doses at LHSC

Between November 1, 2024 and March 30, 2025



- Single dose bivalent vaccine
- Per Pfizer Canada . . .

Indication

- 1. Immunization of pregnant individuals from 32 to 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age
- 2. The prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older by active immunization

PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION

ABRYSVOTM

Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine

Lyophilized Powder for Solution, 120 mcg RSV stabilized prefusion F protein per 0.5 mL,

Reconstituted Solution for Intramuscular Injection

Active Immunizing Agent

- Single dose bivalent vaccine
- Per Pfizer Canada . . .

Dosage

1. Administered intramuscularly as a single dosage (0.5mL) in the third trimester of pregnancy

PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION

ABRYSVOTM

Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine

Lyophilized Powder for Solution, 120 mcg RSV stabilized prefusion F protein per 0.5 mL,

Reconstituted Solution for Intramuscular Injection

Active Immunizing Agent

- MATISSE Clinical Trial (2023)
 - o Phase 3 double-blind trial in 18 countries
 - o Bivalent RSVpreF vaccine (vs. placebo)
 - o Pregnant women 24 to 36 weeks
 - o Primary end points:
 - 1. Medically attended severe RSV-associated LRTI
 - 2. Medically attended RSV-associated lower respiratory tract illness, RSV-associated hospitalization, and medically attended lower respiratory tract illness of any cause

ON THIS DAY IN 2023

Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

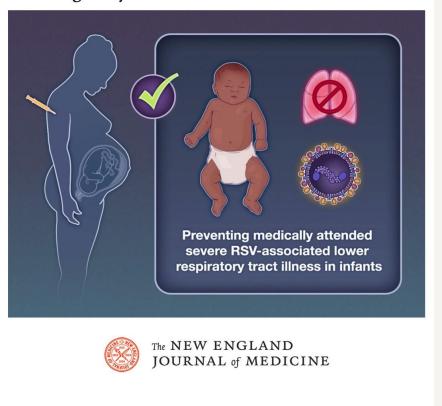


^{1.} Kampmann, B., Madhi, S. A., Munjal, I., Simoes, E., Pahud, B., Llapur, C., & Baker, J. (2023). Bivalent Prefusion F vaccine in pregnancy to prevent RSV illness in infants. New England Journal of Medicine, 388(16), 1451-1464. https://doi.org/10.1056/nejmc2307729

- MATISSE Clinical Trial (2023)
 - o Phase 3 double-blind trial in 18 countries
 - o Bivalent RSVpreF vaccine (vs. placebo)
 - o Pregnant women 24 to 36 weeks
 - Exploratory end points:
 - 1. Medically attended RSV-associated respiratory tract illness and medically attended RSV-associated lower respiratory tract illness due to RSV A or RSV B

ON THIS DAY IN 2023

Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants



1. Kampmann, B., Madhi, S. A., Munjal, I., Simoes, E., Pahud, B., Llapur, C., & Baker, J. (2023). Bivalent Prefusion F vaccine in pregnancy to prevent RSV illness in infants. New England Journal of Medicine, 388(16), 1451-1464. https://doi.org/10.1056/nejmc2307729

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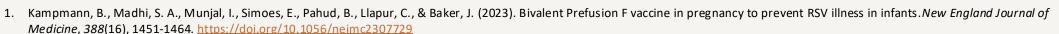
- MATISSE Clinical Trial (2023)
 - o Phase 3 double-blind trial in 18 countries
 - o Bivalent RSVpreF vaccine (vs. placebo)
 - o Pregnant women 24 to 36 weeks
 - o Safety end points:
 - 1. Reactogenicity
 - 2. Adverse events*

*both maternal participants and infants

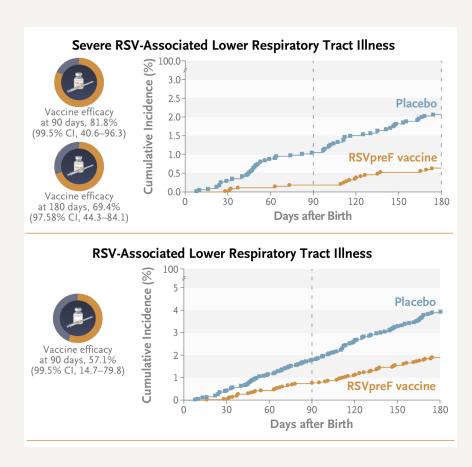


Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants





- 7358 women in trial
- Vaccine efficacy for severe LRTI
 - o 81.8% within 90 days after birth
 - o 69.4% within 180 days after birth
- Safety: side effect profile similar to Phase I/II, with mild to moderate events (redness, swelling, injection site pain)



^{1.} Kampmann, B., Madhi, S. A., Munjal, I., Simoes, E., Pahud, B., Llapur, C., & Baker, J. (2023). Bivalent Prefusion F vaccine in pregnancy to prevent RSV illness in infants. New England Journal of Medicine, 388(16), 1451-1464. https://doi.org/10.1056/nejmc2307729

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CONCLUSIONS

When administered to women late in pregnancy, RSVpreF vaccine was effective against medically attended severe RSV-associated lower respiratory tract illness in infants.

^{1.} Kampmann, B., Madhi, S. A., Munjal, I., Simoes, E., Pahud, B., Llapur, C., & Baker, J. (2023). Bivalent Prefusion F vaccine in pregnancy to prevent RSV illness in infants. *New England Journal of Medicine*, 388(16), 1451-1464. https://doi.org/10.1056/neimc2307729

- Multicentre (12 hospitals) retrospective case-control study across Argentina from April to September of 2024
- Aim: to evaluate the effectiveness of a national maternal immunization programmed with RSVpreF as the primary strategy to prevent RSV disease among infants
- 3-year study → report following the first season
 - o 140,000 pregnant individuals received RSVpreF
 - o 60% of pregnant population



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^{1.} Pérez Marc, G., Vizzotti, C., Fell, D. B., Di Nunzio, L., Olszevicki, S., Mankiewicz, S. W., Braem, V., Rearte, R., Atwell, J. E., Bianchi, A., Fuentes, N., Zadoff, R., Vecchio, G., Gabriela Abalos, M., Fan, R., Del Carmen Morales, G., Gessner, B. D., Jodar, L., Libster, R., ... Rearte, A. (2025). 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*, 25(9), 1044-1054. https://doi.org/10.1016/s1473-3099(25)00156-2

- Primary outcome
 - RSV-associated LRTD leading to hospitalization
- Secondary outcome
 - o RSV-associated severe LRTD requiring hospitalization
 - Mechanical ventilation or high-flow oxygen
 - SpO2 <90%
 - ICU admission for >4h
 - Failure to respond or loss of consciousness

1. Pérez Marc, G., Vizzotti, C., Fell, D. B., Di Nunzio, L., Olszevicki, S., Mankiewicz, S. W., Braem, V., Rearte, R., Atwell, J. E., Bianchi, A., Fuentes, N., Zadoff, R., Vecchio, G., Gabriela Abalos, M., Fan, R., Del Carmen Morales, G., Gessner, B. D., Jodar, L., Libster, R., ... Rearte, A. (2025). 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*, 25(9), 1044-1054. https://doi.org/10.1016/s1473-3099(25)00156-2

	Case infants (RSV positive)		Control infants (RSV negative)		Crude odds ratio (95% CI)*	VE (95% CI)
	Mother received RSVpreF vaccine n/N (%)	Mother did not receive RSVpreF vaccine n/N (%)	Mother received RSVpreF vaccine n/N (%)	Mother did not receive RSVpreF vaccine n/N (%)		
RSV-associated LRTD leading to hospitalisation						
0 to ≤3 months (0 to ≤90 days)	39/201 (19%)	162/201 (81%)	82/145 (57%)	63/145 (43%)	0.18 (0.11-0.30)	78.6% (62.1–87.9)†
0 to ≤6 months (0 to ≤180 days)	51/286 (18%)	235/286 (82%)	109/219 (50%)	110/219 (50%)	0.21 (0.14-0.32)	71.3% (53.3–82.3)‡
RSV-associated severe LRTD leading to hospitalisation						
0 to ≤6 months (0 to ≤180 days)	22/142 (15%)	120/142 (85%)	31/65 (48%)	34/65 (52%)	0.19 (0.10-0.38)	76.9% (45.0–90.3)§

Data are n (%) unless stated otherwise. LRTD=lower respiratory tract disease; RSV=respiratory syncytial virus. RSVpreF=respiratory syncytial virus prefusion F vaccine. VE=vaccine effectiveness. *Crude OR calculated using multi-level logistic regression model with site-specific random effect. †VE calculated as (1-adjusted OR) x 100, where the adjusted OR was generated using a multilevel logistic regression model with site-specific random effect, conception date, and calendar date of hospitalisation as natural cubic splines, inverse probability-of-treatment weights, and a fixed effect for infant sex (see appendix 2 p 8 for information on inverse probability-of-treatment weight methodology). ‡VE calculated as (1-adjusted OR) x 100, where the adjusted OR was generated using a multilevel logistic regression model with site-specific random effect, conception date, calendar date of hospitalisation, and infant age at hospitalisation as natural cubic splines; and inverse probability-of-treatment weights. §VE calculated as (1-adjusted OR) x 100, where the adjusted OR was generated using a multilevel logistic regression model with site-specific random effect, calendar date of hospitalisation and infant age at hospitalisation as natural cubic splines, inverse probability-of-treatment weights, and a fixed effect for complete exposure window.

Table 3: Effectiveness of maternal RSVpreF vaccination during pregnancy against RSV-associated LRTD and severe LRTD leading to hospitalisation among infants from birth to 6 months of age

^{1.} Pérez Marc, G., Vizzotti, C., Fell, D. B., Di Nunzio, L., Olszevicki, S., Mankiewicz, S. W., Braem, V., Rearte, R., Atwell, J. E., Bianchi, A., Fuentes, N., Zadoff, R., Vecchio, G., Gabriela Abalos, M., Fan, R., Del Carmen Morales, G., Gessner, B. D., Jodar, L., Libster, R., ... Rearte, A. (2025). 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*, 25(9), 1044-1054. https://doi.org/10.1016/s1473-3099(25)00156-2

Vaccine effectiveness against RSV-associated severe LRTD leading to hospitalization from birth to age 6 months in BERNI (76.9%, 95% CI 45.0-90.3) was similar to efficacy against medically attended severe RSV-associated LRTD in MATISSE (69.4%, 97.58% CI 44.3-84.1)

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^{1.} Pérez Marc, G., Vizzotti, C., Fell, D. B., Di Nunzio, L., Olszevicki, S., Mankiewicz, S. W., Braem, V., Rearte, R., Atwell, J. E., Bianchi, A., Fuentes, N., Zadoff, R., Vecchio, G., Gabriela Abalos, M., Fan, R., Del Carmen Morales, G., Gessner, B. D., Jodar, L., Libster, R., ... Rearte, A. (2025). 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*, 25(9), 1044-1054. https://doi.org/10.1016/s1473-3099(25)00156-2

Motivation for Vaccination

Barriers to Vaccination

Vaccine Promotion Strategies Recommendations, Choices



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^{1.} Wang, B., Lassi, Z., Andraweera, P., Chen, G., Ong, J. J., McMillian, M., & Marshall, H. (2025). Pregnant women's choices for preventing respiratory syncytial virus (RSV). *Vaccine*, 48, 126790. https://doi.org/10.1016/j.vaccine.2025.126790

Motivation for Vaccination

- Lived experience
- Desire to protect baby
- Protection of the population including children
- Vulnerability during pregnancy*



^{1.} Wang, B., Lassi, Z., Andraweera, P., Chen, G., Ong, J. J., McMillian, M., & Marshall, H. (2025). Pregnant women's choices for preventing respiratory syncytial virus (RSV). *Vaccine*, 48, 126790. https://doi.org/10.1016/j.vaccine.2025.126790

Barriers to Vaccination

9/15/2025

- Safety Concerns
- Duration of Protection
- Costs*
- Preference for More Evidence
- Impact of COVID-19 on Vaccine Perception
- Additional Vaccines



^{1.} Wang, B., Lassi, Z., Andraweera, P., Chen, G., Ong, J. J., McMillian, M., & Marshall, H. (2025). Pregnant women's choices for preventing respiratory syncytial virus (RSV). *Vaccine*, 48, 126790. https://doi.org/10.1016/j.vaccine.2025.126790

Vaccine Promotion Strategies

- Incorporate into Routine Antenatal Care
- Reminders
- Availability at Pharmacies
- Increased Awareness
- Early Discussions
- Traditional Promotion and Social Media*
- Multiple Languages
- Offering Incentives?*



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^{1.} Wang, B., Lassi, Z., Andraweera, P., Chen, G., Ong, J. J., McMillian, M., & Marshall, H. (2025). Pregnant women's choices for preventing respiratory syncytial virus (RSV). *Vaccine*, 48, 126790. https://doi.org/10.1016/j.vaccine.2025.126790

Recommendations, Choices

- Recommendations
- Maternal vs. Infant



^{1.} Wang, B., Lassi, Z., Andraweera, P., Chen, G., Ong, J. J., McMillian, M., & Marshall, H. (2025). Pregnant women's choices for preventing respiratory syncytial virus (RSV). *Vaccine*, 48, 126790. https://doi.org/10.1016/j.vaccine.2025.126790

Consider this . . .

- 33-year-old G2 1-0-0-1 at 22 weeks and 4 days presents to clinic for routine antenatal visit
- Reports having new cough, SOB on exertion, worsening fatigue
- Sick contacts: 2-year-old daughter recently sick at home
- Respiratory panel collected:

Consider this . . .

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- Reports having new cough, SOB on exertion, worsening fatigue
- Sick contacts: 2-year-old daughter recently sick at home
- Respiratory panel collected:

Microbiology/Virology	
COVID19 Interpretation	* COVID-19
Influenza A Interpretation	Not Detecte
Influenza B Interpretation	Not Detecte
Respiratory Syncytial virus Interp	# Detected

Hause et al. 2018

The Journal of Infectious Diseases









A Cross-sectional Surveillance Study of the Frequency and Etiology of Acute Respiratory Illness Among Pregnant Women

Anne M. Hause, ^{1,2} Vasanthi Avadhanula, ¹ Maurizio L. Maccato, ^{1,3,4} Phillip M. Pinell, ^{1,3,4} Nanette Bond, ¹ Patricia Santarcangelo, ¹ Laura Ferlic-Stark, ¹ Flor M. Munoz, ^{1,3} and Pedro A. Piedra ^{1,3}

¹Department of Molecular Virology and Microbiology, ²Department of Translational Biology and Molecular Medicine, and ³Department of Pediatrics, Baylor College of Medicine, and ⁴Woman's OB/GYN Specialists, Houston, Texas

- 1. Wheeler, S. M., Dotters-Katz, S., Heine, R. P., Grotegut, C. A., & Swamy, G. K. (2015). Maternal effects of respiratory syncytial virus infection during pregnancy. *Emerging Infectious Diseases*, 21(11), 1951-1955. https://doi.org/10.3201/eid2111.150497
- 2. Hause, A. M., Avadhanula, V., Maccato, M. L., Pinell, P. M., Bond, N., Santarcangelo, P., Ferlic-Stark, L., Munoz, F. M., & Piedra, P. A. (2018). A cross-sectional surveillance study of the frequency and etiology of acute respiratory illness among pregnant women. *The Journal of Infectious Diseases*, 218(4), 528-535. https://doi.org/10.1093/infdis/jiy167

- Hause et al. 2018
 - Pregnant women in outpatient
 obstetrics clinic in Houston Texas
 - o October 2015 to May 2016
 - Amongst patients with symptoms of respiratory illness, 52 had respiratory pathogens - including 8 with RSV

Table 4. Respiratory Pathogens Identified by Real-Time Reverse-Transcription Polymerase Chain Reaction in Pregnant Women With (Cases) and Those Without (Controls) Acute Respiratory Illness

Pathogen Detected	Cases, No. (%) (n = 81) ^a	Controls, No. (%) (n = 91)	Р
Human rhinovirus	22 (27)	6 (7)	<.01
HCoV	14 (17)	2 (2)	<.01
HCoV HKU1	6 (7)	1 (1)	
HCoV NL63	6 (7)	0	
HCoV OC43	2 (2)	1 (1)	
Respiratory syncytial virus	8 (10)	0	<.01
Group A	7 (9)	0	
Group B	1 (1)	0	
Influenza virus	4 (5)	0	
A(H3N2)	2 (2)	0	
A(H1N1)pdm09	2 (2)	0	
Human metapneumovirus	2 (2)	0	
Parainfluenza virus 1	1 (1)	0	
Bordetella pertussis	1 (1)	0	
Bocavirus	0	1 (1)	
Adenovirus	0	1 (1)	
None	30 (37)	81 (89)	<.01

Abbreviations: A(H1N1)pdm09, 2009 pandemic influenza A(H1N1) virus; HCoV, human coronavirus.

^aOne case positive for RSV group A was also positive for human rhinovirus.

^{1.} Hause, A. M., Avadhanula, V., Maccato, M. L., Pinell, P. M., Bond, N., Santarcangelo, P., Ferlic-Stark, L., Munoz, F. M., & Piedra, P. A. (2018). A cross-sectional surveillance study of the frequency and etiology of acute respiratory illness among pregnant women. *The Journal of Infectious Diseases, 218*(4), 528-535. https://doi.org/10.1093/infdis/jiy167

- Hause et al. 2019
 - Pregnant women in obstetrics clinic in Houston Texas
 - o November 2015 to May 2016
 - Assessed RSV by PCR or serology
 - Compared women with PCR-confirmed infection to women enrolled as healthy controls

- Symptoms
 - o Cough
 - o Congestion
 - Sore throat

^{1.} Hause, A. M., Avadhanula, V., Maccato, M. L., Pinell, P. M., Bond, N., Santarcangelo, P., Ferlic-Stark, L., Ye, X., Iwuchukwu, O., Maurer, L., Aideyan, L., Dao, K., McBride, T., Piedra, P. A., & Munoz, F. M. (2019). Clinical characteristics and outcomes of respiratory syncytial virus infection in pregnant women. *Vaccine*, *37*(26), 3464-3471. https://doi.org/10.1016/j.vaccine.2019.04.098

- Hause et al. 2019
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- Symptoms
 - o Cough
 - o Congestion
 - Sore throat
 - o SOB
 - Wheezing
 - o Fever
 - Chest pain
 - o Pneumonia
 - Hospitalization

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^{1.} Hause, A. M., Avadhanula, V., Maccato, M. L., Pinell, P. M., Bond, N., Santarcangelo, P., Ferlic-Stark, L., Ye, X., Iwuchukwu, O., Maurer, L., Aideyan, L., Dao, K., McBride, T., Piedra, P. A., & Munoz, F. M. (2019). Clinical characteristics and outcomes of respiratory syncytial virus infection in pregnant women. *Vaccine*, *37*(26), 3464-3471. https://doi.org/10.1016/j.vaccine.2019.04.098

In summary, RSV is a common cause of ARI during pregnancy with appreciable morbidity. Although the primary goal of maternal immunization against RSV is to protect young infants who are at increased risk for severe disease, a maternal RSV vaccine may also directly benefit pregnant women. As maternal RSV vaccine candidates move forward in evaluation, additional priority should be placed on evaluating the impact of RSV disease prevention in pregnant women.

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^{1.} Hause, A. M., Avadhanula, V., Maccato, M. L., Pinell, P. M., Bond, N., Santarcangelo, P., Ferlic-Stark, L., Ye, X., Iwuchukwu, O., Maurer, L., Aideyan, L., Dao, K., McBride, T., Piedra, P. A., & Munoz, F. M. (2019). Clinical characteristics and outcomes of respiratory syncytial virus infection in pregnant women. *Vaccine*, *37*(26), 3464-3471. https://doi.org/10.1016/j.vaccine.2019.04.098

Pregnant patients with respiratory syncytial virus infection: Assessment of characteristics and maternal morbidity at delivery

- Published in AJOG 2024
- Cross-section study
- Patients with diagnosis of RSV infection (co-infection with influenza excluded) between 2016 and 2019
 - o Total of 16, 350 patients who had RSV infection in pregnancy
- Outcomes measured:
 - Seasonal RSV rates
 - Pregnancy and delivery characteristics
 - o Severe maternal morbidity at delivery associated with RSV

^{1.} Cox, K. R., Mandelbaum, R. S., Brueggmann, D., Ouzounian, J. G., & Matsuo, K. (2024). Pregnant patients with respiratory syncytial virus infection: Assessment of characteristics and maternal morbidity at delivery. *AJOG Global Reports*, *4*(1), 100289. https://doi.org/10.1016/j.xagr.2023.100289

TABLE								
Severe maternal morbidity								
Outcome measure	RSV (—) ^a	RSV (+) ^a	aOR (95% CI) ^b	<i>P</i> value				
Severe maternal morbidity (composite)								
Any ^c	17.3	49.8	1.82 (1.69-1.96)	<.001				
Except for blood transfusion	7.6	29.7	1.94 (1.76-2.14)	<.001				
Except for blood transfusion/hysterectomy	6.9	26.6	1.94 (1.75-2.14)	<.001				
Individual morbidity indicator ^d								
Blood products transfusion	11.1	25.4	1.60 (1.45-1.77)	<.001				
Acute renal failure	1.2	6.1	1.88 (0.53-2.30)	<.001				
Adult respiratory distress syndrome	0.8	5.5	2.62 (2.12-3.24)	<.001				
Sepsis	1.0	5.2	2.63 (2.15-3.32)	<.001				
Coagulopathy	1.7	4.6	1.83 (1.46-2.30)	<.001				
Hysterectomy	0.9	3.7	1.60 (1.14-2.26)	.007				
Pulmonary edema/acute heart failure	0.7	3.4	1.54 (1.18-2.02)	.002				
-OD - di-stad - dddi O/fidi-t	at - 1 - 2							

aOR, adjusted odds ratio; CI, confidence interval; RSV, respiratory syncytial virus.

 $Cox.\ Respiratory\ syncytial\ virus\ infection\ and\ maternal\ morbidity.\ Am\ J\ Obstet\ Gynecol\ Glob\ Rep\ 2023.$

1. Cox, K. R., Mandelbaum, R. S., Brueggmann, D., Ouzounian, J. G., & Matsuo, K. (2024). Pregnant patients with respiratory syncytial virus infection: Assessment of characteristics and maternal morbidity at delivery. *AJOG Global Reports*, *4*(1), 100289. https://doi.org/10.1016/j.xagr.2023.100289

^a Outcome rates per 1000 deliveries were estimated;

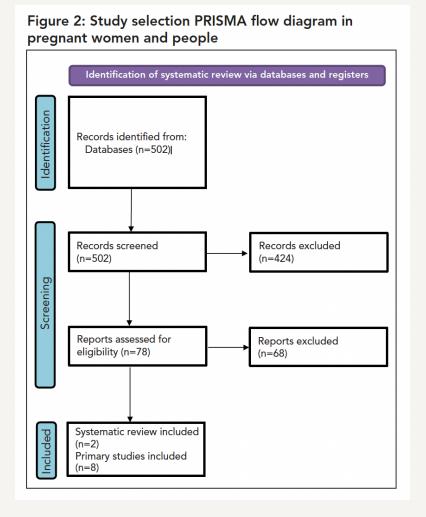
^b The exposure-outcome association was adjusted for patient demographics and pregnancy/delivery factors selected a priori (age, race/ethnicity, obesity, asthma, hypertensive disorder, diabetes mellitus, tobacco use, illicit drug use, region, gestational age, delivery mode, placenta accreta spectrum, placenta abruption, uterine rupture, hospital bed capacity, and hospital teaching setting). Effect size of the exposure group (RSV-infected patients compared with noninfected) on outcome measures (severe maternal morbidity). The non-RSV group served as the referent;

c Included any one of the 21 indicators for severe maternal morbidity per the Centers for Disease Control and Prevention definition: acute myocardial infarction, aneurysm, acute renal failure, adult respiratory distress syndrome, amniotic fluid embolism, cardiac arrest/ventricular fibrillation, cardiac rhythm conversion, disseminated intravascular coagulation, eclampsia, heart failure/arrest during surgery or procedure, puerperal cerebrovascular disorders, pulmonary edema/acute heart failure, severe anesthesia complications, sepsis, shock, sickle cell disease with crisis, air and thrombotic embolism, blood products transfusion, hysterectomy, temporary tracheostomy, and ventilation;

 $^{^{}d}$ Individual indicators with outcome rates \geq 3 per 1000 in the RSV group are displayed for the outcome rates in descending order.

Burden of disease of respiratory syncytial virus in infants, young children, and pregnant women and people

- PHAC 2025 Canada Communicable Disease Report
- Reviews include Canadian surveillance data
- Included 2 systematic reviewed and 8 primary studies



^{1.} Abrams, E. M., Doyon-Plourde, P. D., Davis, P., Brousseau, N., Irwin, A., Siu, W., & Killikelly, A. (2024). Burden of disease of respiratory syncytial virus in infants, young children and pregnant women and people. Can Commun Dis Rep, 50(1/2), 1-15. https://doi.org/10.14745/ccdr.v50i12a01

Maternal RSV

Burden of disease of respiratory syncytial virus in infants, young children, and pregnant women and people

- 10% of lower respiratory tract illness in pregnant people were RSV
- Higher hospitalization rates from RSV amongst pregnant women vs. nonpregnant adults
- Adverse outcomes in pregnant individuals hospitalized with RSV:
 - o Pneumonia
 - Respiratory failure
 - o Sepsis
 - o Preterm contraction
 - Co-infections
 - o Pre-eclampsia

^{1.} Abrams, E. M., Doyon-Plourde, P. D., Davis, P., Brousseau, N., Irwin, A., Siu, W., & Killikelly, A. (2024). Burden of disease of respiratory syncytial virus in infants, young children and pregnant women and people. *Can Commun Dis Rep*, 50(1/2), 1-15. https://doi.org/10.14745/ccdr.v50i12a01

Abrysvo in High-Risk Adults

- 2023 RENOIR Trial: Demonstrated efficacy and safety of RSVpreF in adults >60 y.o.
- Study of safety and immunogenicity of RSVpreF in adults 18-59 years old at high risk of severe RSV
 - o 3.3 to 6.2x more likely to be hospitalized due to RSV
- Randomized for RSVpreF 120mcg or placebo
- Outcomes:
 - o Immunogenicity
 - Safety

High Risk Adults

- Chronic pulmonary disease (ie. asthma)
- Cardiovascular disease excluding isolated hypertension
- Renal disease
- Hepatic disease
- Neurologic disease
- Hematologic disorders
- Metabolic disorders

^{1.} Walsh, E. E., Marc, G. P., Zareba, A. M., Falsey, A. R., Jiang, Q., Patton, M., & Polack, F. (2023). Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. *New England Journal of Medicine*, 388(16), 1465-1477. https://doi.org/10.1056/NEJMoa2213836

^{2.} Davis, M., Towner, W., DeHaan, E., Jiang, Q., Li, W., Rahman, F., Patton, M., Wyper, H., Lino, M. M., Sarwar, U. N., Majid-Mahomed, Z., Mehta, S., Howitt, W., Cannon, K., Kalinina, E., Cooper, D., Swanson, K. A., Anderson, A. S., Gurtman, A., & Munjal, I. (2025). Bivalent RSVpreF vaccine in adults 18 to <60 years old with high-risk conditions. *Clinical Infectious Diseases*, 80(4), 911-920. https://doi.org/10.1093/cid/ciae550

Abrysvo in High-Risk Adults

- Study of safety and immunogenicity of RSVpreF in adults 18-59 years old at high risk of severe RSV
- A single dose of RSVpreF:
 - o Robust neutralizing responses meeting immunogenicity endpoints
 - o Safety and tolerability acceptable
 - Mild or moderate local reactions and systemic events
 - Injection site pain more common
 - o Limits: Did not include those with immunocompromised conditions

High Risk Adults

- Chronic pulmonary disease (ie. asthma)
- Cardiovascular disease excluding isolated hypertension
- Renal disease
- Hepatic disease
- Neurologic disease
- Hematologic disorders

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Metabolic disorders

- 1. Walsh, E. E., Marc, G. P., Zareba, A. M., Falsey, A. R., Jiang, Q., Patton, M., & Polack, F. (2023). Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults. *New England Journal of Medicine*, 388(16), 1465-1477. https://doi.org/10.1056/NEJMoa2213836
- 2. Davis, M., Towner, W., DeHaan, E., Jiang, Q., Li, W., Rahman, F., Patton, M., Wyper, H., Lino, M. M., Sarwar, U. N., Majid-Mahomed, Z., Mehta, S., Howitt, W., Cannon, K., Kalinina, E., Cooper, D., Swanson, K. A., Anderson, A. S., Gurtman, A., & Munjal, I. (2025). Bivalent RSVpreF vaccine in adults 18 to <60 years old with high-risk conditions. *Clinical Infectious Diseases*, 80(4), 911-920. https://doi.org/10.1093/cid/ciae550

Current Recommendations

- SOGC (2024): Maternal vaccination and infant nirsevimab are both effective in reducing the burden of RSV disease and hospitalization in newborns. If both are available, nirsevimab is currently first-line recommended option
- NACI (2025): NACI recommends building towards a universal RSV immunization program for all infants. Currently, nirsevimab is preferred over RSVpreF



Current Recommendations

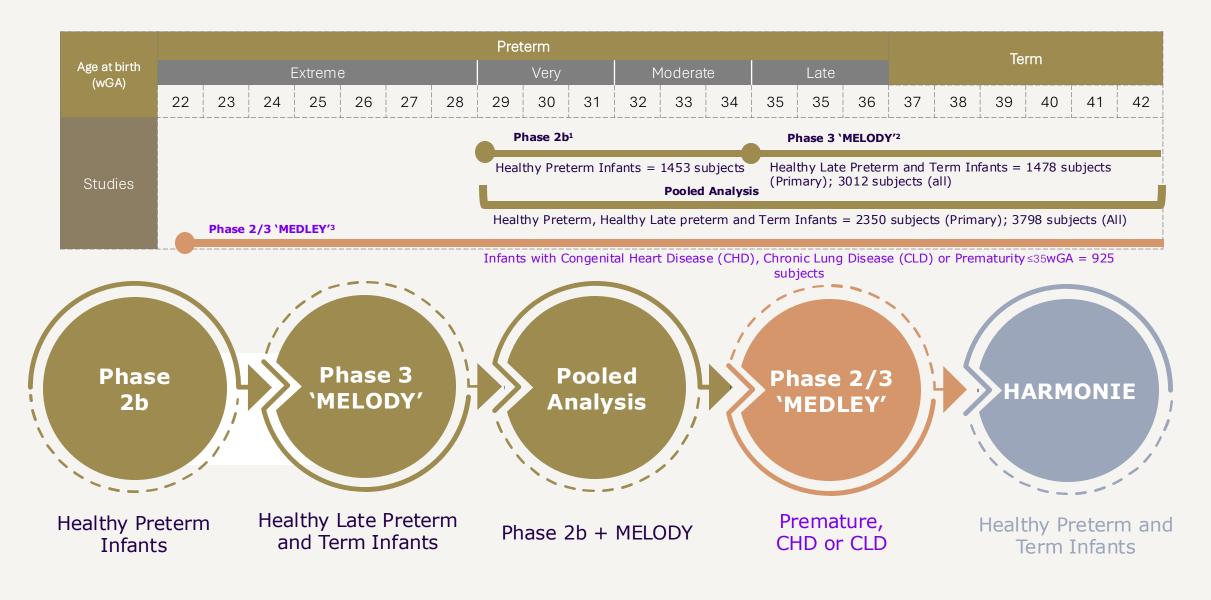
- ACOG (2025): Recommends Abrysvo using seasonal administration. If patient opts out of maternal RSV, the infant needs monoclonal antibody at birth. "There is no preferential recommendation for maternal vaccine or nirsevimab"
- **EBCOG** (2025): EBCOG endorses the recommendation for the administration of 120 µg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine to pregnant women early in the third trimester. This provides protection against RSV and its attendant comorbidities both to the mother and the infant
- JCVI (2025): The mainstay of infant RSV prevention in the UK is antenatal maternal vaccination. All pregnant women should be offered RSV vaccination in every pregnancy, from week 28
- RANZCOG (2024): A single dose of Abrysvo is recommended for pregnant women at 28–36 weeks gestation to protect the infant



Nirsevimab (Beyfortus)

- Long acting monoclonal antibody
- Works specifically on the Fusion protein
 - Rapid and direct protection against medically attended RSV LRTI
 - Extended half-life offers season-long protection with a <u>single fixed dose</u>
 - Weight-banded dosing (50mg/0.5ml <5kg and 100mg/1ml ≥5kg)
 - Prefilled syringe
 - "Nirsevimab can be given concomitantly with childhood vaccines."

Nirsevimab is Designed to Protect All Infants from RSV LRTI



Phase 2b Phase 3 (MELODY) Pooled Analysis Phase 2/3 (MEDLEY) Conclusion

In Pre-Specified Pooled Analysis, Nirsevimab Demonstrated Consistent Efficacy Across RSV-confirmed MA LRTIs of Different Severities

Definition	Efficacy (n=3872)			
Dominion	Efficacy (RRR)	95% CI		
Medically-attended RSV LRTI	79.0%	68.5-86.1		
RSV LRTI with hospitalization	80.6%	62.3-90.1		
RSV LRTI with hospitalization (very severe)	86.2%	68.1-94.0		
RSV LRTI with ICU Admission ¹	90.0%	16.4-98.8		

LRTI, lower respiratory tract infection; MA, medically attended; RSV, respiratory syncytial virus. Very severe = hospitalization + requirement for supplemental oxygen and/or intravenous fluids

MELODY subjects N=3012Ph 2b recommended dose subjects N=860

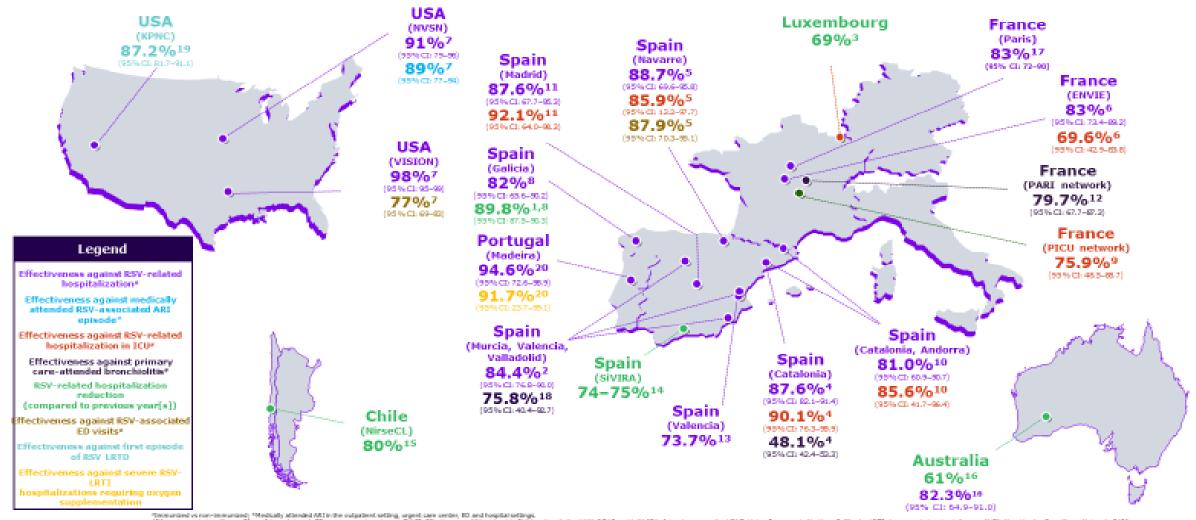
Incidence of LRTI Hospitalizations through the RSV Season

Efficacy through RSV Season

HARMONIE subjects N=8058

Definition	No Intervention (N=4021)		Nirsevimab (N=4037)		Efficacy	
	n	%	n	%	Efficacy	95% CI
RSV LRTI Hospitalization	60	1.5	11	0.3	83.2	67.8-92.0
Very Severe RSV LRTI	19	0.5	5	0.1	75.7	32.8-92.9
All-Cause LRTI	98	2.4	45	1.1	58.0	39.7-71.2

Summary of Real-World Impact on RSV-Related Outcomes



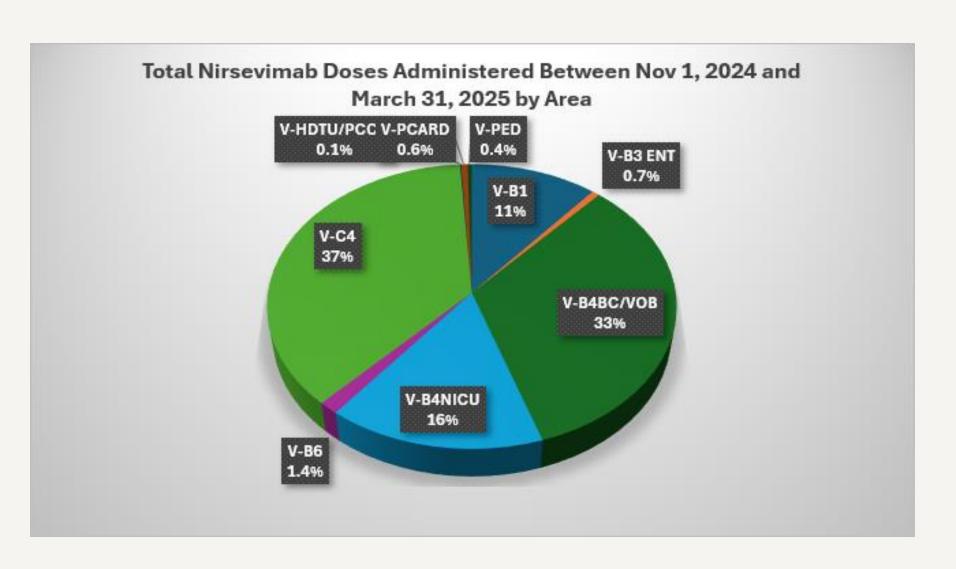


ARI, acute respiration linears: CL combiners interest: ED, emergency department: EDVE, Effectiveness of Newsymbia CRistman Respiration With \$5V Investigation interest in CRIST, lower respiration instructions and the second service interest in CRIST, lower respiration interest in CRIST, lower respiration interest in CRIST, lower respiration interest. ED, emergency department: EDVE, Respiration interest in CRIST, lower respiration interest in CRIST, lower respiration in CRIST rediates ambstidiony research in infrastrous diseases; PCCI, pediates internive care unit, RIII, respiratory sympytial virus; IDCRA, The Austr Respiratory Infrastro Burvellance Bystem (in Spanish).

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2024 - 2025 Nirsevimab Doses Given



Provided just under 2000 doses of Nirsevimab from November to March

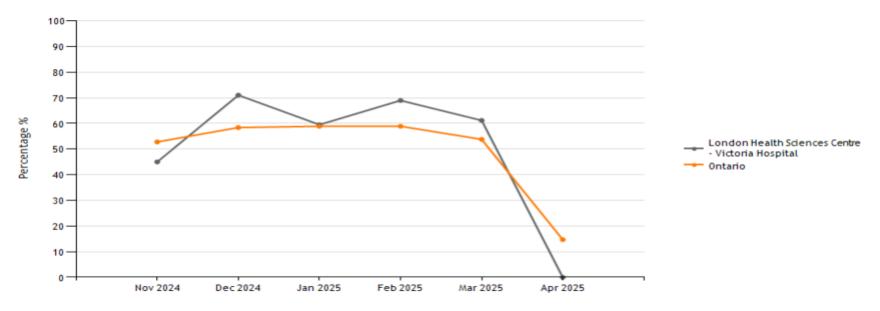


Respiratory Syncytial Virus (RSV) Prevention Program Report

Percentage of live born infants who received RSV immunization (Beyfortus/Nirsevimab)

London Health Sciences Centre - Victoria Hospital

Infants born from Nov-2024 to Apr-2025



Data source

BORN Ontario, 2024-2025

Definition of indicator

Percentage of live born infants who received RSV immunization, expressed as a percentage of total live infants born in Ontario in a given period.

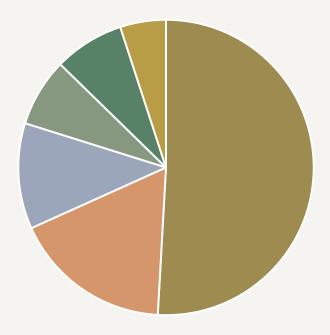
Notes

- 1.Only live born infants are included in the denominator. Live birth outcome is based on the assumption that an infant would have been born live to have a BORN Postpartum Child (PPC) or Neonatal Intensive Care Unit (NICU) encounter.
- 2. Only infants that have a BORN Postpartum Child (PPC) or Neonatal Intensive Care Unit (NICU) encounter are included in this report. Infants who were discharged from outpatient clinics are excluded.

Report version: v1.0.3 (05-Feb-2025)

Percentage of live born infants who received RSV immunization (Beyfortus/Nirsevimab)

Reasons Infants Did Not Receive Nirsevimab



- Parents/Guardian Declined
- No supply available
- Received prenatal RSV vaccine >2 weeks before birth and infant NOT high-risk
- Other (specify)
- Missing Data
- Not offered before discharge

9/15/2025

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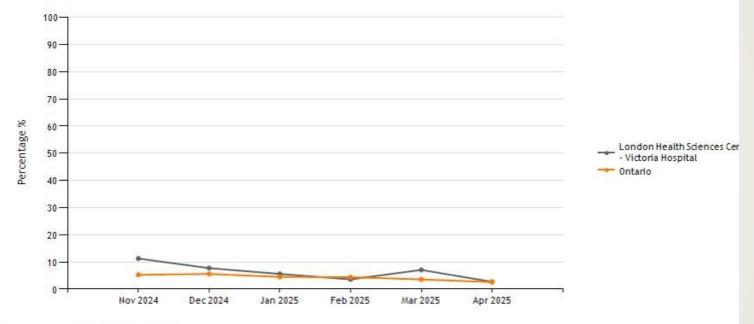


Respiratory Syncytial Virus (RSV) Prevention Program Report

Percentage of pregnant persons who gave birth and received prenatal RSV vaccine

London Health Sciences Centre - Victoria Hospital

Infants born from Nov-2024 to Apr-2025



Data source

BORN Ontario, 2024-2025

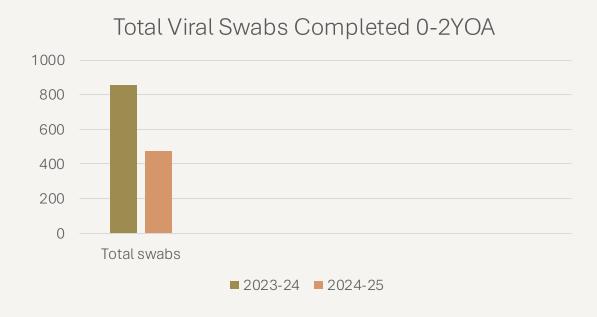
Definition of indicator

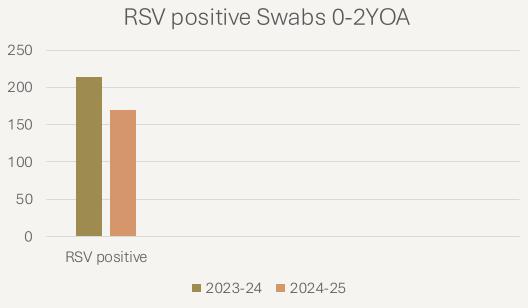
Percentage of pregnant persons who gave birth and received prenatal RSV vaccine, expressed as a percentage of total number of pregnant persons in Ontario in a given period.

Notes

- 1. Only pregnant persons who have a Labour-birth encounter in the hospital are included.
- Prenatal RSV vaccine data collection is optional, therefore this data may not provide a fulsome representation of prenatal RSV vaccine uptake in Ontario.
 Report version: v1.0.3 (05-Feb-2025)

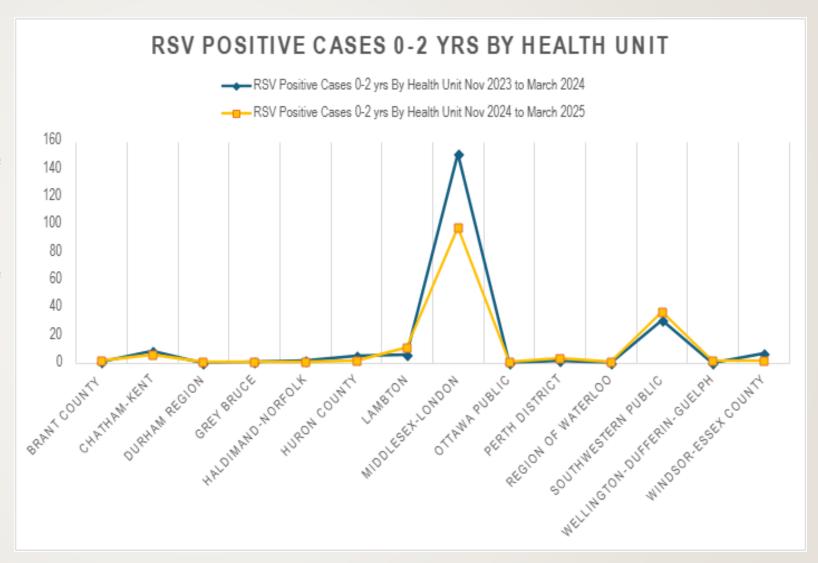
RSV Positive Viral swabs



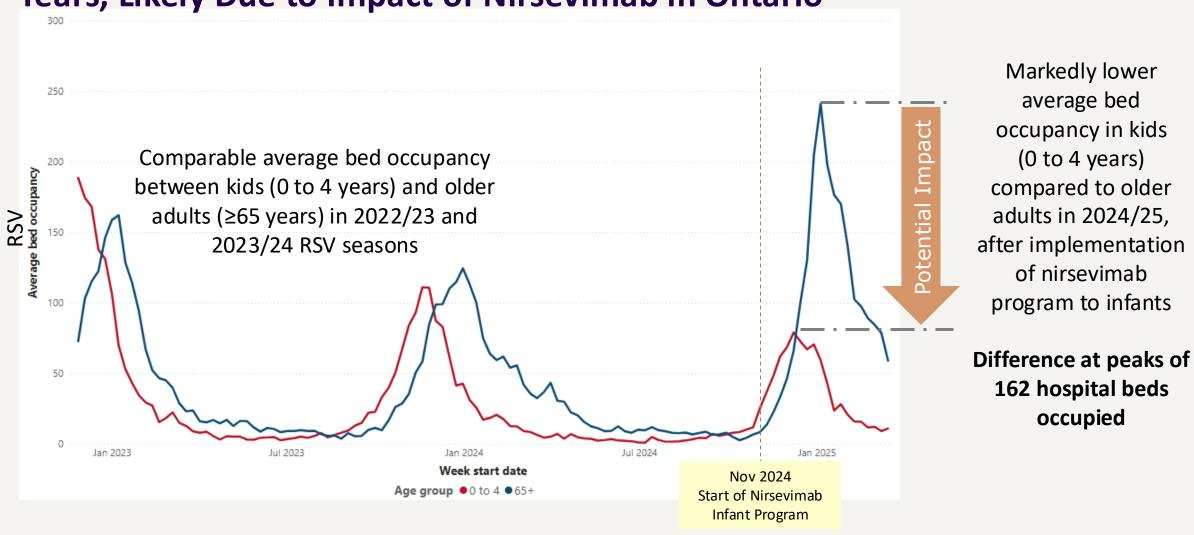


RSV positives by Health Unit

- ≥2023-24 RSV season total positive cases = 214
- ≥2024-25 RSV season total positive cases = 170
- ►MLHU went from 151 to 98!!



2024/25 Season: Hospitalizations for Children Stayed Below Previous Years, Likely Due to Impact of Nirsevimab in Ontario



2025-26 MOH Recommendations

- Season will start on October 1, 2025 and end on March 31, 2026
 - Both Nirsevimab and Abrysvo injections
 - If Abrysvo given, Nirsevimab is not required unless certain criteria are met
- All infants born on or after April 1, 2025 will qualify for Nirsevimab
- Infants meeting high risk criteria and under 2 years of age may qualify for second season
- High risk criteria include:
 - Hemodynamically significant congenital heart disease (CHD) requiring corrective surgery or are on cardiac medication for congestive heart failure or diagnosed with moderate to severe pulmonary hypertension
 - Severe immunodeficiency
 - Trisomy 21
 - Cystic fibrosis with respiratory involvement and/or growth delay
 - Severe congenital airway anomalies impairing the clearing of respiratory secretions
 - Chronic lung disease of prematurity (CLD), including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of RSV season

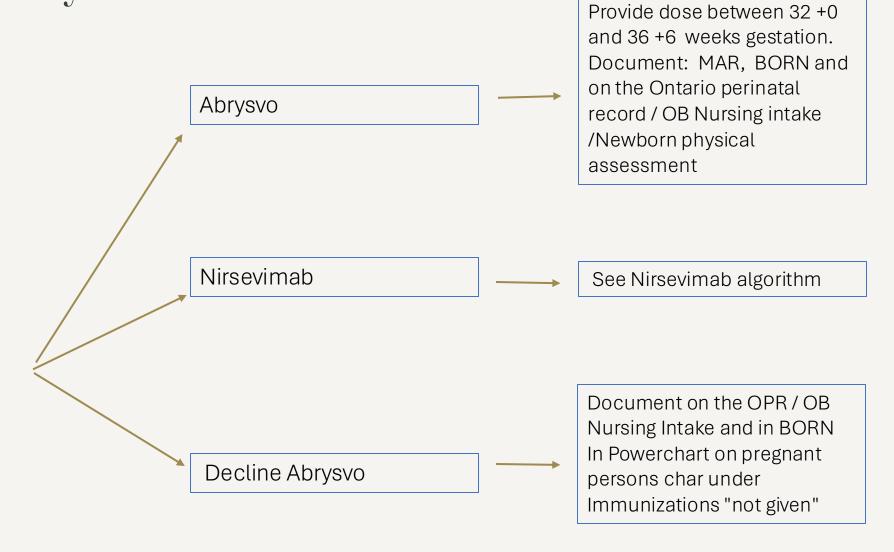


LHSC Protocol for RSV prevention through education and vaccination with Abrysvo

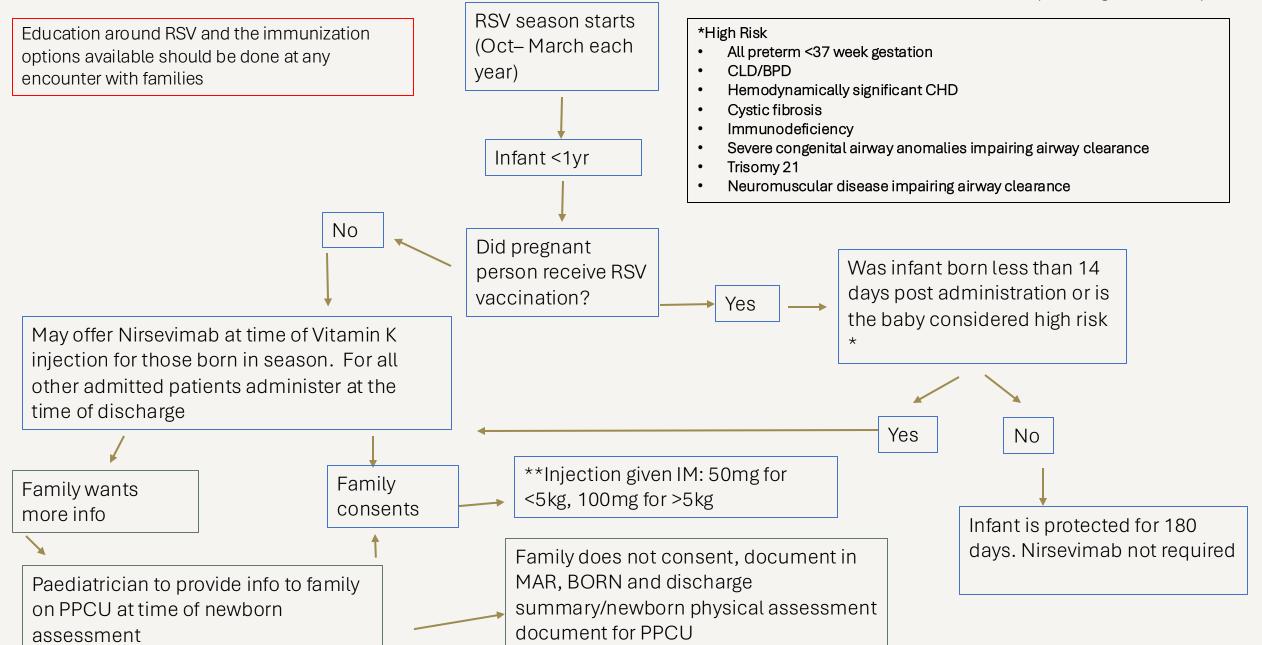
Pregnant person presents to B5/fam doc/ midwife/Antenatal/Triage

Education to be provided to the pregnant person at various touch points during pregnancy and info given on both Nirsevimab and Abrysvo

Preceding RSV season, between 32 +0 - 36 + 6 weeks gestation, discuss RSV prophylaxis and determine what option family would like to proceed with



LHSC Protocol for Nirsevimab Administration (<1 year)



LHSC and Regional Implementation

- Education for all pregnant persons now and going forward
- Information for out of season babies on where and how to access once immunizations begin
 - o Clinics at LHSC will start October 6
- Partnering with local PHU
- Ensuring process for administering in hospital at time of birth
- If not able to do at birth, PPCU or as quickly after going home as possible
- Look for other opportunities within the hospital setting to administer
 - Outpatient paeds clinics
 - o ED



Patient letter for out of season babies

London Health Sciences Centre 800 Commissioners Rd. E., London, ON N6A 5W9 519-685-8500 ext. 50071

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RE: RSV immunization available for infants

Dear parent/guardian,

Ontario Health is now covering the cost of the Respiratory syncytial virus (RSV) immunization – Nirsevimab – for all infants born on or after April 1, 2025 and up until March 31, 2026. Any infant who is a resident of Ontario born in this time frame may obtain the injection. No OHIP required.

Nirsevimab is a long-acting monoclonal antibody that provides passive immunity against RSV infection. While immunization does not stop a child from getting an RSV infection, it has been shown to reduce the chance of serious illness and the need for hospitalization by over 80 per cent.

Parents and guardians are encouraged to book an RSV immunization appointment for their child this fall. The immunization will be available for administration as of October 1, 2025, and the immunization period will end on March 31, 2026.

If you have a primary care provider (i.e. family physician, paediatrician or nurse practitioner) in the community, your child may receive the immunization through their office.

Alternatively, you can also have your child immunized at the Children's Hospital RSV prophylaxis clinic which is held in the Paediatric Medical Day Unit (PMDU) located in B1-200. **Appointments for children born on or after April 1, 2025** can be booked by calling 519-685-8500 ext. 50071. **This line will be accepting messages as of September 1, 2025**.

Your child can also be immunized if you're here for a scheduled visit.

For more information, please visit <u>Respiratory Viruses and Immunizations – PCMCH</u> or contact your child's health-care provider.

Sincerely,

PCMH

Protecting Your Child from RSV

FOR PARENTS AND EXPECTANT PARENTS



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What is RSV?

Respiratory syncytial virus (RSV) causes an illness that affects the airway and lungs, especially in babies and young children.

RSV often leads to cold-like symptoms and is the most common cause of a chest infection called bronchiolitis. Babies and young children often have mild illness from RSV and recover quickly. However, some may develop a severe infection that leads to hospitalization and can be life-threatening.

Almost all children get RSV by age two, and it is the main reason children in this age group are hospitalized.

RSV spreads easily and is most active from late fall to early spring. You and your child can get RSV by having direct contact with a person or surface infected with RSV. You can also get it by being around someone infected by RSV who is coughing or sneezing.





Is my child eligible to receive **Beyfortus?**

Your child can get Beyfortus during the RSV season in Ontario if they are:

- Born April 1 or after **and** less than eight months of age up to the end of the RSV season
- Under two years old and at risk from severe RSV illness during their second RSV season*

RSV season usually runs from November to the end of March, but the exact timing can change every year and may depend on where you live in Ontario.

prematurity (bronchopulmonary dysplasia), congenital heart disease,



Is Beyfortus safe?

Yes. Clinical trials have shown that **Beyfortus is safe for babies** and young children. Beyfortus has been shown to prevent RSV-related illnesses such as bronchiolitis and to prevent severe RSV infections.

Side effects after getting Beyfortus are usually mild and last only a few days. These may include redness, swelling and pain at the injection site, rash and/or fever.

Beyfortus may safely be given at the same time as other immunizations.

Getting Beyfortus will not give a child RSV. Although rare, it is possible for a child to get severely ill from RSV even if they have received Beyfortus.



How is Beyfortus given to my child?

Beyfortus is given as a one-time injection (often in the thigh muscle). The treatment provides immunity against RSV as soon as it is received and works best within the first five months after it is given.



When can my child get **Beyfortus?**

- If your baby is born during the RSV season, Beyfortus should be given soon after birth. This will provide protection during the early months when your baby is most vulnerable.
- If your baby is born before the RSV season and is eight months old or younger, Beyfortus should be given shortly before the RSV season begins.
- If your baby remains at high risk from RSV infection and is entering their second RSV season, Beyfortus should be given shortly before the RSV season begins.

If your child misses these times, they can still get Beyfortus at any point during the RSV season.



Where can my child get Beyfortus?

Newborns should get Beyfortus in hospital before going home after birth. If not, it can also be given by your midwife, primary care provider or through your local public health unit. For young children that are eligible, Beyfortus may be given at their paediatrician or primary care provider's office, as well as through outpatient hospital clinics.

PCMH

Abrysvo[™] (also known by the name of RSVpreF) is a vaccine that can be given to a pregnant person to prevent RSV infection in their baby.

- It is given between 32 and 36 weeks of pregnancy if your baby is due during or near the start of the RSV season.
- The vaccine helps the pregnant person's immune system make antibodies that can be passed to the baby during pregnancy. These antibodies will protect the baby from RSV infection for the first few months of life, usually up to six months.

! Speak with your healthcare provider or local public health unit for more information.

PCMH

What else can I do to protect against RSV?



Stay home when sick and avoid close contact with sick people



Wash your hands often



Clean and disinfect surfaces regularly



Cough or sneeze into your arm



Feed your baby breast/chest milk (contains protective antibodies)



Avoid exposure to smoking

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