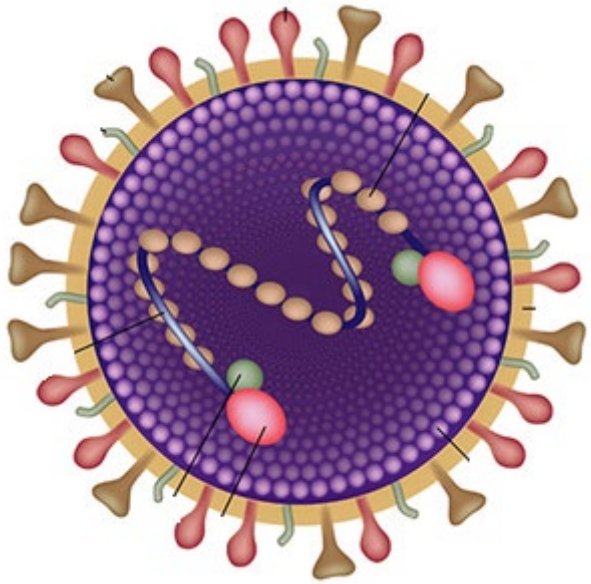
Respiratory Syncytial Virus Immunization Strategies for Preventing Severe Infant RSV Infections



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a place of mind
UBC

COI disclosure

I have no relevant disclosures

Objectives

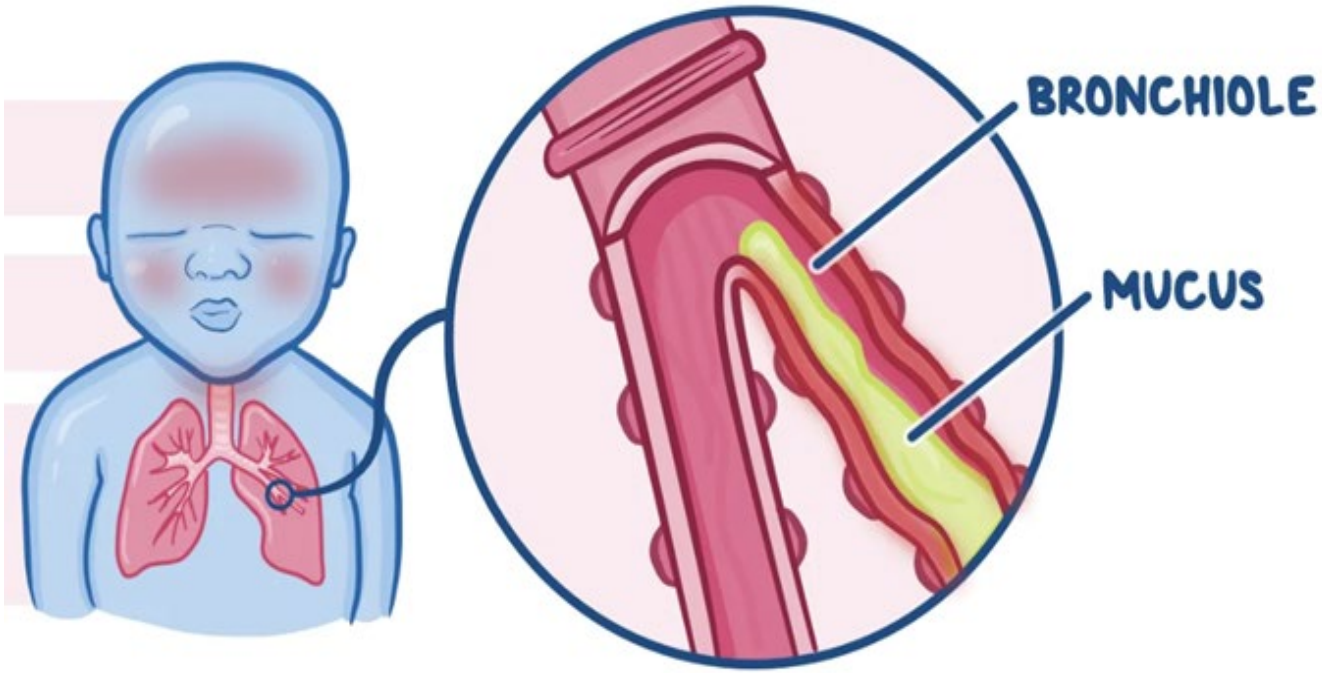
1. Review the effectiveness, safety, uptake, cost and acceptability of available RSV immunization strategies to prevent severe RSV infections in infants.

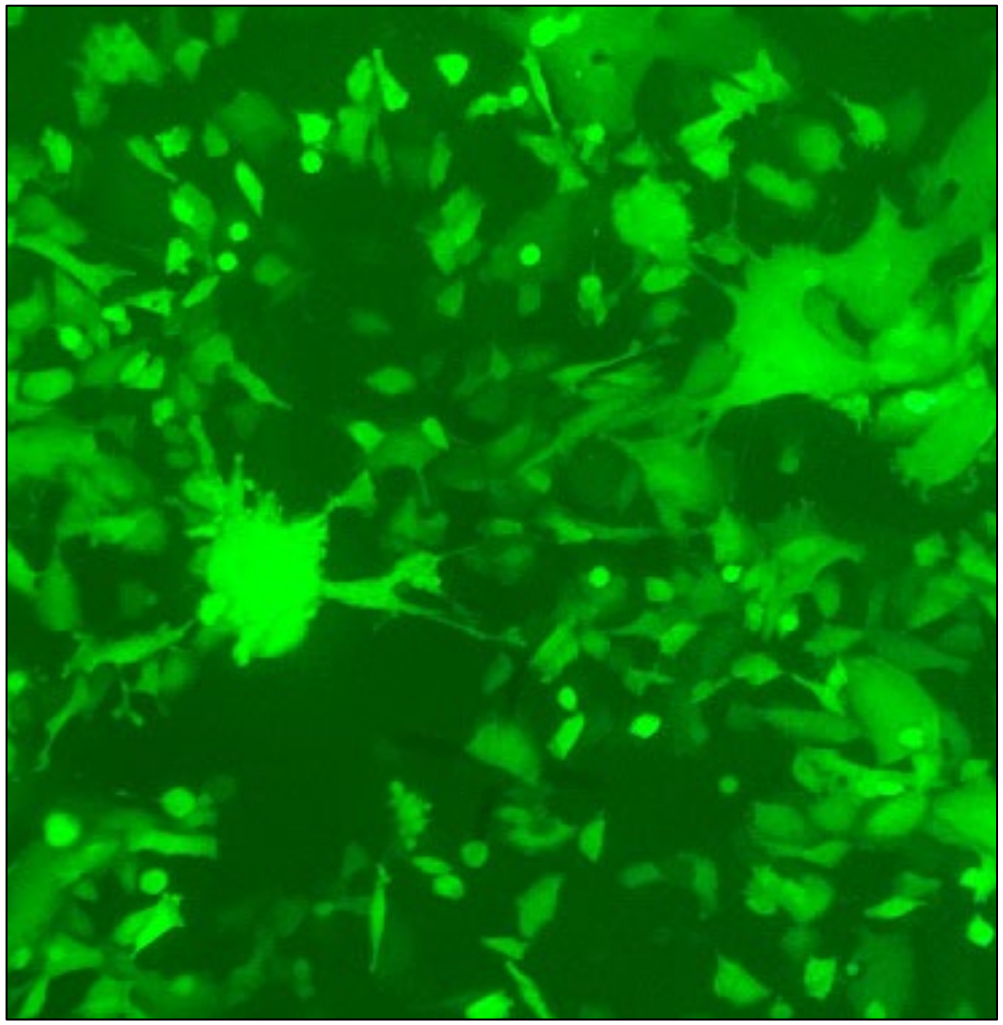
2. Highlight the evolution and future direction of the RSV immunization program in British Columbia.

Respiratory syncytial virus (RSV)

1 in 6 infants will have a medically attended respiratory infection

1 in 60 will be hospitalized

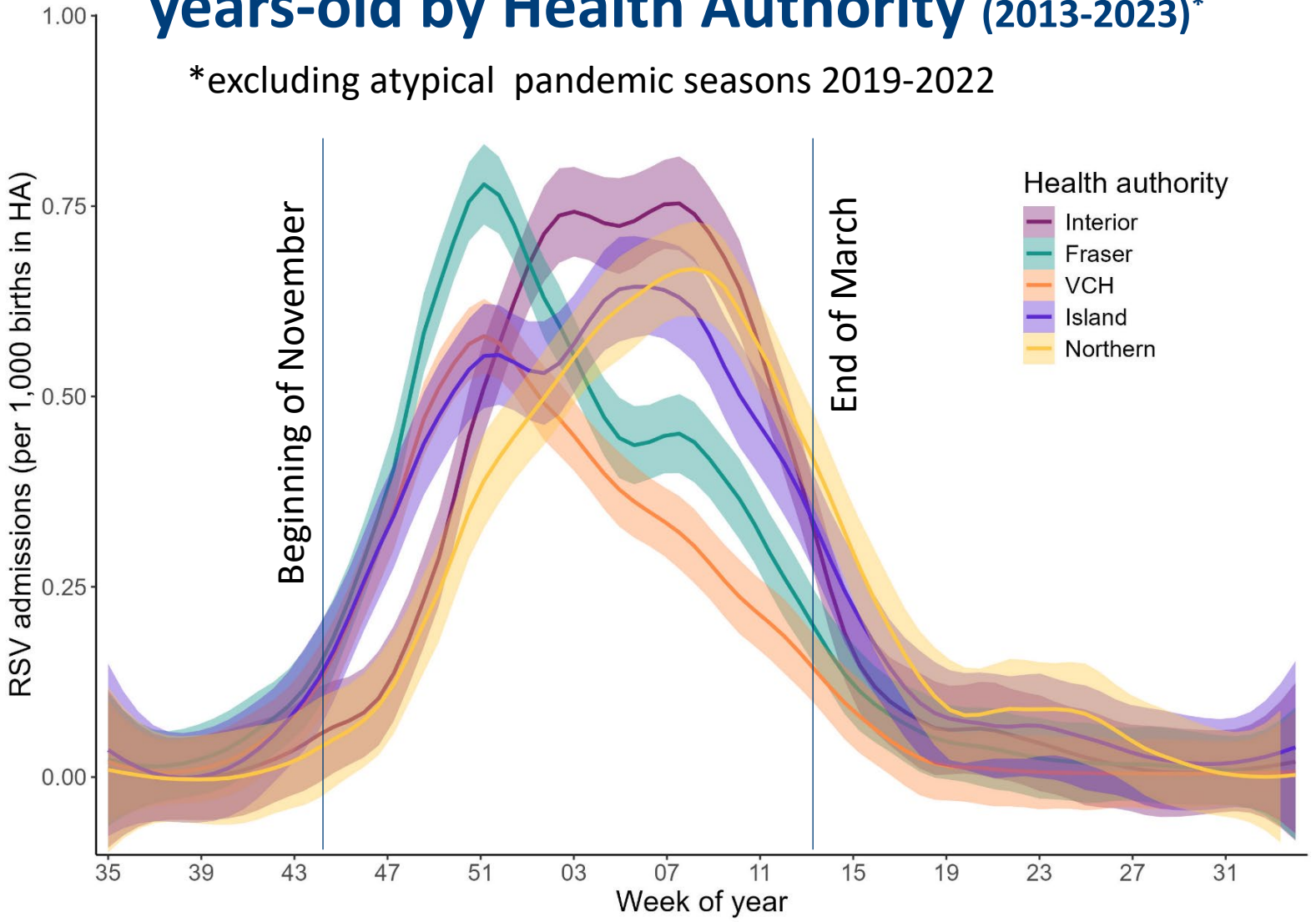




RSV circulation

Weekly RSV admissions in BC under 2 years-old by Health Authority (2013-2023)*

*excluding atypical pandemic seasons 2019-2022

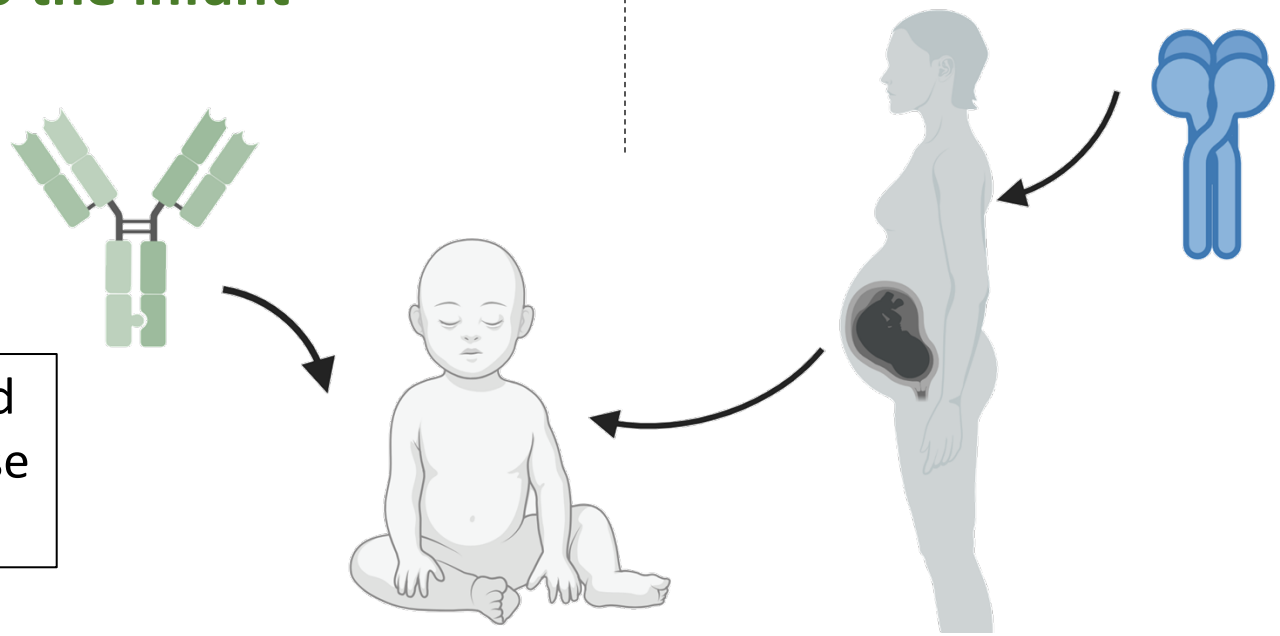


Data from MOH/PANDA/RSV Program analytics – do not re-use without permission

Nirsevimab

~80-85% efficacy against RSV hospitalization

Protects for at least 6 months from the time of administration to the infant



Nirsevimab is approved by Health Canada for use **under 2 years of age**

RSVpreF

~72-79%* efficacy against RSV hospitalization

(*particularly when given >14 days prior to birth)

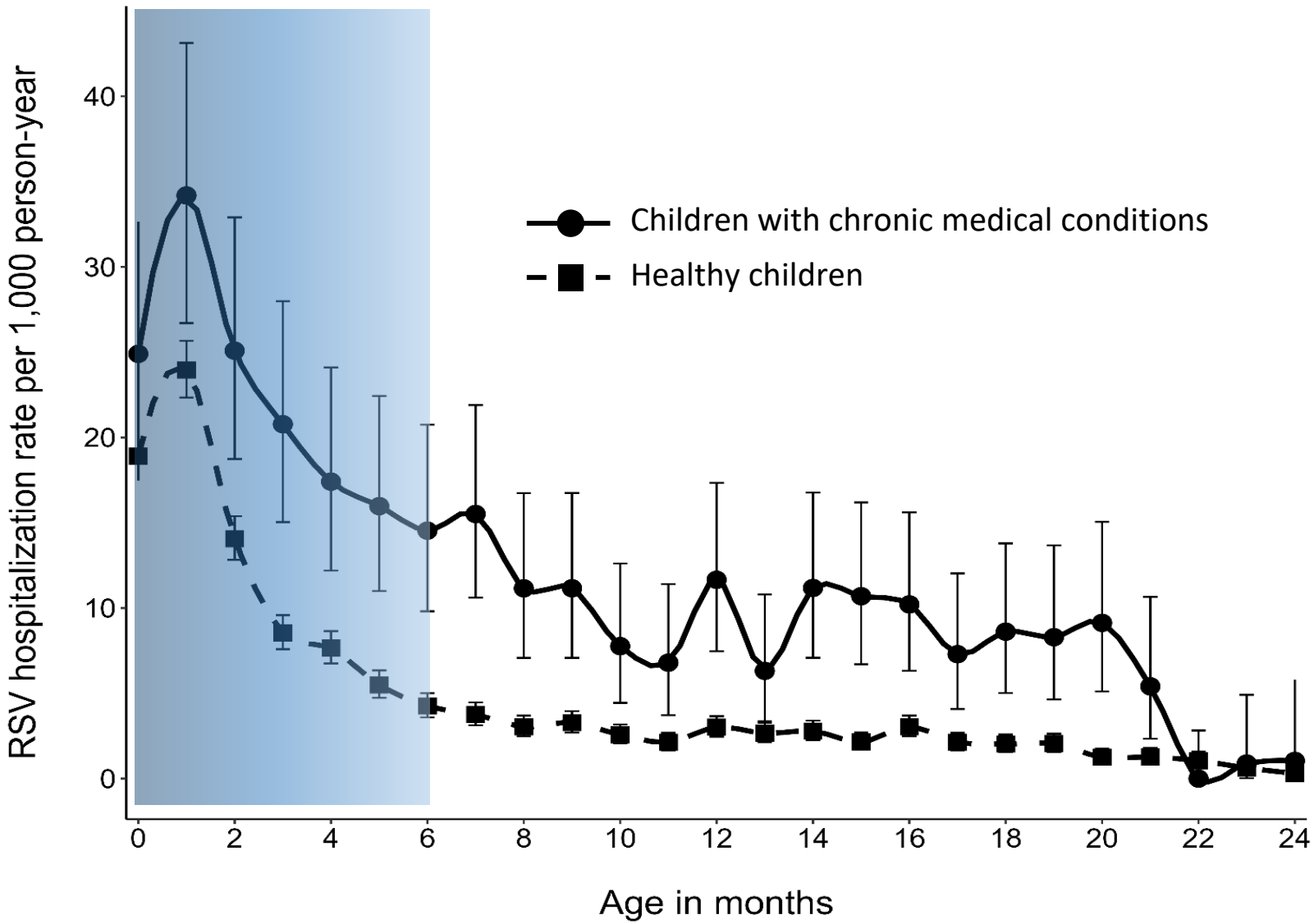
Protects for up to 6 months from the time of birth

RSVpreF is approved by Health Canada for administration between **32 and 36^{+6} weeks of gestation**

Griffin MP 2020; Hammitt LL 2022; Muller WJ 2023; Simões EAF 2023; Drysdale SB 2023; Assad Z N 2024; Sumsuzzman DM 2025; Munro APS, 2025

Kampmann B 2023; Simões EAF 2025; Pérez Marc G 2025; Gentile A 2025; Williams TC 2025

Prolonged RSV hospitalization risk in children with chronic medical conditions



Vineta M, JAMA Network Open 2025

National Advisory Committee on Immunization (NACI) 2024

Recommends building towards a universal RSV immunization program, in stages, depending on access, cost-effectiveness and affordability of available options, prioritizing infant at higher risk (e.g. preterms, indigenous or those living in remote communities)

Nirsevimab - Effectiveness

- Four randomized trials (Phase 2B, MEDLEY, MELODY, HARMONIE - >12,000 infants) showed nirsevimab is safe and ~80% efficacious reducing medically-attended RSV LRTI, RSV-related hospitalization, ICU admissions…
- Efficacy confirmed by all countries that implemented programs

Systematic review and meta-analysis (32 studies from 5 countries):

83% reduction in RSV-related hospitalizations, 91% reduction in ICU admissions, 75% reduction in LRTI in infants 0 to 12 months.

- Follow-up HARMONIE trial – efficacy maintains at 180 days

Griffin MP 2020; Hammitt LL 2022; Muller WJ 2023; Simões EAF 2023;
Drysdale SB 2023; Assad Z N 2024; Sumsuzzman DM 2025; Munro APS, 2025

RSV Prevention with Nirsevimab (Beyfortus®)

Respiratory Syncytial Virus (RSV) is a common virus that spreads in the fall and winter.
It mostly affects babies under the 6 months old and can make it hard for them to breathe or feed.
Most babies get better in a few days, but about 1 in 100 will need to be treated in the hospital.

What is Nirsevimab?

A **one-time shot** that helps protect babies from getting very sick with RSV. It is given in the thigh before or during the RSV season and **protects them the whole season** (that usually runs between October and March).

Benefits of Nirsevimab

- ✓ Makes RSV infections less severe
- ✓ Lowers the risk of hospitalization by 80 per cent
- ✓ Protects children while they develop their own immunity to the virus

Side effects to expect after nirsevimab

Nirsevimab is safe.
Some babies may have mild side effects:
- 5 per cent develop a minor reaction at the injection site
- 1-2 per cent get a fever during the first few days
- Less than 1 per cent develop a rash

Serious side effects are very rare.

Nirsevimab can be administered with other routine vaccines.

If you received the RSV pregnancy vaccination, your child may not require nirsevimab to be protected from RSV

Protect your child from RSV

Breastfeed if you can

Wash your hands often

Stay away from people who are coughing or have fevers

Keep your child away from **cigarette** or **vape smoke**

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Provincial Health Services Authority

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Source: Perinatal Services BC Health Hub – RSV; based on Vineta Paramo M, under review

Cost-effective analysis of RSV Immunization options for BC

Analysis by Javad Taleshi, Hind Sbihi et al., PUBLISHED in Vaccine (online Nov 2025)

Strategies	Total Cost*	Product Cost	Incremental Cost$^{\delta}$	Incremental QALY$^{\delta}$	ICER
Palivizumab (current state)	$7,946,177	$1,233,553	0	0	NA
Nirsevimab – high-risk only	$6,801,192	$259,823	-$1,144,985	0.4	-$3,144,864
Nirsevimab – high & moderate-risks	**$7,669,809**	**$1,744,508**	**-$276,369**	**3.7**	**-$74,335**
Seasonal maternal vaccination + Nirsevimab – high-risk only	$7,778,515	$2,123,903	-$167,662	8.1	-$20,803
Seasonal maternal vaccination + Nirsevimab - high & moderate risks	$8,377,058	$3,126,852	$430,881	10.5	$41,158
Nirsevimab – All Infants (Universal)	$17,627,256	$13,422,602	$9,681,079	28.5	$339,669

ICER = Incremental cost-effectiveness ratio

$^{\delta}$Relative to current state; QALY = Quality-adjusted life year

*Cost of direct RSV-related in- and outpatient health care + cost of product purchase (nirsevimab and/or maternal vaccine) for children in 1st or 2nd RSV season.

Using standard ICER $50,000

Cost-saving

Cost-effective

NOT cost-effective

Based on NACI, nirsevimab should still be administered to the following infants whose gestational parent received RSVpreF.

Which of these infants should received nirsevimab even if their birthing parent received RSVpreF:

a. **Infants who are born <2 weeks after administration of RSVpreF**
b. **Hemodynamically significant chronic cardiac disease**
c. **Severe immunodeficiency**
d. **Severe congenital airway anomalies impairing clearing of secretions**
e. **Down syndrome**
f. **All of the above**

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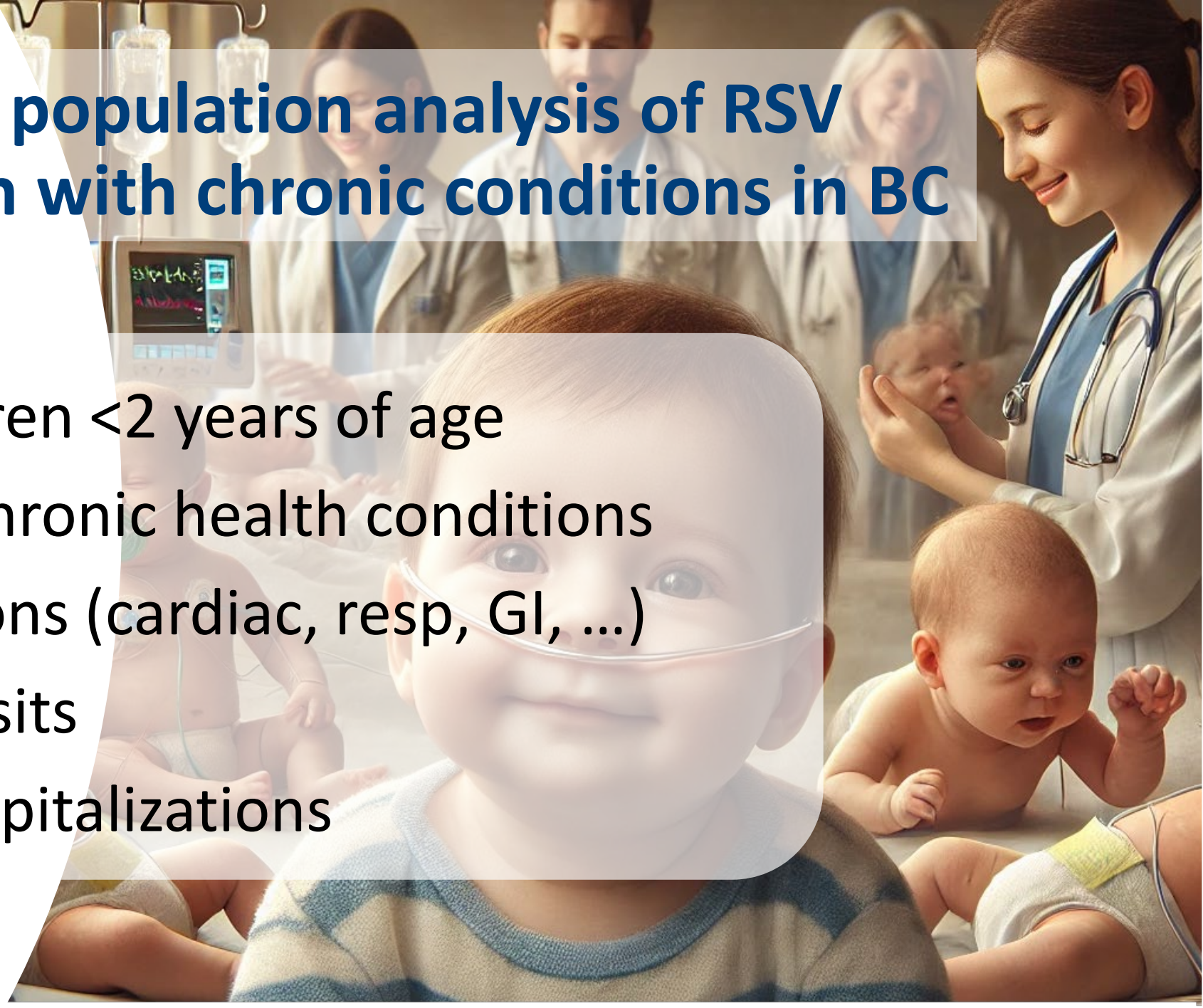
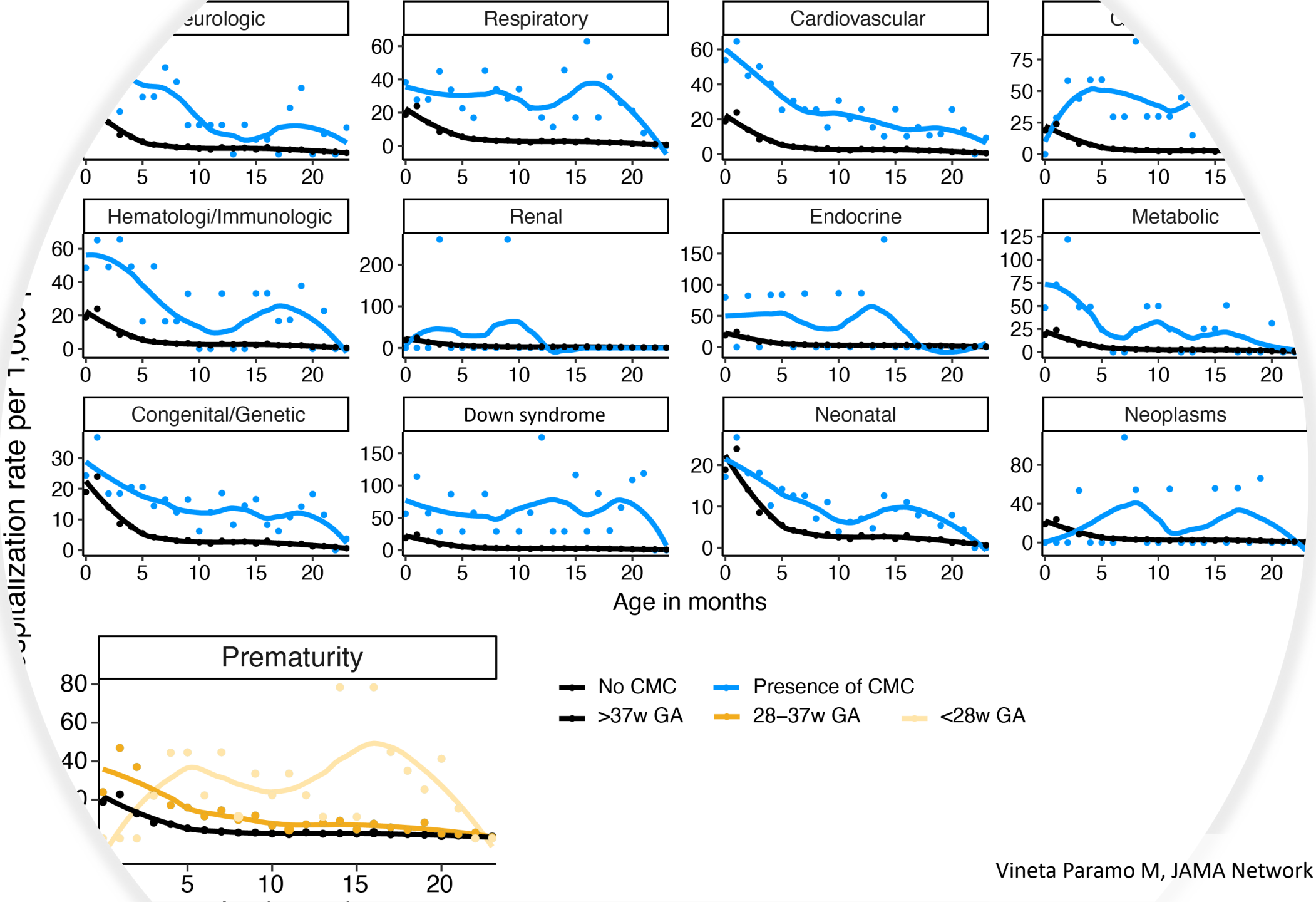
Season-stratified, population analysis of RSV burden in children with chronic conditions in BC



- 431,937 children <2 years of age
- 25,452 with chronic health conditions
- 1,116 conditions (cardiac, resp, GI, …)
- >14,000 ED visits
- 4,592 RSV hospitalizations

Vineta M, JAMA Network Open 2025



Vineta Paramo M, JAMA Network Open 2025

Children at high risk of severe RSV infection

These infants would not be sufficiently protected by the maternal RSV vaccine beyond 6 months of age

The following children under 2 years of age (at the time of dosing):

- Chronic lung disease requiring ongoing assisted ventilation / oxygen therapy (e.g. Home O2, CPAP, BIPAP)
- Hemodynamically significant congenital cardiac disease or cardiomyopathy
- Severe or profound combined immunodeficiencies (e.g. SCID, CD40 ligand deficiency, DOCK8, etc., … requires adjudication by a Pediatric Immunologist)
- Severe congenital airway anomalies impairing clearing of respiratory secretions
- Neuromuscular disease impairing clearing of respiratory secretions
- Cystic fibrosis with respiratory involvement and/or growth delay
- Down syndrome

List 1: Definition of infants at increased risk of severe RSV disease

Infants at increased risk of severe RSV disease during their first RSV season:

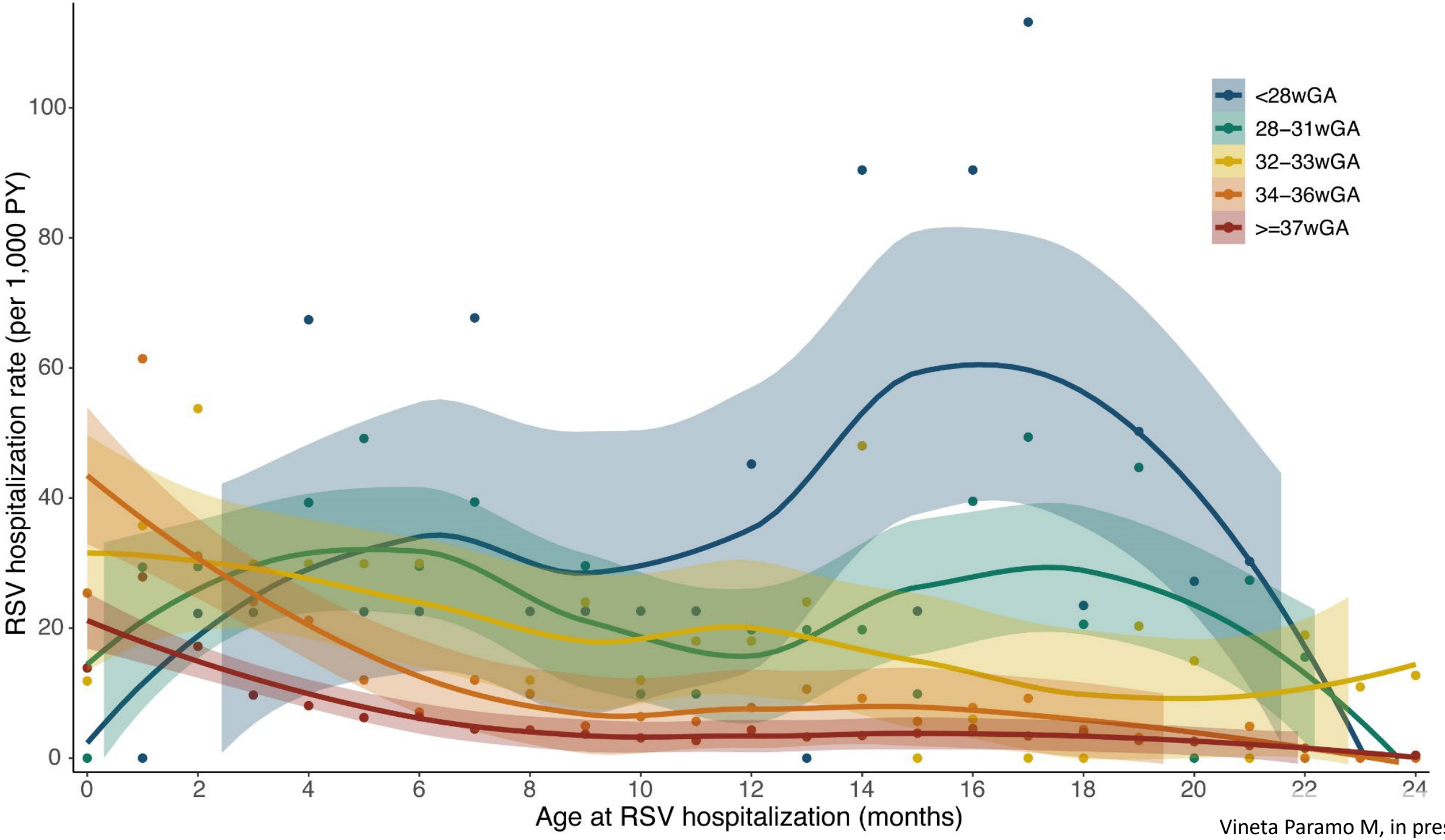
- All premature infants (i.e., born less than 37 wGA)
- Chronic lung disease, including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of the RSV season
- Cystic fibrosis with respiratory involvement and/or growth delay
- Haemodynamically significant chronic cardiac disease
- Severe immunodeficiency
- Severe congenital airway anomalies impairing clearing of respiratory secretions

- Neuromuscular disease impairing clearing of respiratory secretions
- Down syndrome

Source: NACI Statement on the prevention of respiratory syncytial virus disease in infants – May 2024

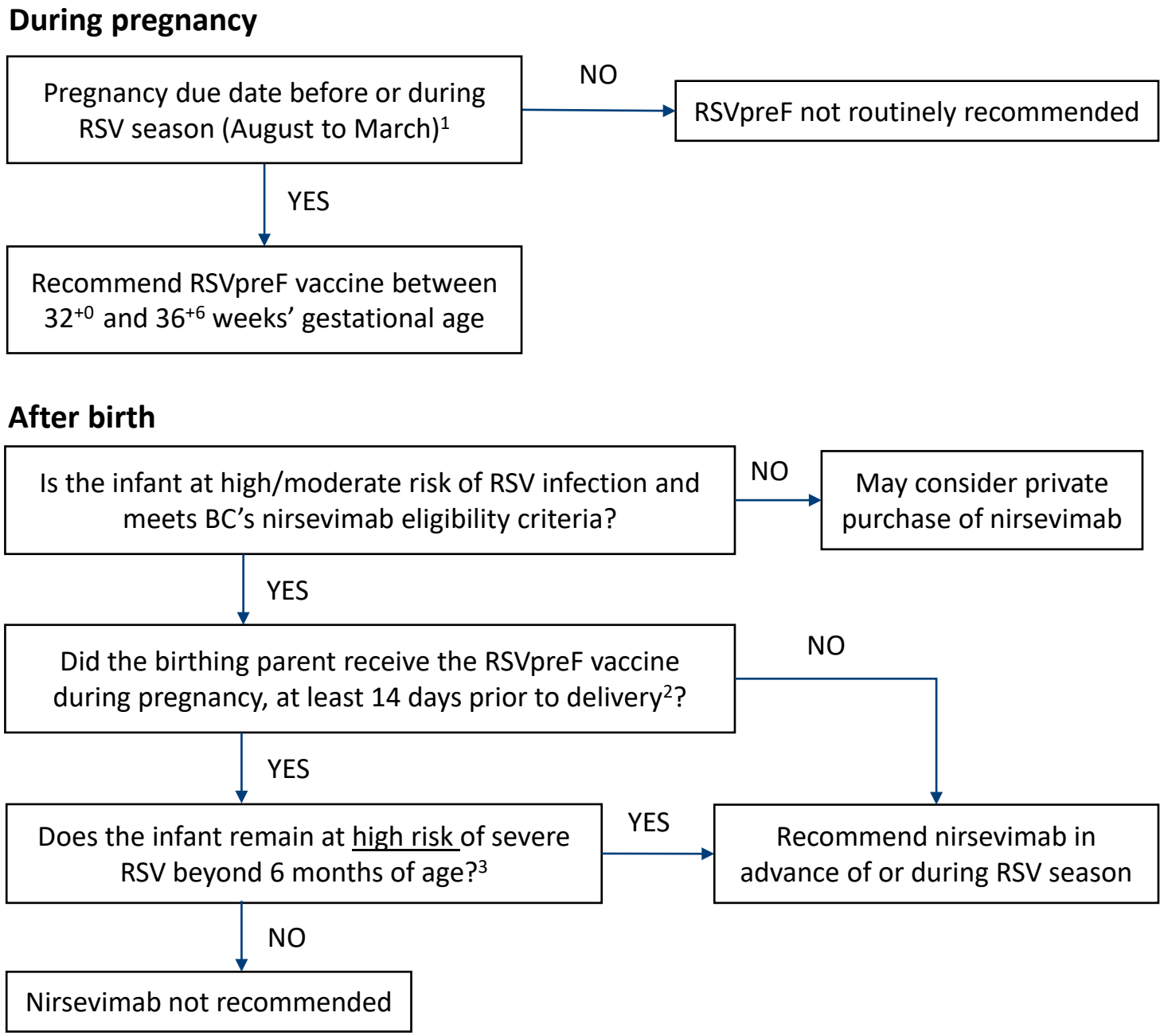
Gestational age strata	**≥37wGA N = 397,883**	**34-36wGA N = 37,236**	**32-33wGA N = 4,399**
RSV outcomes in first season			
Adjusted* hospital admission rates per 1,000 PY (95%CI)	6.95 (6.68 - 7.22)	13.54 (12.34 - 14.74)	15.79 (12.14 - 19.44)
PICU admissions, N (% hospitalizations)	245 (9.6%)	61 (12%)	13 (18%)

Vineta Paramo M, in press



Vineta Paramo M, in press

Proposed decision algorithm for RSV immunization options in BC



Source: Wong JMH, Lavoie PM. RSV immunization in pregnancy and infancy BC Medical Journal (Dec 2026)

Clinical cases…

- Infant with complex, hemodynamically significant congenital heart disease born in June

If their birthing parent received RSVpreF, would you still recommend nirsevimab? **Yes**

Clinical cases…

- 4-month-old child admitted for meconium aspiration syndrome, discharged home on day 4 feeding well.

Should this child receive nirsevimab during RSV season if their birthing parent received RSVpreF >14 days before birth?

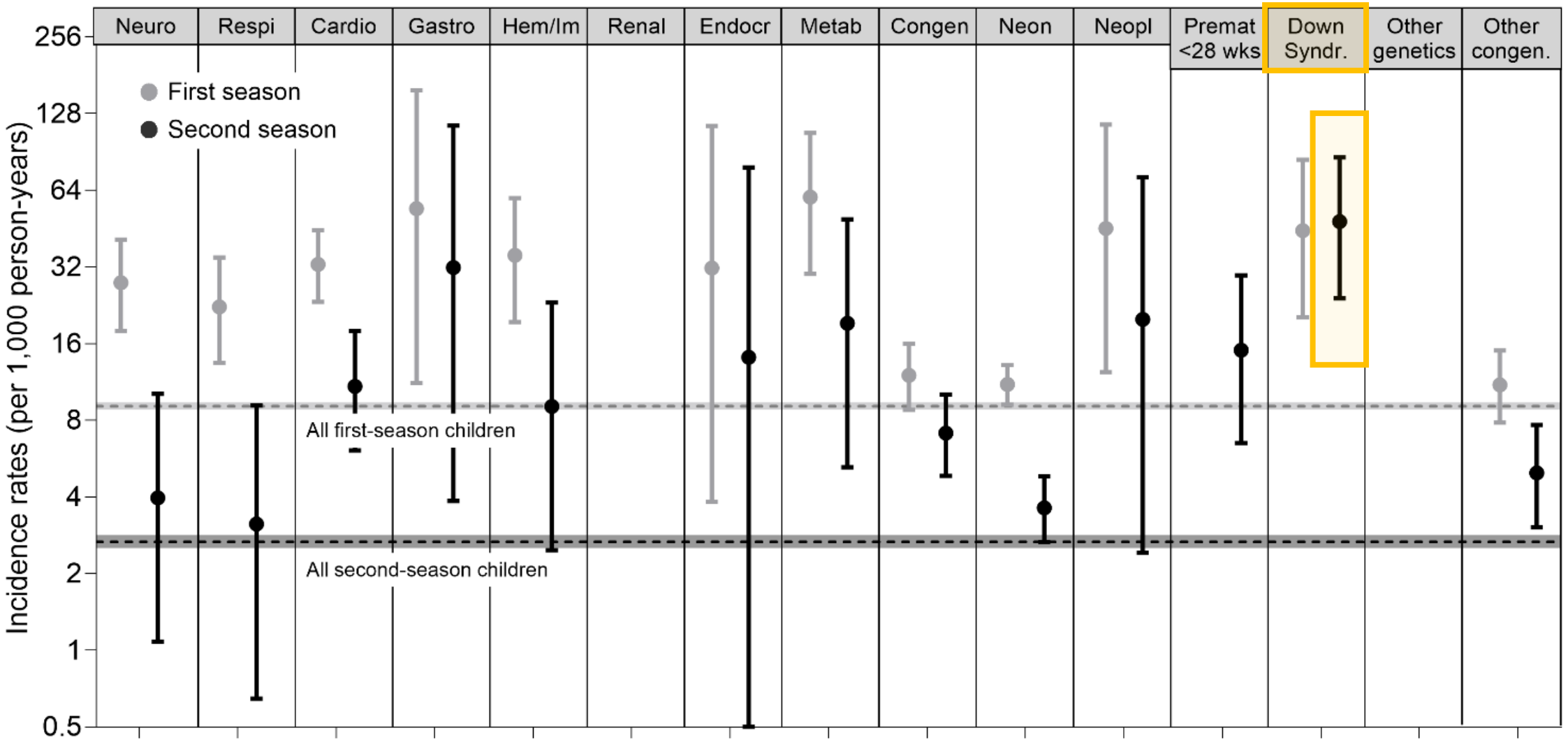
No, sufficiently protected

National Advisory Committee on Immunization (NACI) recommends nirsevimab administration for a second RSV season in children under 24 months who remain at *ongoing increased risk of severe RSV disease*

Which of these groups of children remain at ongoing risk of severe RSV disease in their second season?

a. Healthy 35 weeks-born preterm infant
b. Children on ongoing assisted ventilation at home
c. Severe immunodeficiency
d. All of the above
e. Down syndrome
f. b, c and e

RSV hospitalization rates with isolated conditions



Vineta Paramo M, JAMA Network Open 2025

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Take aways

- The vast majority of infants are sufficiently protected with either RSVpreF or nirsevimab (or clesrovimab)
- Children with chronic medical conditions remains at increased risk of RSV hospitalization for a longer period of time
- “High-risk” children require mAbs for a second RSV season, and most require mAbs in their first RSV season regardless of parenteral vaccination status

Nirsevimab is not indicated in children >2 years of age

Infant RSV Immunity (IRIS) Study

Understanding the impact of early life RSV infections on infant immunity and long-term health

RSV Immunization Strategies: a Focus on Vaccination in Pregnancy

Western Immunization Forum 2026

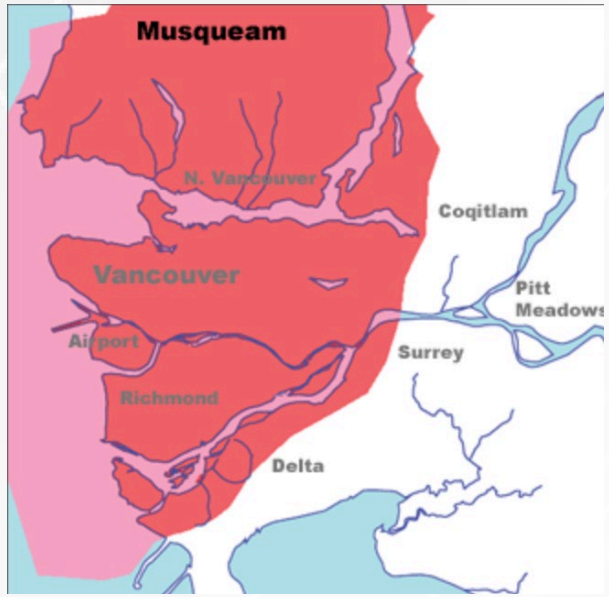
Jeffrey Wong, MD, FRCSC

Reproductive Infectious Diseases Specialist,
BC Women's Hospital & Health Centre and St. Paul's Hospital
Clinical Assistant Professor, Department of Obstetrics and Gynaecology, UBC

BC WOMEN'S HOSPITAL+ HEALTH CENTRE

BC CHILDREN'S HOSPITAL

Land Acknowledgement



I would like to acknowledge that I work, live and play on the traditional, ancestral and unceded territories of the Coast Salish Peoples, including the xʷməθkʷəy̓əm (Musqueam), Sḵwx̱wú7mesh (Squamish), and səlilwətaɬ (Tsleil-Waututh) Nations.

Conflicts of Interest and Recent Funding

- Postdoctoral Fellowship Salary Award (2022-2024) from ViiV Healthcare (GSK) / Canadian HIV Trials Network
- Women's Health Research Institute Catalyst Award (2025)
- University of British Columbia New Faculty Research Award (2025)

Health Canada Approval: RSVpreF (January 2024)

Health

Health Canada approves RSV vaccine for maternal immunization

Single-shot dose approved for third trimester of pregnancy, Canadians aged 60+

Jessica Wong · CBC News · Posted: Jan 04, 2024 1:24 PM PST | Last Updated: January 5

HEALTH | News

Health Canada approves RSV vaccine for use in pregnancy to immunize infants

Health Canada approval of RSV vaccine for expectant mothers could help alleviate toll on pediatric hospitals

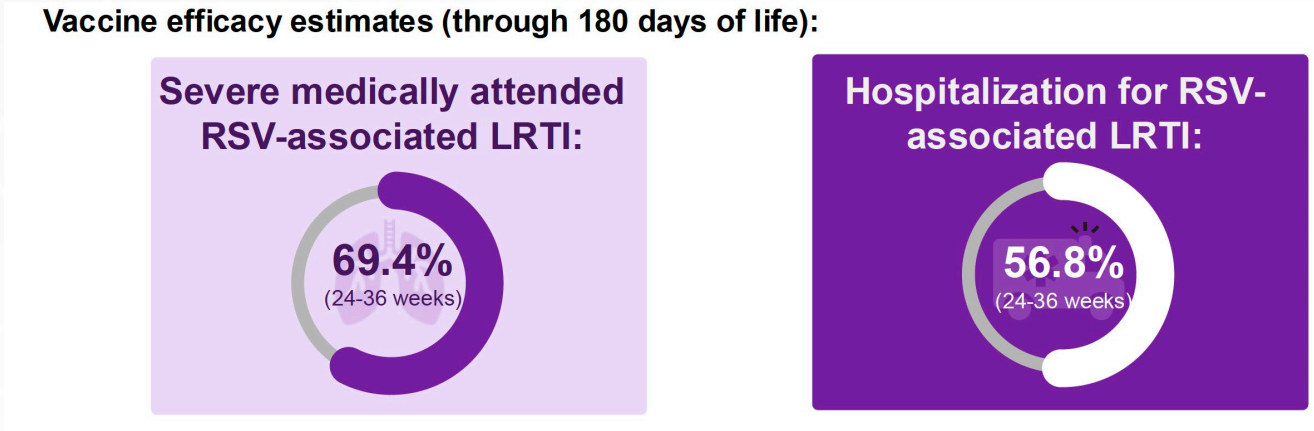
News / Local News

Health Canada approves RSV vaccine for pregnant people

Health Canada approves RSV vaccine for use in pregnancy to immunize infants

Phase III RSVpreF Vaccine Trial (MATISSE): Data on Efficacy

- **Double-blind RCT in 18 countries, with 1-2 year follow up**
  - **Study population:** 24-36 weeks gestational age, uncomplicated pregnancies
  - Total recruitment: 7358 pregnant people
    - 55 (0.7%) people recruited in Canada (Montréal)



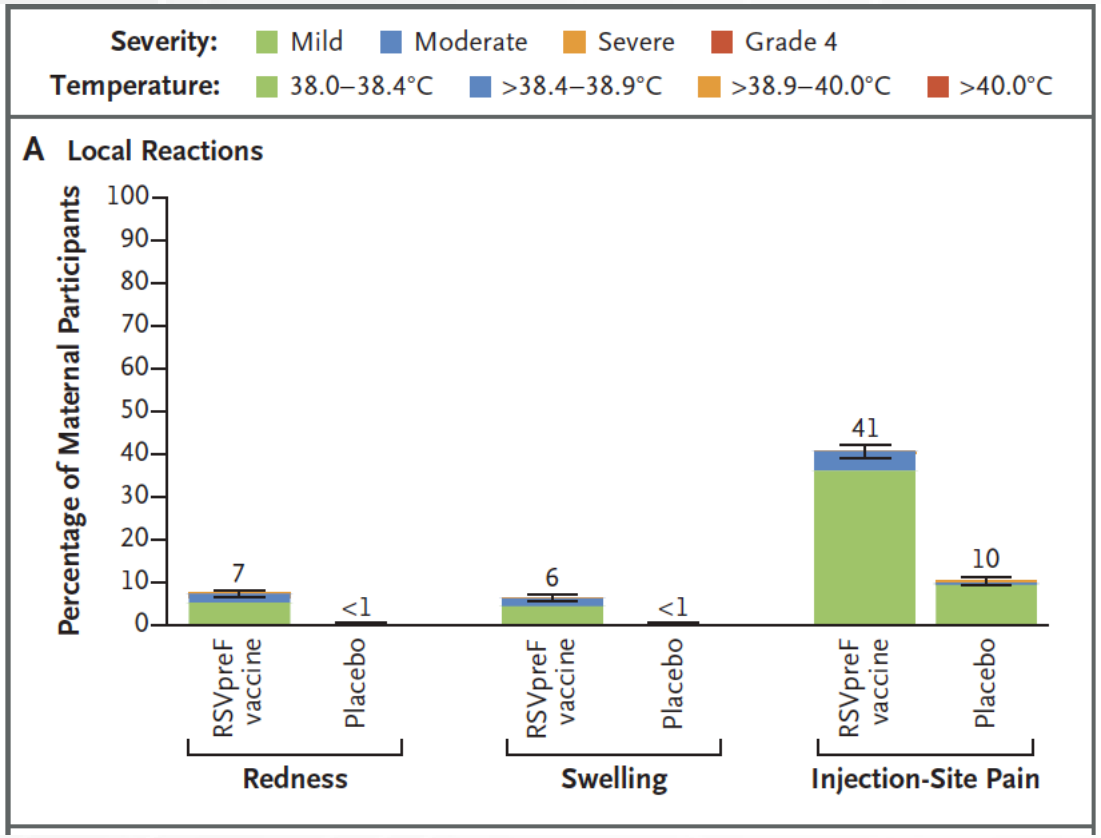
Kampmann, 2023; Slide from Haben Debessai

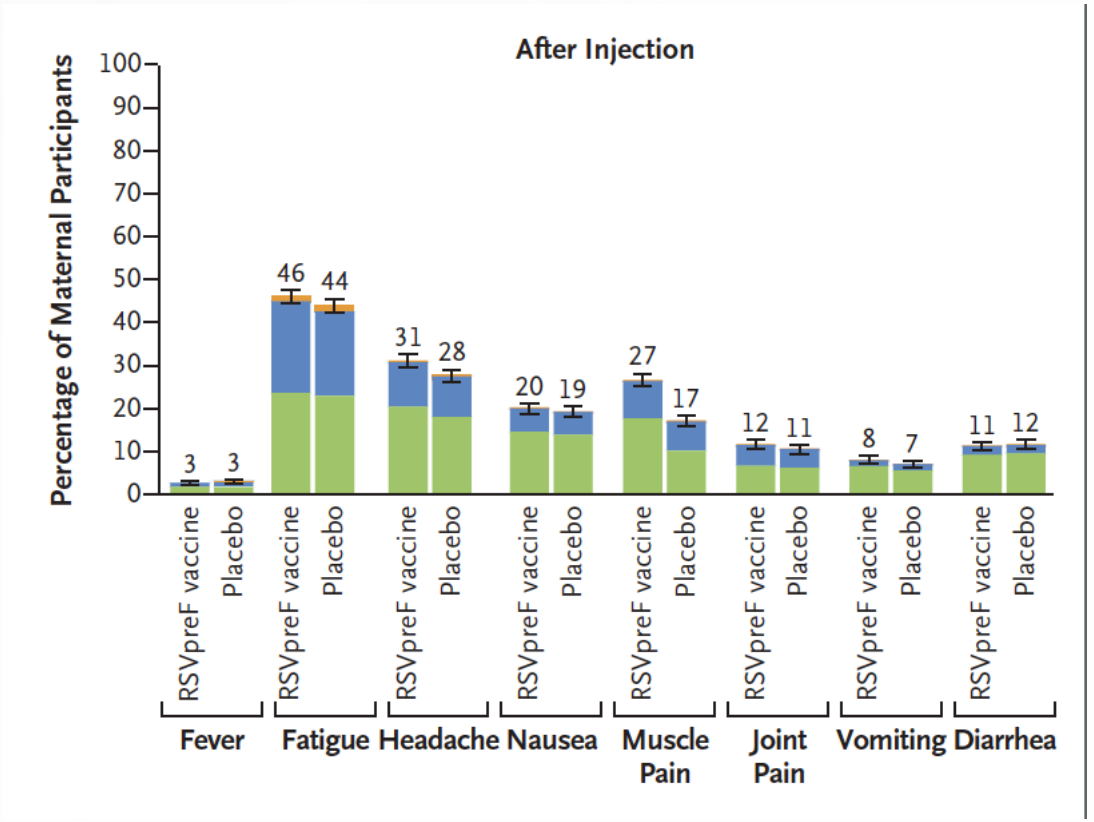
RSVpreF: Effectiveness Data (Argentina)

	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)§

Perez Marc, 2025

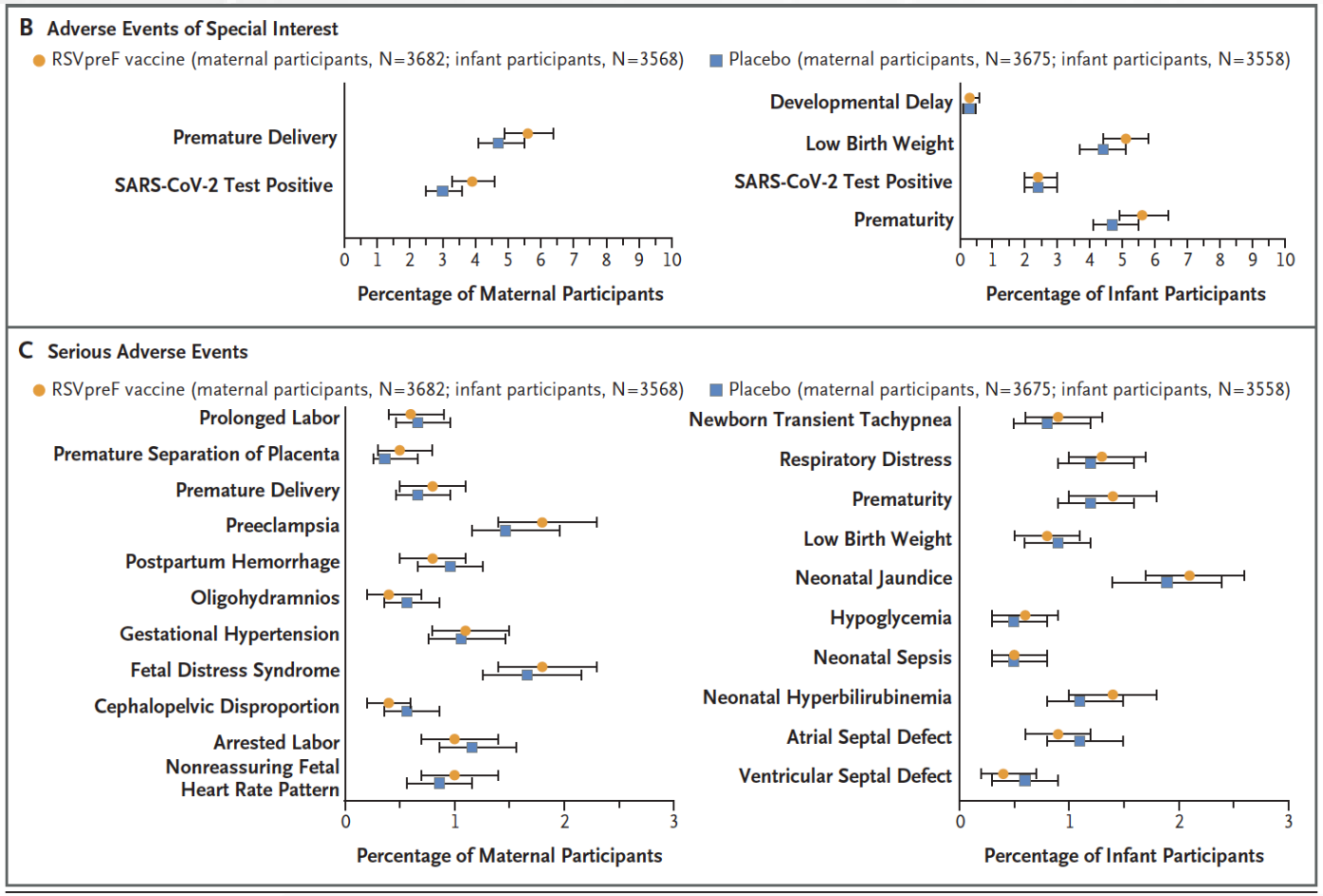
RSVpreF: Adverse Effect Rates





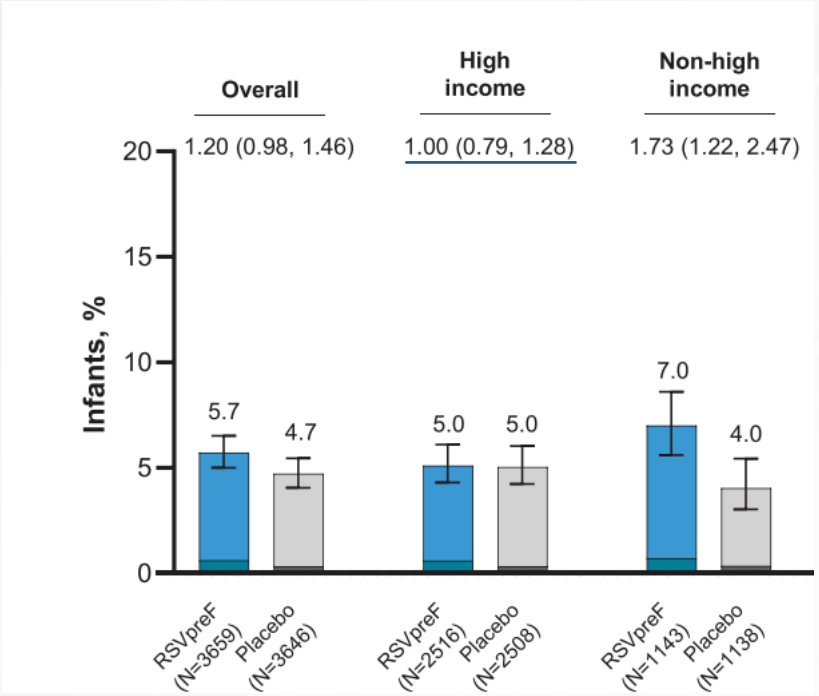
Kampmann B et al., 2023

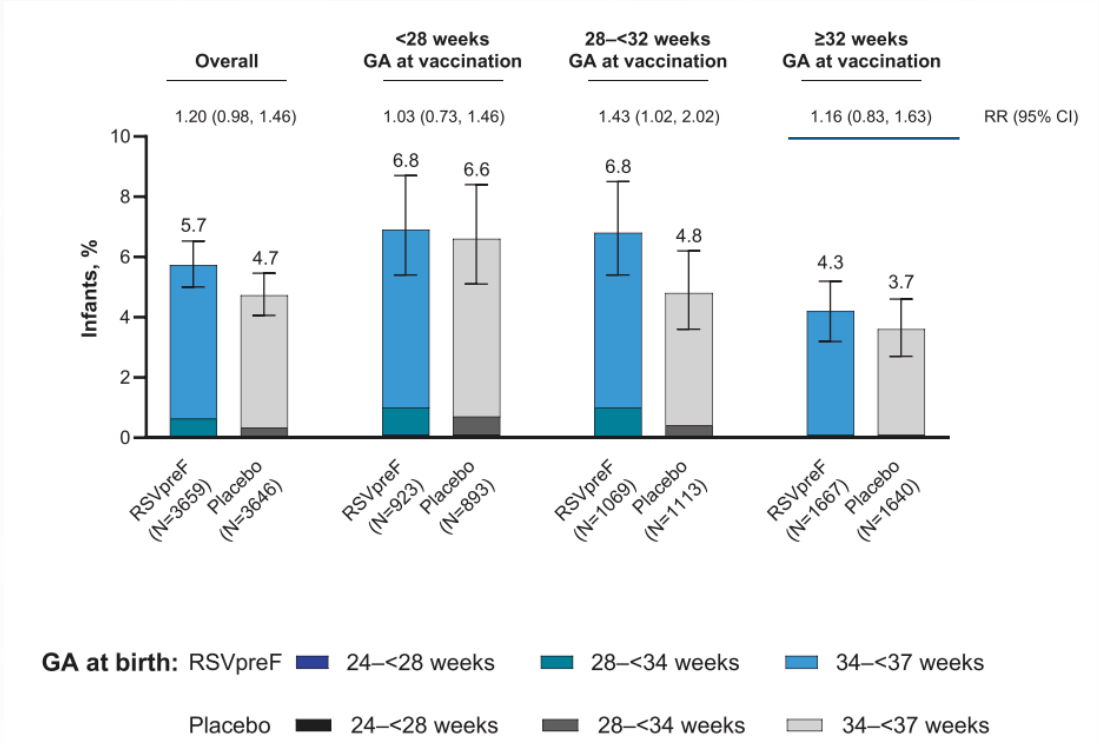
RSVpreF: Adverse Effect Rates



No significant differences in rate of adverse events

RSVpreF: Closer Look at Preterm Birth





Madhi, 2025

While no difference in preterm birth rates, subgroup analysis noted higher rates of preterm birth in:

- Non-high income countries -- RR: 1.75 (95% CI: 1.25, 2.47)
- When administered between 28-32 weeks gestational age – RR: 1.43 (95% CI: 1.02– 2.02)

RSVpreF: Reassuring Preterm Birth Data

Table 2. Interim Prevalence of Prespecified Safety Outcomes After Exact and Propensity Score Matching

Safety outcome	No. (%) RSVpreF[a]	No. (%) No RSVpreF[a]	Adjusted HR (95% CI)	*P* value
Preterm birth[b]	282 (4.2)	366 (5.5)	0.76 (0.63-0.91)	<.001
PROM[b]	960 (14.0)	922 (13.5)	1.02 (0.88-1.18)	.82
Preterm PROM[b]	120 (1.8)	154 (2.3)	0.77 (0.59-0.99)	.042
Overall hypertensive disorders of pregnancy[b]	939 (14.3)	858 (13.1)	1.07 (0.92-1.24)	.39
Gestational hypertension[b]	635 (9.7)	635 (9.7)	NA[c]	
PE/E[b]	389 (5.9)	367 (5.6)	NA[c]	
Postpartum hypertension[d]	170 (2.6)	176 (2.7)	NA[c]	
Chronic hypertension superimposed with PE/E[b]	62 (0.9)	45 (0.7)	NA[c]	
HELPP syndrome[b]	13 (0.2)	13 (0.2)	NA[c]	

Abbreviations: HELLP, hemolysis, elevated liver enzymes, low platelet count; HR, hazard ratio; NA, not available; PE/E, preeclampsia or eclampsia; PROM, premature rupture of membranes; RSVpreF, bivalent prefusion F subunit–based respiratory syncytial virus vaccine.

[a] Denominator for percentages is the total pregnancies eligible for the outcome. For the composite hypertensive disorders of pregnancy outcome, a pregnancy may have had more than 1 component of the composite outcome, so total percentages may sum to more than 100%.

[b] Evaluated from the day after the index date though 42 days after the index date. The index date in RSVpreF-vaccinated pregnancies and the pseudovaccination date in unvaccinated pregnancies is defined as the gestational age at vaccination in the matched RSVpreF-vaccinated pregnancy.

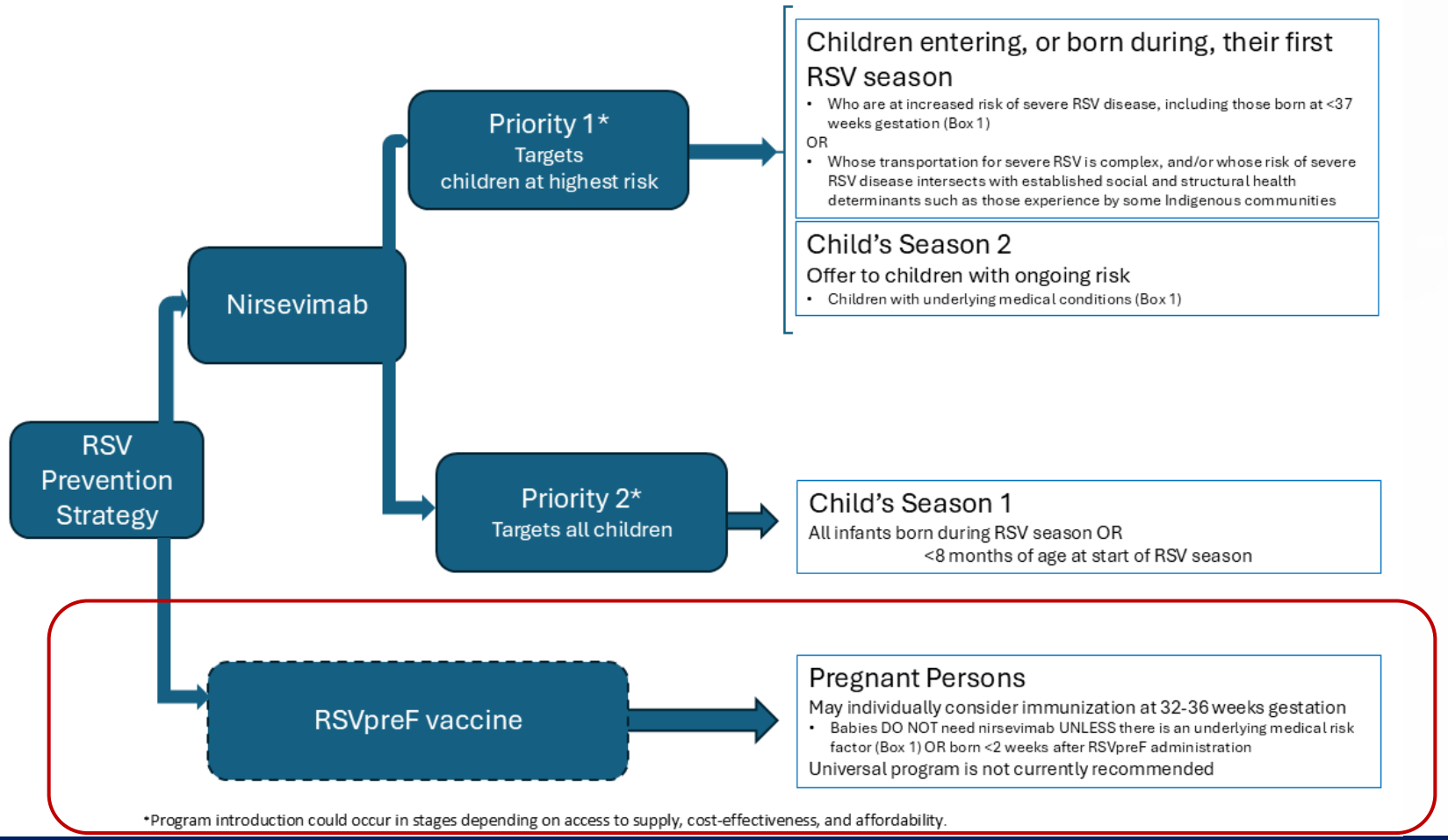
[c] No hypothesis testing was conducted for components of this composite outcome, but all absolute values of standardized mean differences less than 0.1.

[d] Evaluated from the delivery date through 42 days after the index date.

(Michnick, 2026)

With 1:1 matching of 6857 unvaccinated to vaccinated pregnancies using US Health Plan Data

NACI Recommendations on RSV Immunization



(NACI, May 2024)
Adapted from CPS

SOGC Statement on RSV Immunization to Prevent Infant RSV Infection

If there is no expected supply of nirsevimab for infant immunization or if the pregnant patient plans to decline infant immunization, maternal RSV vaccination should be offered between 32^{+0} and 36^{+6} weeks.

FULL STATEMENT

Limitations of Evidence (at the time of statements)

1. Limited real-world effectiveness nirsevimab and RSVpreF vaccine

2. Guidelines are made with limited studies on acceptance in Canadian population

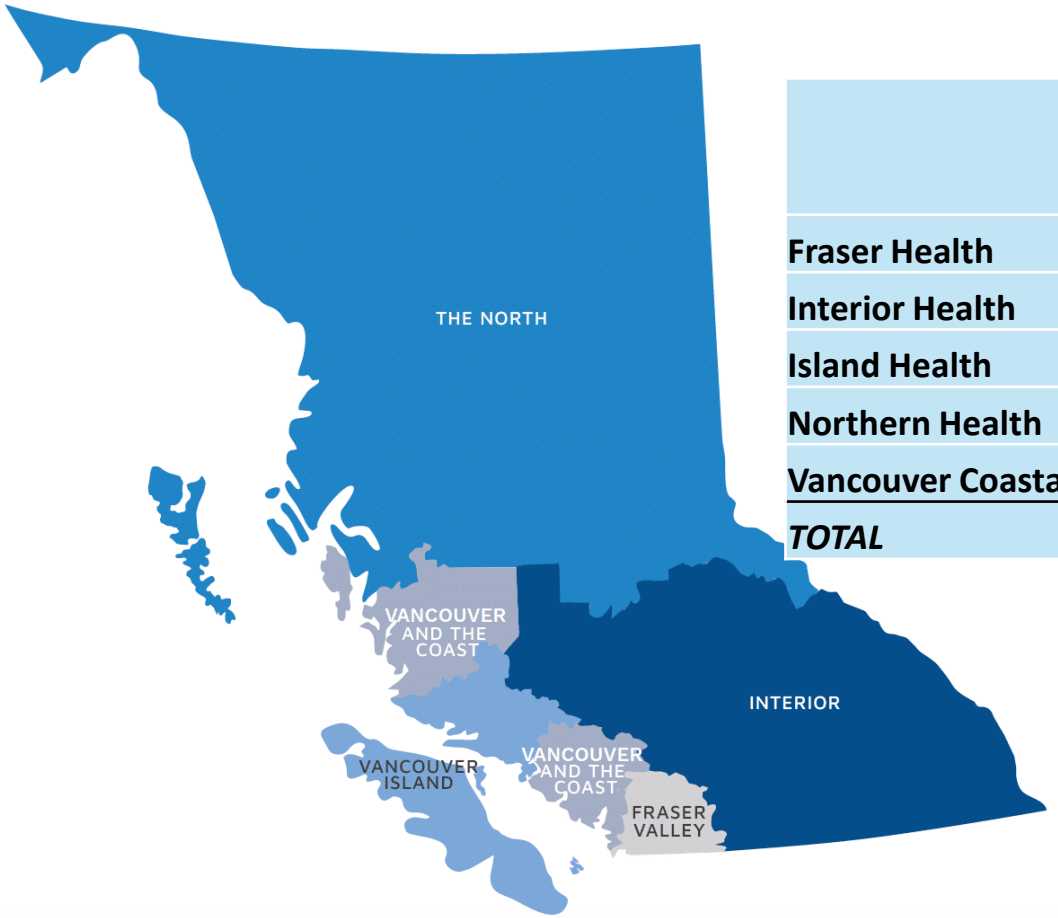
3. Lack of co-administration data with other vaccines in pregnancy, though concurrent administration remains permitted

4. Lack of long-term post-immunization studies:
   - Subsequent pregnancies
   - Impact on RSV severity beyond 180 days

Canadian RSV Immunization Strategies (2024/2025)

Alberta	Palivizumab for select high-risk infants
British Columbia	Nirsevimab and palivizumab for select high risk infants
Manitoba	Palivizumab for select high-risk infants
New Brunswick	Palivizumab for select high-risk infants
Newfoundland and Labrador	Palivizumab for select high-risk infants
Nova Scotia	Nirsevimab and palivizumab for select high risk infants
Northwest Territories	Nirsevimab **universal coverage**
Nunavut	Nirsevimab **universal coverage**
Ontario	Nirsevimab and RSVpreF **universal coverage**
Prince Edward Island	Palivizumab for select high-risk infants
Quebec	Nirsevimab **universal coverage**
Saskatchewan	Palivizumab for select high-risk infants
Yukon	Nirsevimab **universal coverage**

Previous Season's Immunization Strategy



	Number of RSV vaccines	Number of Births per 6 months (2023)	Proportion of births vaccinated
Fraser Health	1975	9078	22%
Interior Health	424	2830	14%
Island Health	586	2717	22%
Northern Health	62	1375	5%
Vancouver Coastal Health	1464	4368	34%
TOTAL	*4511*	*20368*	*22%*

Varying rates of immunization between health authorities

Canadian RSV Immunization Strategies (2025/2026)

Alberta	Nirsevimab for select high risk infants
British Columbia	Nirsevimab for select high risk infants
Manitoba	Nirsevimab **universal coverage**
New Brunswick	Nirsevimab for select high risk infants
Newfoundland and Labrador	Nirsevimab for select high risk infants
Nova Scotia	Nirsevimab **universal coverage**
Northwest Territories	Nirsevimab **universal coverage**
Nunavut	Nirsevimab **universal coverage**
Ontario	Nirsevimab and RSVpreF **universal coverage**
Prince Edward Island	Nirsevimab **universal coverage**
Quebec	Nirsevimab **universal coverage**
Saskatchewan	Nirsevimab **universal coverage**
Yukon	Nirsevimab **universal coverage**

2025/2026 RSV Season: Immunization Program

- Late preterm and term infants without other medical conditions *(i.e. 90% of infants born in BC)* will **NOT** qualify for funded nirsevimab
- Instead, these infants will once again rely on RSV vaccination in pregnancy to be protected against severe RSV infections

Private Funding for RSV Vaccination in Pregnancy

Cost of RSVpreF: Approximately $280

- Not covered by BC PharmaCare, Interim Federal Health

- Extended insurance providers may cover 80-100%
  - Check online or call insurance providers
  - Drug Identification Number (DIN): 02544040

Payer's Name	For covered, % of lives in BC	RSVpreF Covered?
Pacific Blue Cross	39%	Yes
Canada Life	14%	Yes
GreenShield	12%	Yes
Manulife Financial	9%	Yes
Sun Life Financial	8%	Yes
ClaimSecure (Direct)	4%	Yes
TELUS TPAs	3%	Yes
Beneva (SSQ)	2%	Yes
Others	7%	Depends

* Please note that this chart was provided by Pfizer representative.

Private Funding for RSV Vaccination in Pregnancy

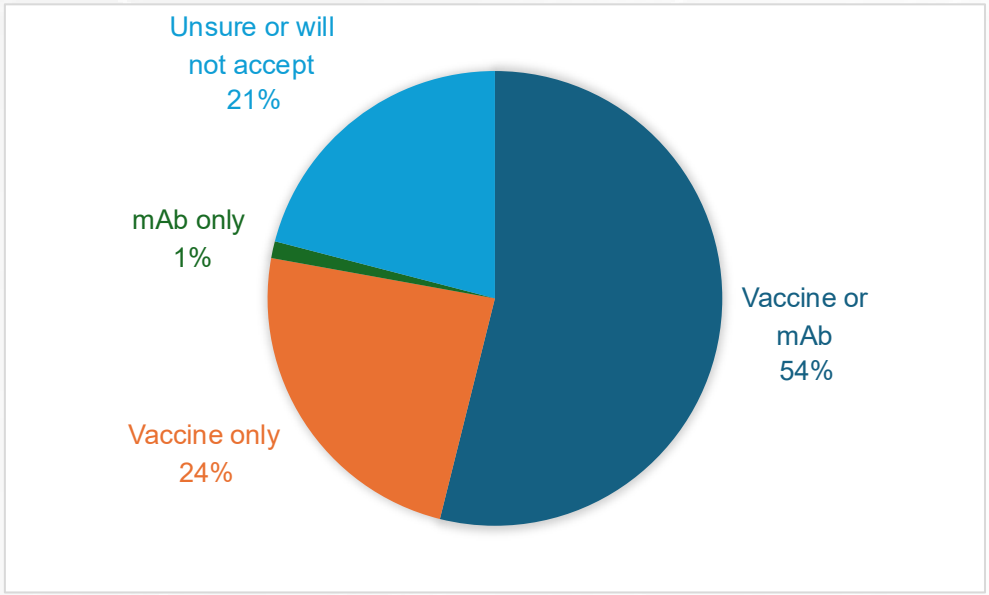
Confirmed for 2025/2026 season

RSVpreF will be covered under First Nations Health Benefits

Acceptability of RSV Immunization: COVERED

- Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals (COVERED) Study – sub-analysis for RSV immunization acceptability

Among 723 survey respondents:

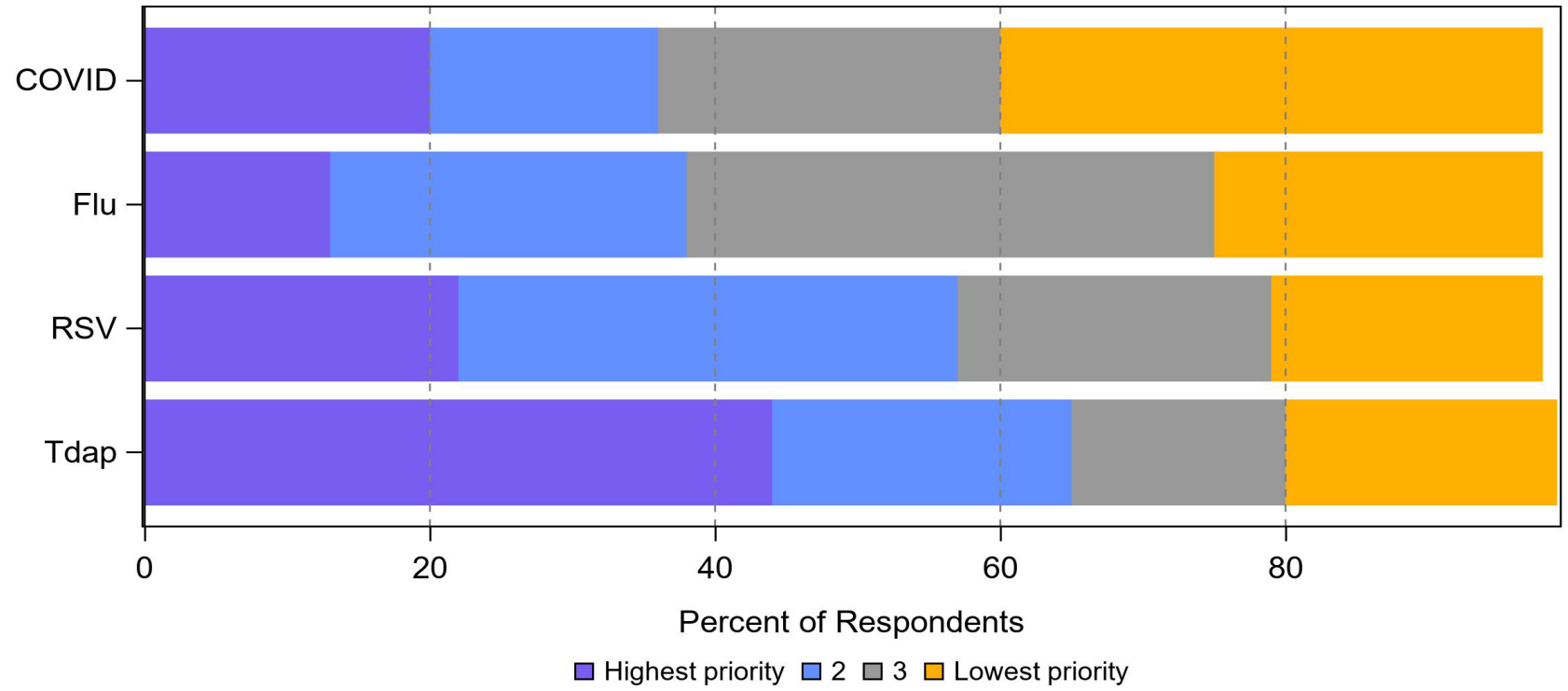


- When asked to choose between vaccine in pregnancy vs infant mAb:
  - **79%** preferred RSV vaccine in pregnancy
  - **4.4%** preferred infant mAb
  - **14%** did not have a preference

(McClymont, 2025)

Patient Priorities on Recommended Immunizations

Patient priority for recommended immunizations against respiratory pathogens (n=1008)



Unpublished Data by BC Reproductive ID Group

Take Home Message

1. RSVpreF is a safe, effective, and acceptable immunization option to reduce severe RSV infections in infants that is preferred by pregnant individuals.

2. Universal funding towards RSV immunization programs will reduce infant hospitalizations, but the approach may vary across jurisdictions.

3. For pregnancies relying on RSVpreF, third-party insurers often cover a significant portion of the vaccine cost.

Questions?