Vaccinations in Pregnancy: Evidence, Safety and Effectiveness

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Canadian Association of Midwives Webinar

Jan. 7 2026

Faculty/Presenter Disclosure

- **Faculty:** Jesse Papenburg

- **Relationships with commercial interests:**
  - **Grants/Research Support:** Merck (site PI, ended 2023)
  - **Consulting Fees:** Enanta (ad hoc advisory board, 2024)

- **Other:**
  - **Voting member National Advisory Committee on Immunization**
  - **Chair Quebec Immunization Committee**

Objectives:

1. Understand why newborns, young infants and pregnant persons are particularly vulnerable to certain infections
2. Describe how vaccination during pregnancy can protect newborns and young infants
3. Outline the evidence surrounding Canadian recommendations for vaccination against pertussis, influenza, RSV and COVID-19, during pregnancy

Vaccination to protect

Pregnant woman?

Unborn?

Newborn?

All of the above… but not for all pathogens!

Protecting the newborn via maternal antibody transfer - closing the window of vulnerability

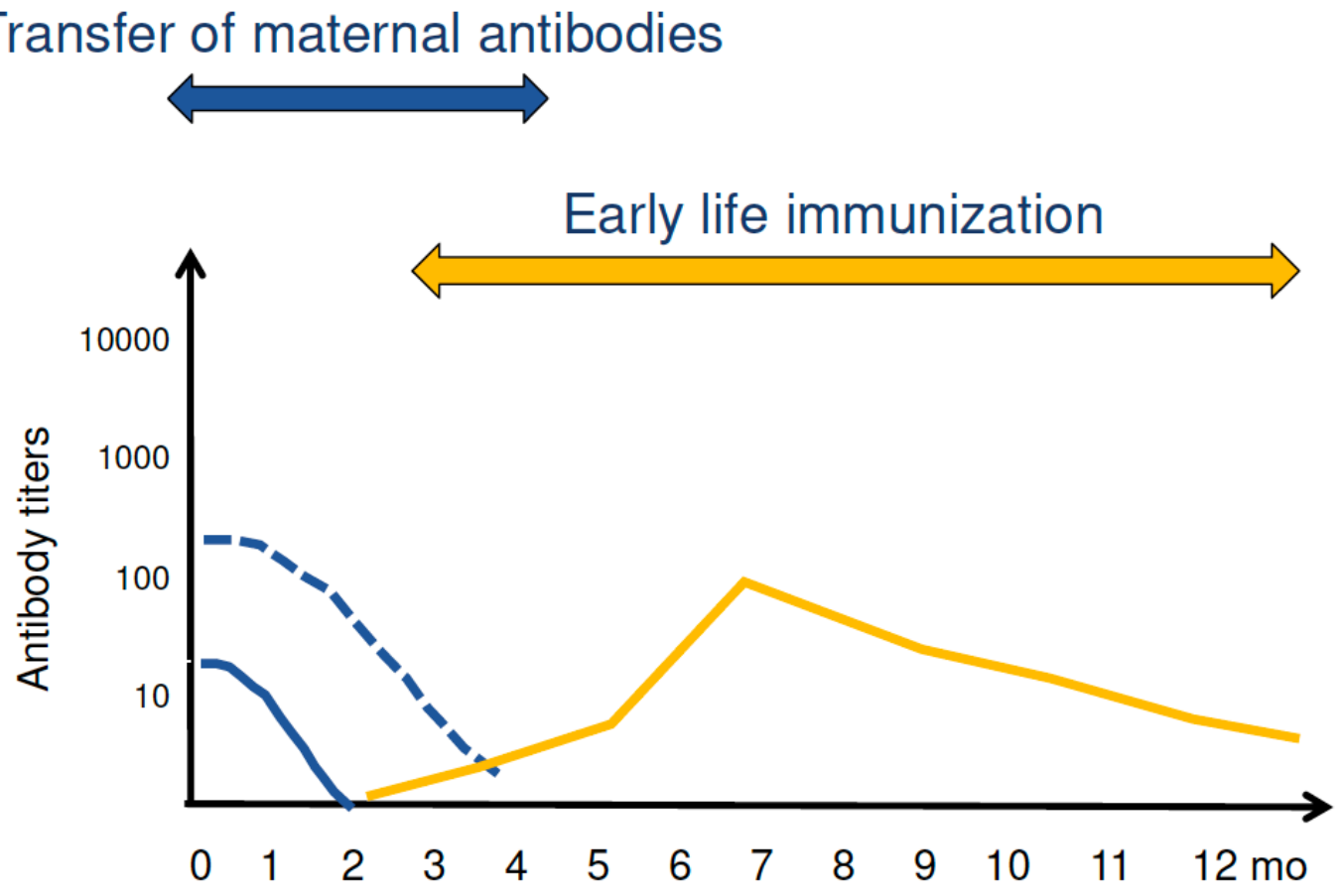


Figure courtesy Dr. Christiane Eberhardt MD, MSc
Center for Vaccinology, University Hospitals of Geneva, Switzerland

Is the immune system in early life immature?

Requirements

Fetus  **Suppression of rejection** (tolerogenic)

Birth  **Prevention of systemic inflammation**

Newborn
(0-28 days)  **Resolution of inflammation**

The early life immune system is perfectly adapted to unique challenges!

Figure courtesy Dr. Christiane Eberhardt MD, MSc
Center for Vaccinology, University Hospitals of Geneva, Switzerland

How does the early-life immune system cope with infections?

Newborn
(0-28 days)

Fulminant severe infections
(most pathogens)

Pyogenic infections with
extracellular bacteria
(Staphylococcus, GBS, E. coli)

Higher rates of chronicity
(HBV, CMV, etc.)

Infant
(1-12 months)

More severe / protracted
viral infections
(influenza, RSV, rotavirus…)

Increased vulnerability to
specific bacteria
(pertussis, encapsulated bacteria…)

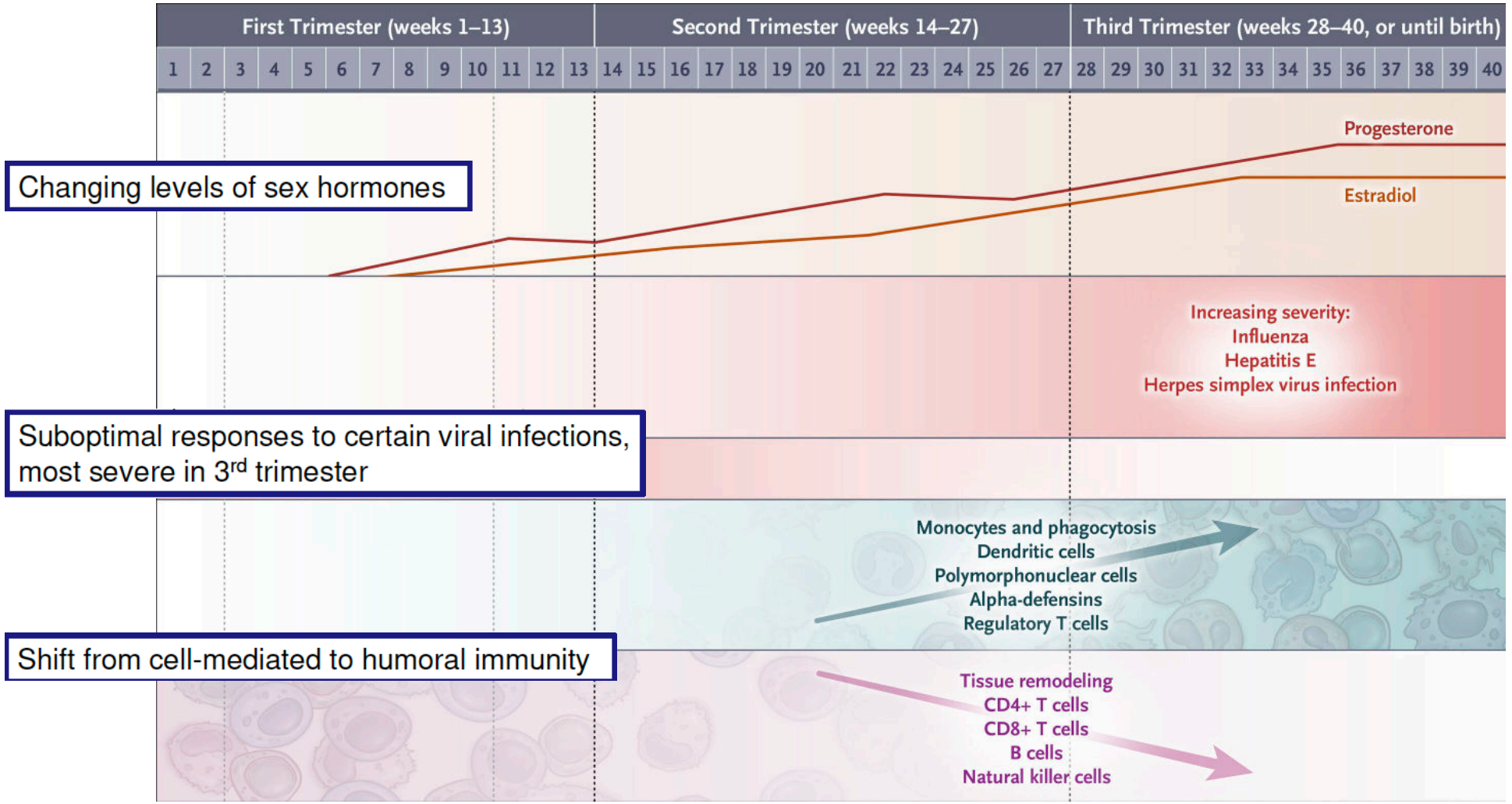
Toddler

Adult-like resistance to viruses

Progressive resistance to
encapsulated bacteria

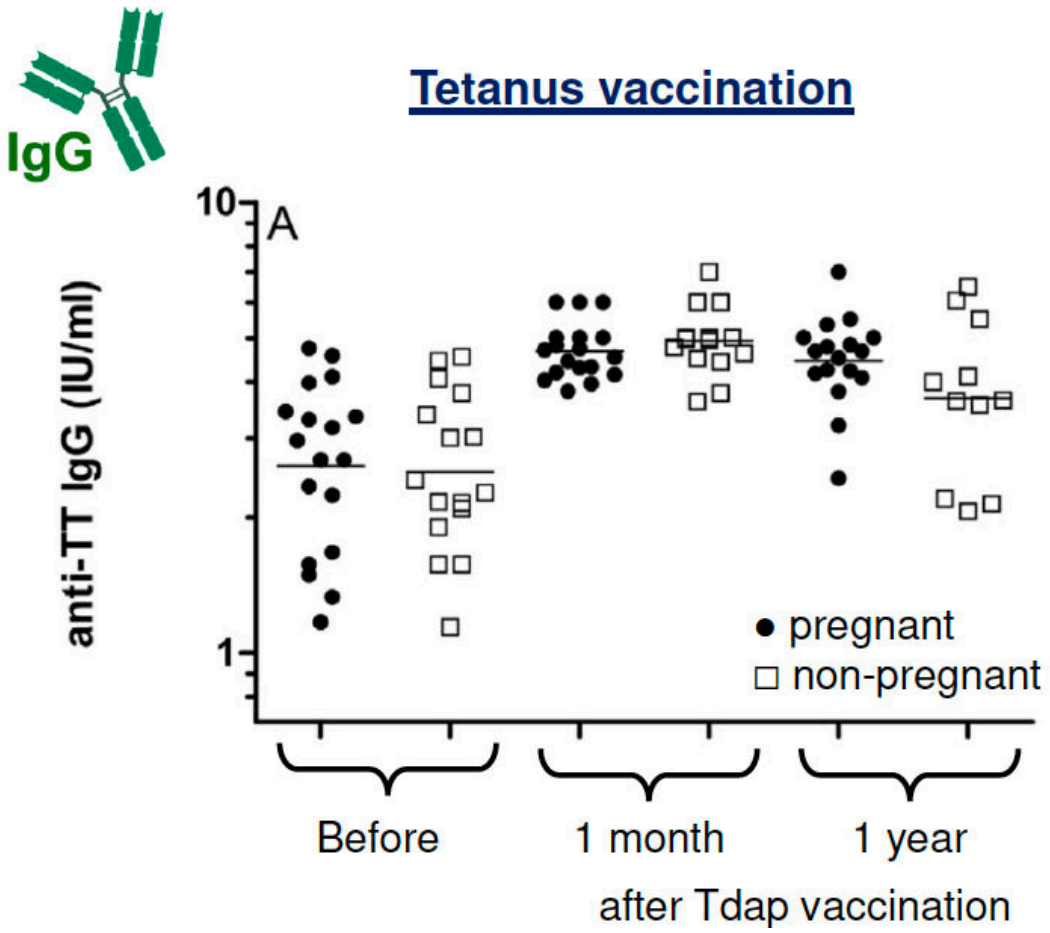
Figure courtesy Dr. Christiane Eberhardt MD, MSc
Center for Vaccinology, University Hospitals of Geneva, Switzerland

How does pregnancy affect immune responses?



Omer SB. N Engl J Med 2017;376:1256–67

Can pregnant women mount antibody responses to vaccination?



Similar responses compared to non-pregnant women also shown for diphteria, pertussis, SARS-CoV and seasonal influenza

Hulka 1964, Murray 1979, Christian 2013, Kay 2015, Munoz, 2014, Gray, 2021, Collier, 2021, Atyeo, 2022, Prabhu, 2023

Figure courtesy Dr. Christiane Eberhardt MD, MSc
Center for Vaccinology, University Hospitals of Geneva, Switzerland

What types of vaccines are recommended or not during pregnancy?

sub-unit

mRNA

(inactivated)

Influenza (TIV, QIV)
Tetanus, **pertussis**, diphtheria
RSV
SARS-CoV-2 (country-dependent)

Numerous studies on Tdap, Influenza, but also SARS-CoV-2 :
no increase in maternal or fetal complications
(stillbirth, congenital malformations, prematurity...)

Live-attenuated

example:
measles, mumps, rubella (MMR)
chickenpox
yellow fever
(live-attenuated influenza vaccine LAIV)

*

Catch-up after delivery !

* no reason for termination of pregnancy
if accidentally given during pregnancy!!

Figure courtesy Dr. Christiane Eberhardt MD, MSc
Center for Vaccinology, University Hospitals of Geneva, Switzerland

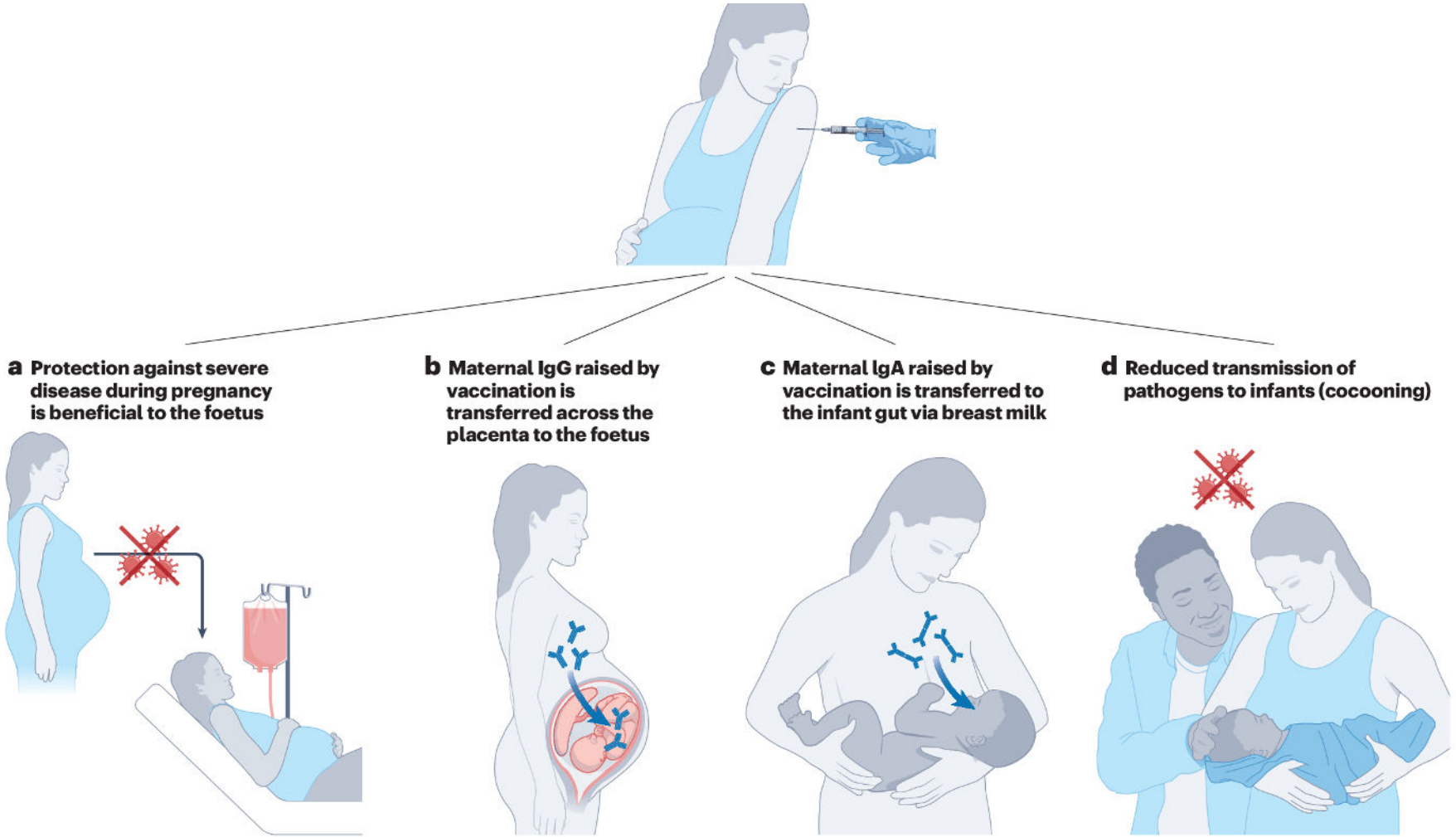
Safety of immunization in pregnancy for the fetus and infant

- There is no theoretical reason to anticipate adverse events in the fetus or infant following vaccination with non-live vaccines during pregnancy.
- There are no published data indicating that currently authorized non-live vaccines are teratogenic or embryotoxic.
- There are no published data confirming a causal relationship between any authorized non-live vaccine and specific adverse pregnancy outcomes.

- **In general, live attenuated viral or bacterial vaccines are contraindicated in pregnancy, as there is a theoretical risk to the fetus**; however, when benefits outweigh this theoretical risk, vaccination with a live attenuated vaccine may be considered (e.g., during a rubella outbreak).

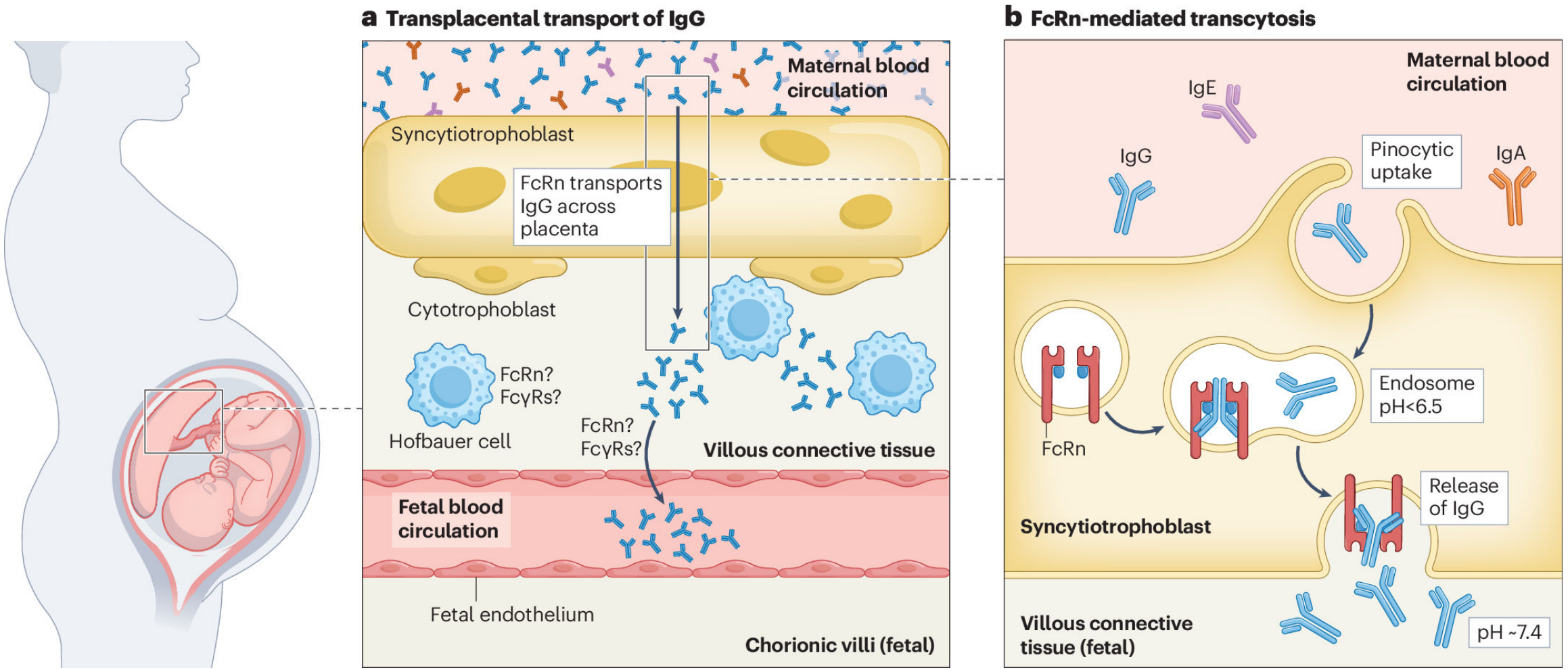
https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-4-immunization-pregnancy-breastfeeding.html

How vaccination during pregnancy protects the newborn



Male, V., Jones, C.E. *Nat Rev Immunol* 2025

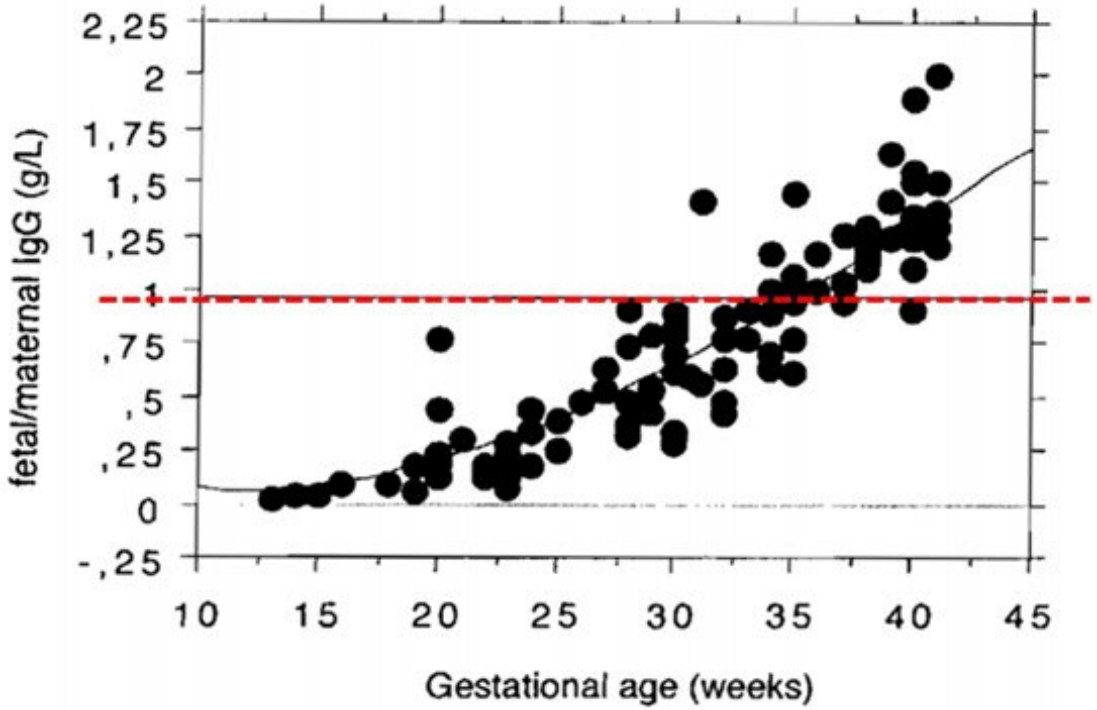
Active transplacental transport of maternal antibodies



Male, V., Jones, C.E. Vaccination in pregnancy to protect the newborn. *Nat Rev Immunol* 2025

Progressive transfer of maternal antibodies to the fetus

- Maternal IgG crosses the placenta by a ***selective*** and ***active*** receptor-mediated transport system (FcRn) (not IgM, IgA or IgE)
- Passage begins at ~ 17 wk, increases with gestation
- 33-35 wk: Mat = Fetal IgG
- 40 wk: Fetal > Mat IgG
- Half life ~ 30-40 days
- High Ab → longer protection
- Vaccination 26-34 wks gestation
  - maximizes cord IgG levels



Palfi and Selbing, AJRI 1998

Slide adapted from Dr Flor Munoz, Baylor College of Medicine
Texas Children's Hospital

Breast Milk Antibodies: Added Benefit

Breastfeeding is associated with:

- **Mucosal Immunity**
- Reduction of burden of **diarrheal and respiratory diseases**
- Especially important in low-resource and settings where diarrheal diseases and malnutrition are prominent

Maternally derived protection for several months

Pathogen specific	⟷	**Pneumococcus**
Secretory IgA		**Influenza**
Secretory IgM		**Hib**
IgG		**RSV**
IgA		**Meningococcus**
IgM		**Pertussis**

Slide adapted from Dr Flor Munoz, Baylor College of Medicine
Texas Children's Hospital

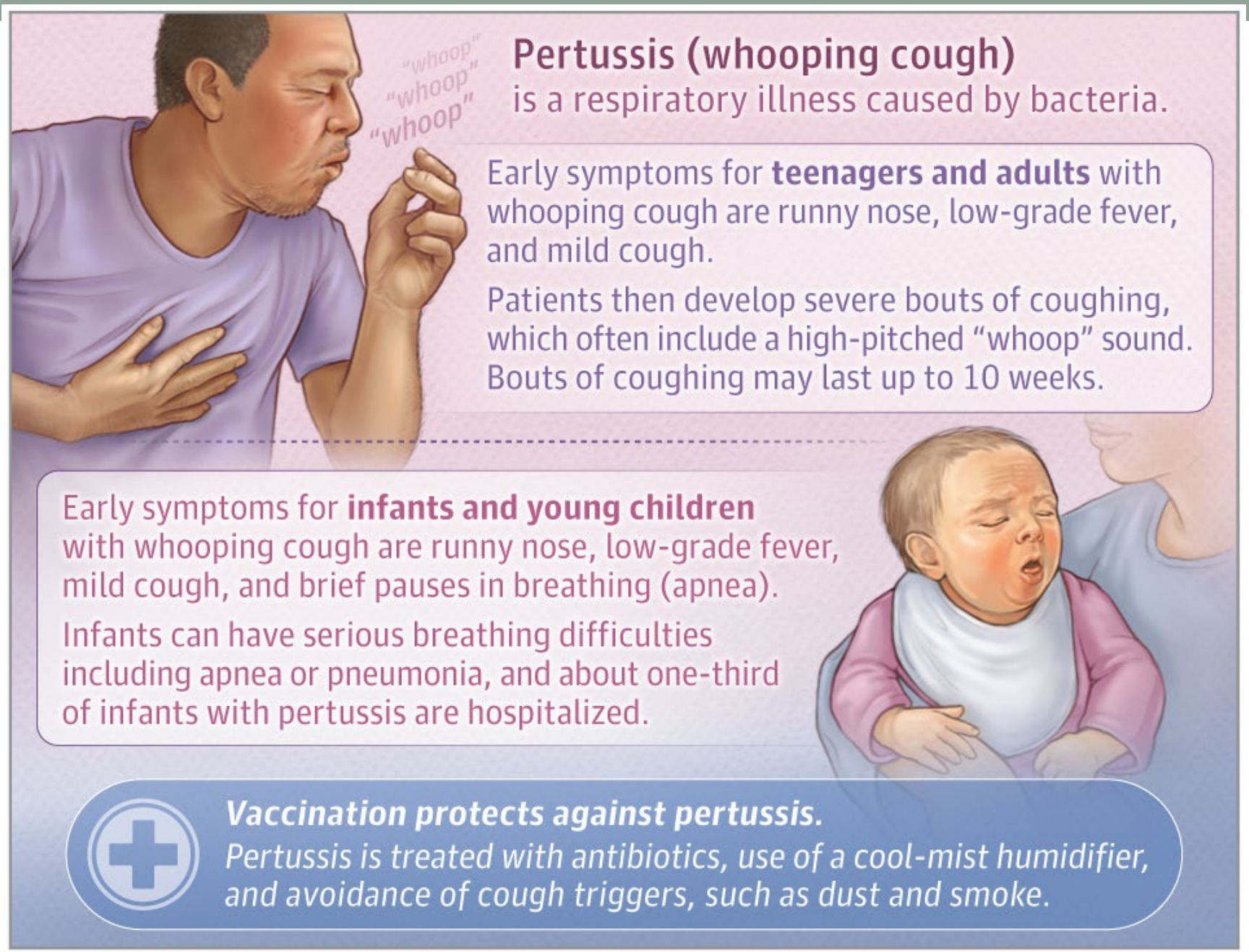
PERTUSSIS

Given as Tdap (tetanus toxoid, diphtheria toxoid, acellular pertussis) vaccine

NACI Recommendation

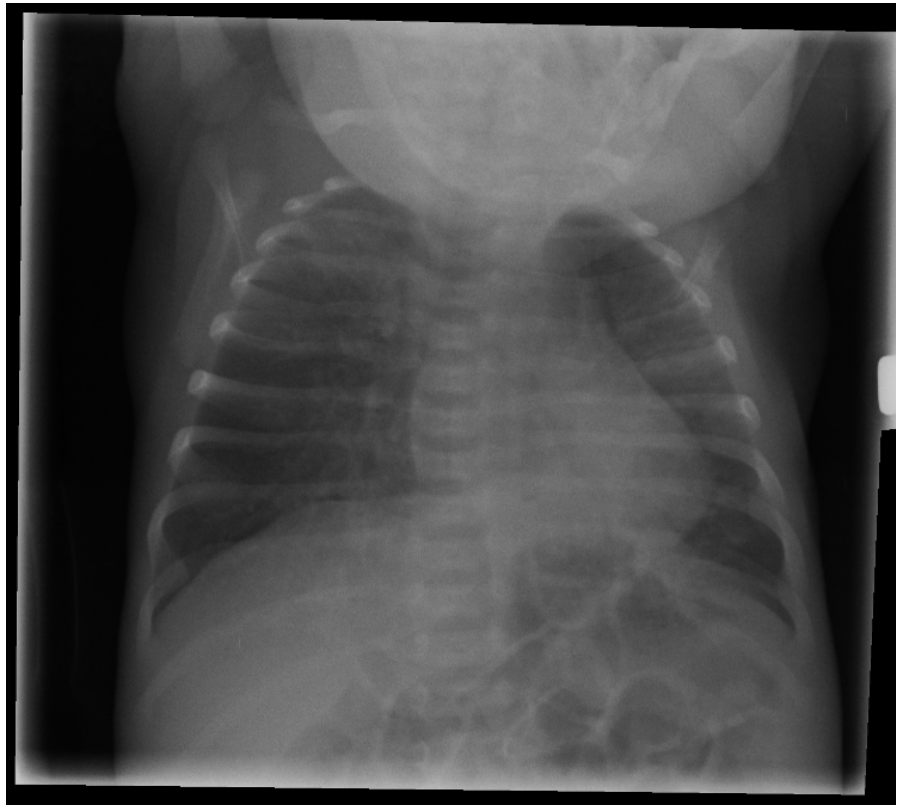
- **All pregnant women and pregnant individuals should be given tetanus toxoid, diphtheria toxoid, acellular pertussis (Tdap) vaccine during every pregnancy**, irrespective of their Tdap immunization history.
- The vaccine should ideally be provided between 27 and 32 weeks of gestation.
  - Immunization between 13 and 26 weeks of gestation may be considered in situations where there may be an increased risk of preterm delivery.
- Although it is preferable that immunization is administered in sufficient time before birth (i.e., 2-4 weeks) to allow optimal transfer of maternal antibodies, if not given earlier it should be given at any time until delivery, to provide partial protection and prevent pertussis infection in pregnancy and subsequent transmission to the newborn.
- Administration of tetanus toxoid in pregnancy has been shown to prevent neonatal tetanus infection and death in countries with high rates of neonatal tetanus.

https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-15-pertussis-vaccine.html



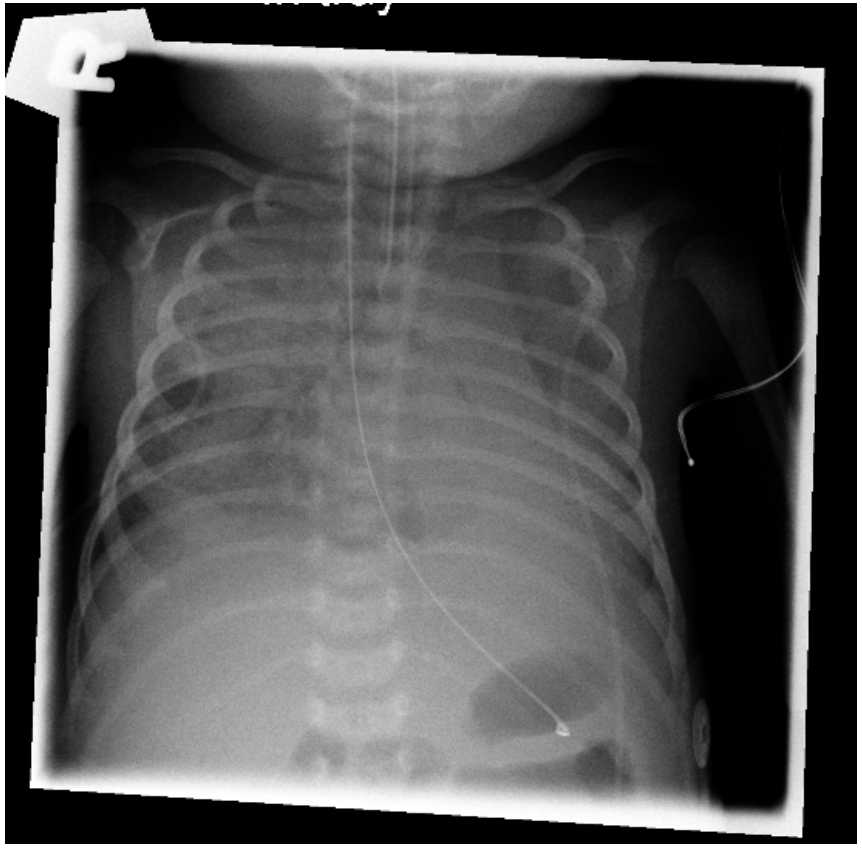
JAMA. 2024;332(12):1030.

25/12



- Patchy moderate to marked alveolar opacities noted at RUL, lower aspect of the LUL, and especially at posteromedial bases, L>R.
- At the LUL, the opacities are confluent such that a bacterial infection is suspected.
- Findings could be on a background of pre-existing viral respiratory tract infection. Clinical correlation required.

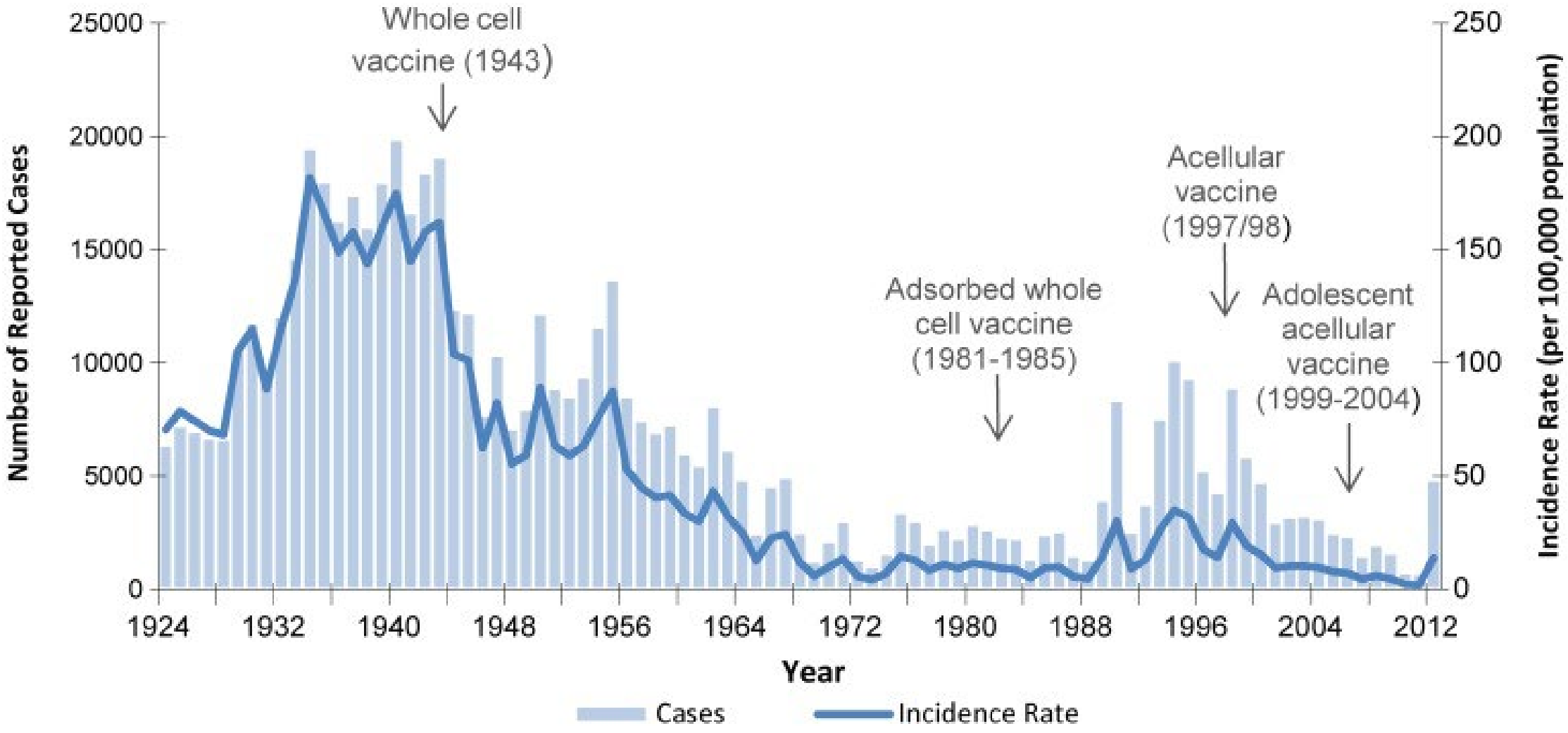
27/12



"widespread alveolar opacities"

- Ampicillin, cefotaxime and azithromycin initiated in PICU

Pertussis in Canada, 1924 to 2012

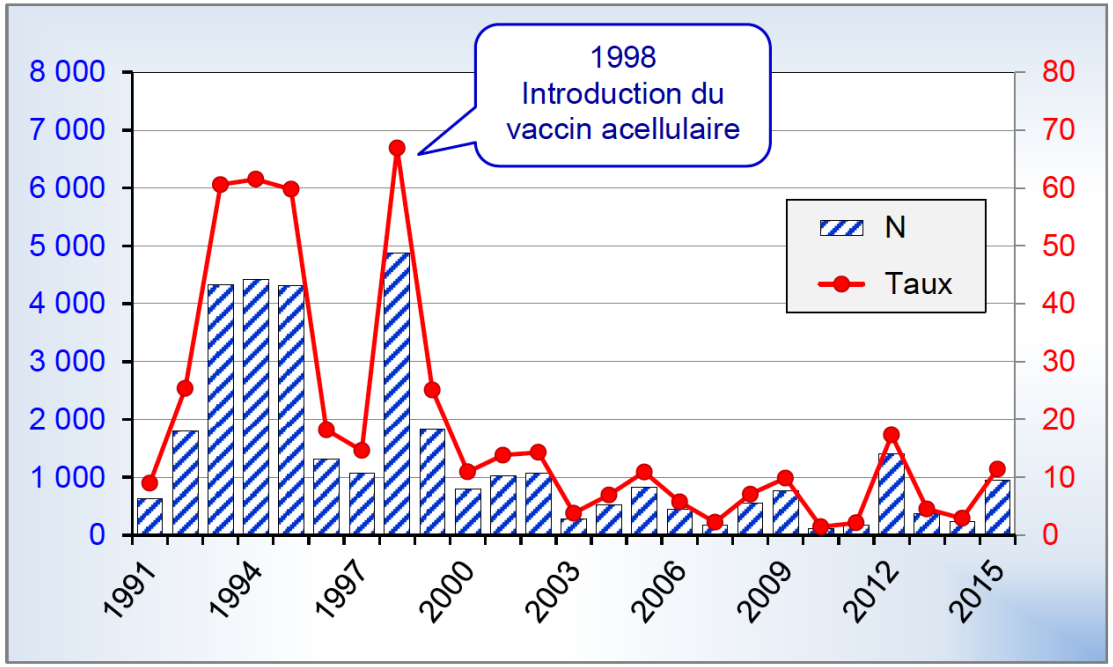


Smith T et al. *Can Commun Dis Rep*. 2014

Clyclical outbreaks

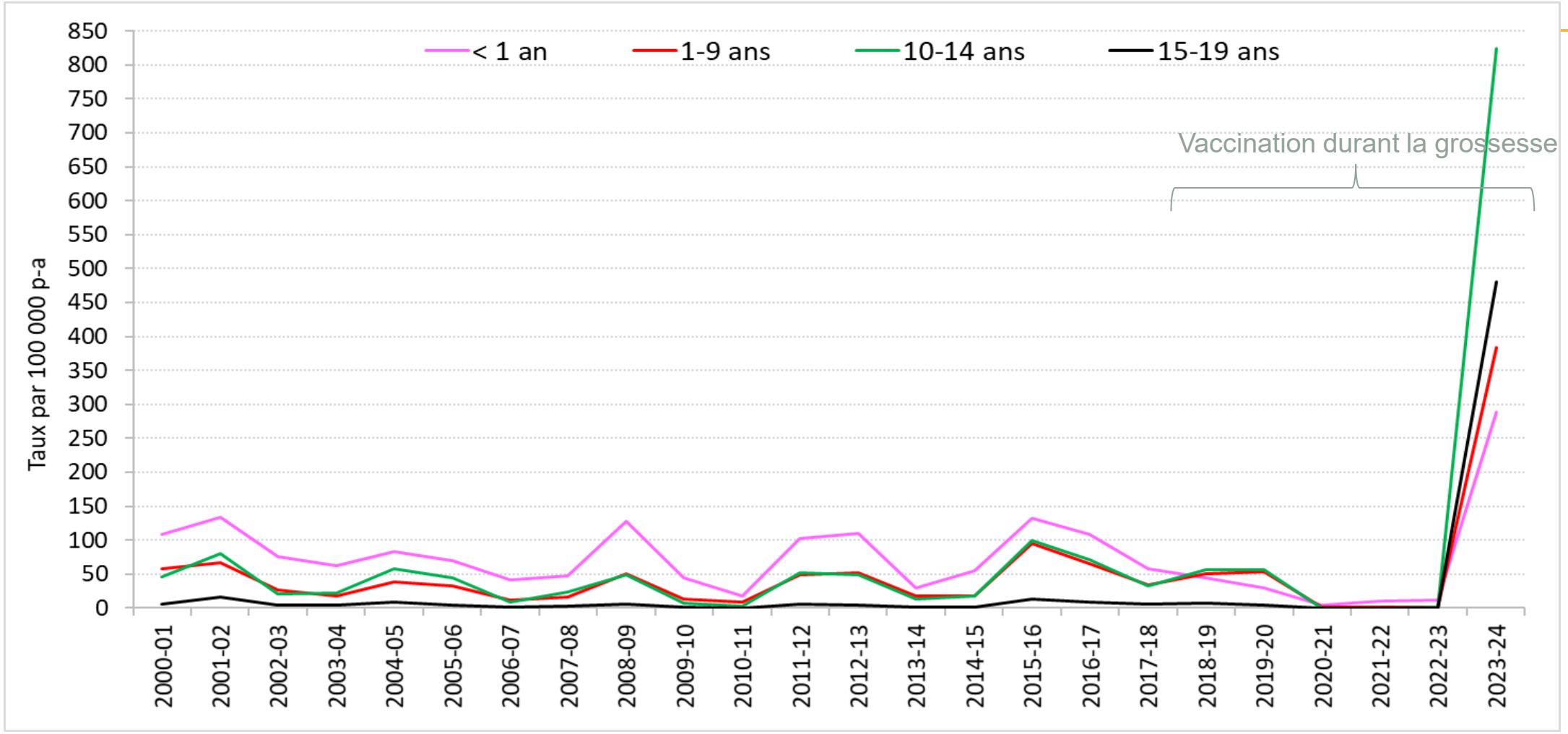
- Since 2000, we have seen pertussis outbreaks every 3-5 years in Quebec

Coqueluche : nombre de cas déclarés et taux brut d'incidence, Québec, 1992 à 2015
(Taux pour 100 000 h.)



MSSS, Flash Vigie, Janvier 2016.

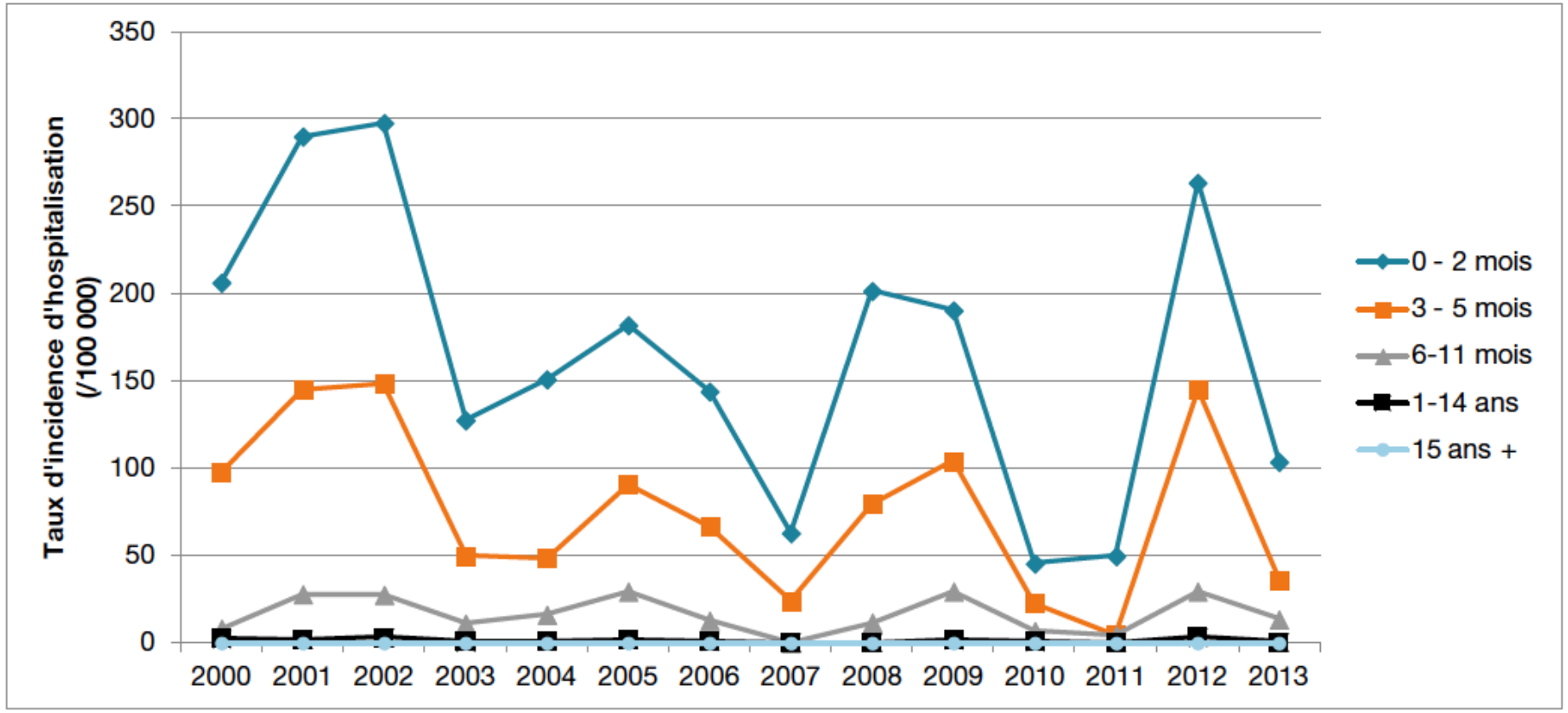
Taux de coqueluche par groupe d'âge, 2000 – 2024
Pertussis incidence by age group, 2000 – 2024



Source : Infocentre de santé publique, extraction le 4 septembre 2024.

Severe pertussis disproportionately affects young infants

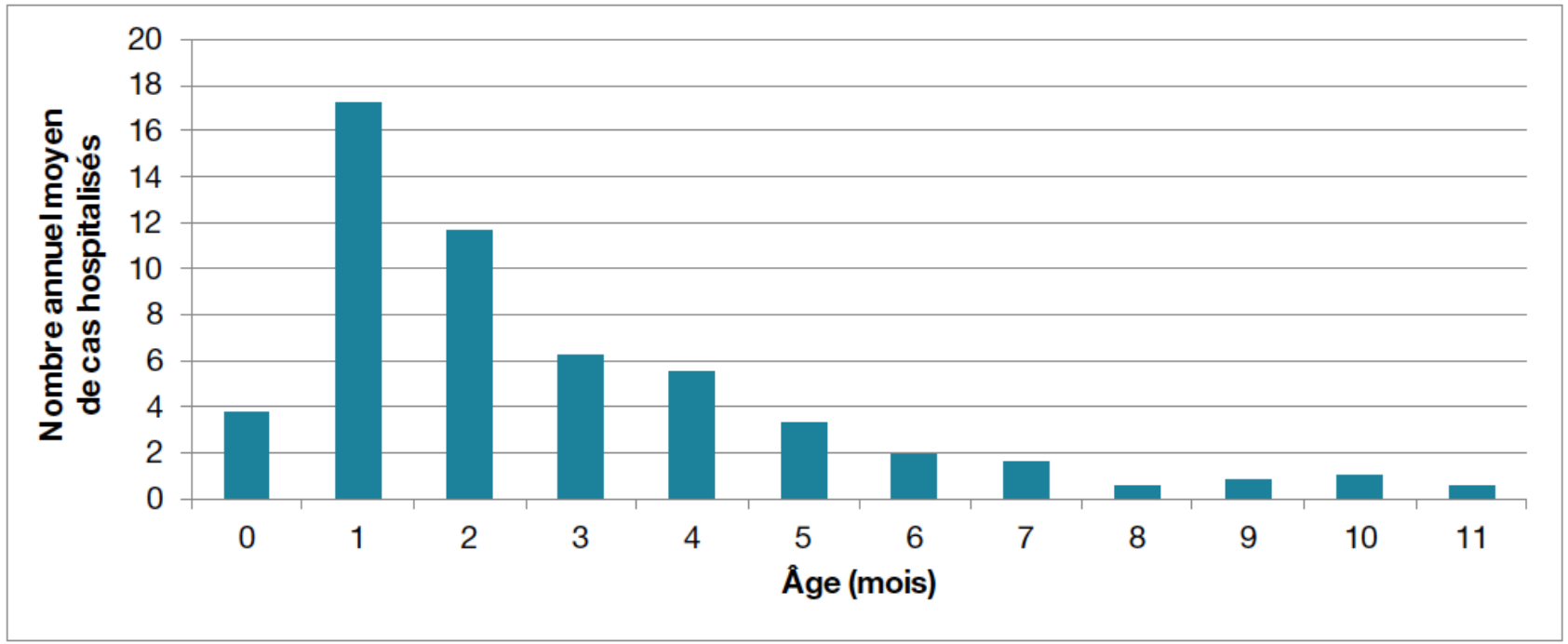
Figure 7 **Taux d'incidence brut d'hospitalisation pour coqueluche, par groupe d'âge, Québec, 2000-2013**



INSPQ, 2015

Severe pertussis disproportionately affects young infants

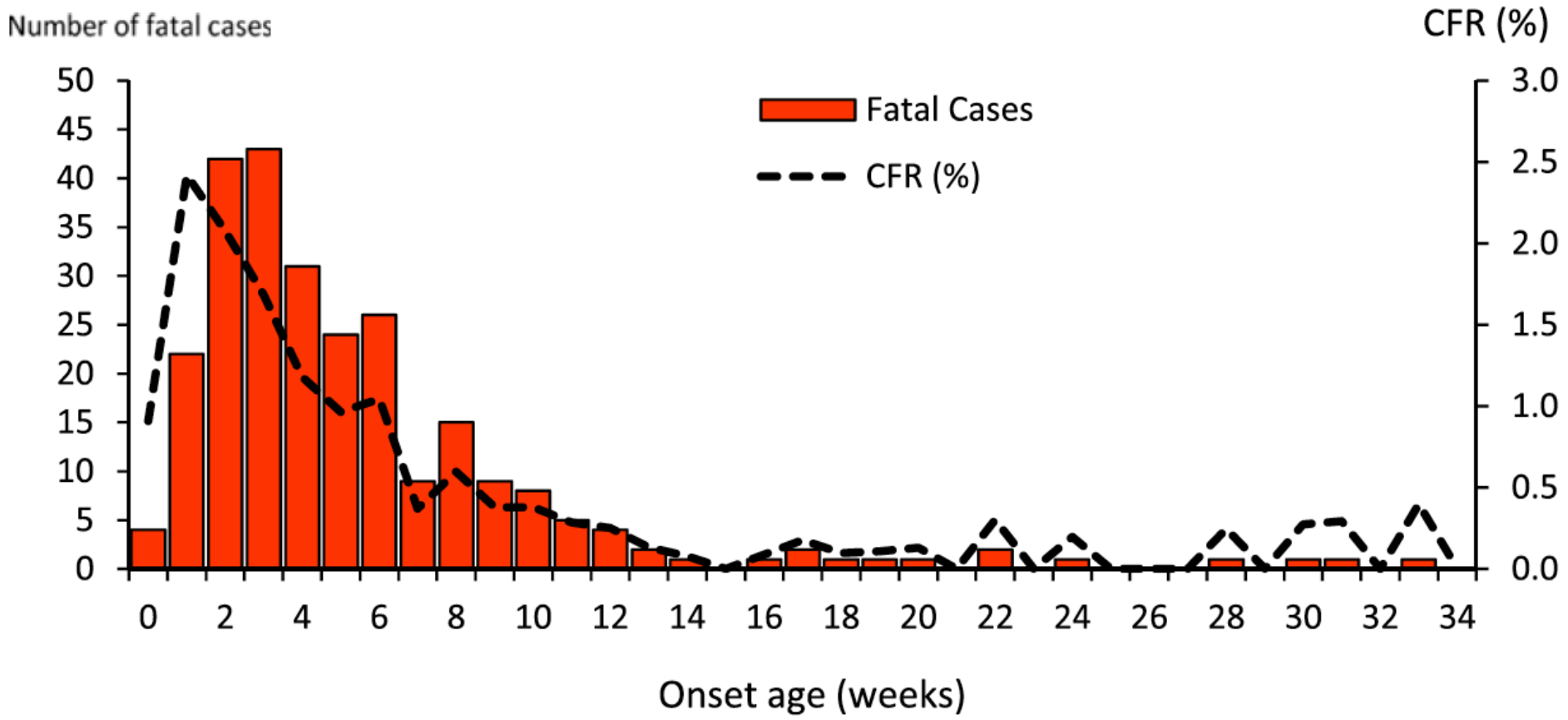
Figure 8 **Nombre annuel moyen d'enfants de moins d'un an hospitalisés pour la coqueluche, par mois d'âge, Québec, 2000-2013**



0-2 months old (2000-2013):

- Average of 33 hospitalisations per year
- 14% required PICU admission

Pertussis deaths, USA, 1991-2008



Tiwari et al., Pediatrics 2015

Safety and effectiveness of acellular pertussis vaccination during pregnancy

- 66-94% reduction in hospitalisations due to pertussis in the first three months of life if vaccine given > 1 week prior to delivery
- 95% reduction in deaths due to pertussis in the first two months of life
- Additional protection up to 6 months of life
- Safe for the pregnancy and the newborn
  - No increase in adverse perinatal outcomes

Vaccine coverage of 70-75% in Québec

Vygen-Bonnet et al. Safety and effectiveness of acellular pertussis vaccination during pregnancy: a systematic review. *BMC Infect. Dis*. 2020

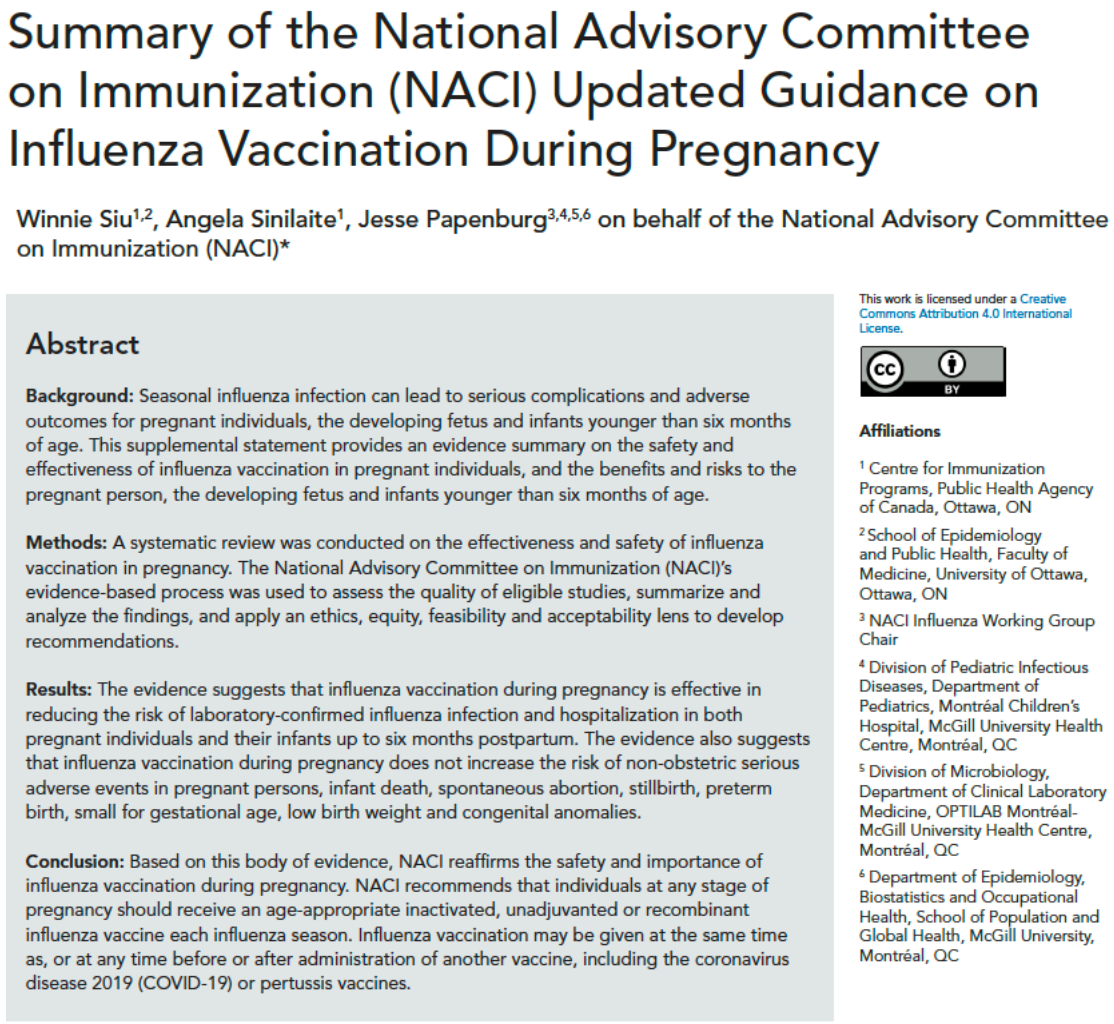
INFLUENZA

Non-live influenza vaccines

NACI Recommendations

- NACI reaffirms the safety and importance of influenza vaccination during pregnancy.
- NACI recommends that individuals at any stage of pregnancy should receive an age-appropriate inactivated, unadjuvanted or recombinant influenza vaccine each influenza season.
- Influenza vaccination may be given at the same time as, or at any time before or after administration of another vaccine

https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-updated-guidance-influenza-vaccination-during-pregnancy.html



Summary of the National Advisory Committee on Immunization (NACI) Updated Guidance on Influenza Vaccination During Pregnancy

Winnie Siu[1,2], Angela Sinilaite[1], Jesse Papenburg[3,4,5,6] on behalf of the National Advisory Committee on Immunization (NACI)*

Abstract

Background: Seasonal influenza infection can lead to serious complications and adverse outcomes for pregnant individuals, the developing fetus and infants younger than six months of age. This supplemental statement provides an evidence summary on the safety and effectiveness of influenza vaccination in pregnant individuals, and the benefits and risks to the pregnant person, the developing fetus and infants younger than six months of age.

Methods: A systematic review was conducted on the effectiveness and safety of influenza vaccination in pregnancy. The National Advisory Committee on Immunization (NACI)'s evidence-based process was used to assess the quality of eligible studies, summarize and analyze the findings, and apply an ethics, equity, feasibility and acceptability lens to develop recommendations.

Results: The evidence suggests that influenza vaccination during pregnancy is effective in reducing the risk of laboratory-confirmed influenza infection and hospitalization in both pregnant individuals and their infants up to six months postpartum. The evidence also suggests that influenza vaccination during pregnancy does not increase the risk of non-obstetric serious adverse events in pregnant persons, infant death, spontaneous abortion, stillbirth, preterm birth, small for gestational age, low birth weight and congenital anomalies.

Conclusion: Based on this body of evidence, NACI reaffirms the safety and importance of influenza vaccination during pregnancy. NACI recommends that individuals at any stage of pregnancy should receive an age-appropriate inactivated, unadjuvanted or recombinant influenza vaccine each influenza season. Influenza vaccination may be given at the same time as, or at any time before or after administration of another vaccine, including the coronavirus disease 2019 (COVID-19) or pertussis vaccines.

Affiliations

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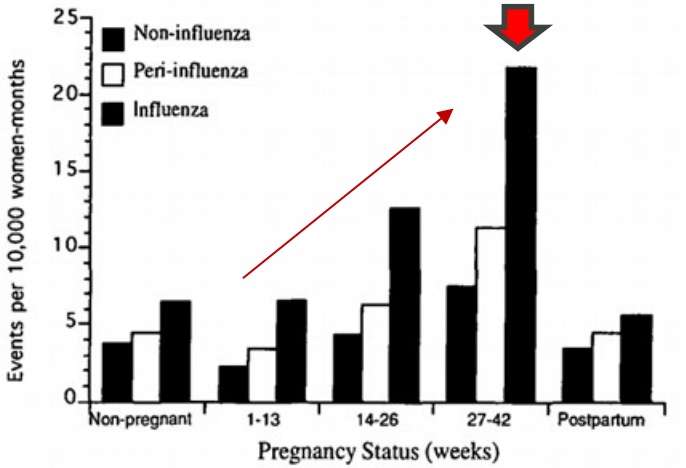
[6] Department of Epidemiology, Biostatistics and Occupational Health, School of Population and Global Health, McGill University, Montréal, QC

Pregnant Women are at Increased Risk of Morbidity and Mortality from Seasonal Influenza

Physiologic changes

- Decreased lung capacity
- Increased O2 carriage, heart rate, stroke volume
- Decrease in concentration of IgG by hemodilution (18% IgG decrease from 2nd to 3rd trimester)



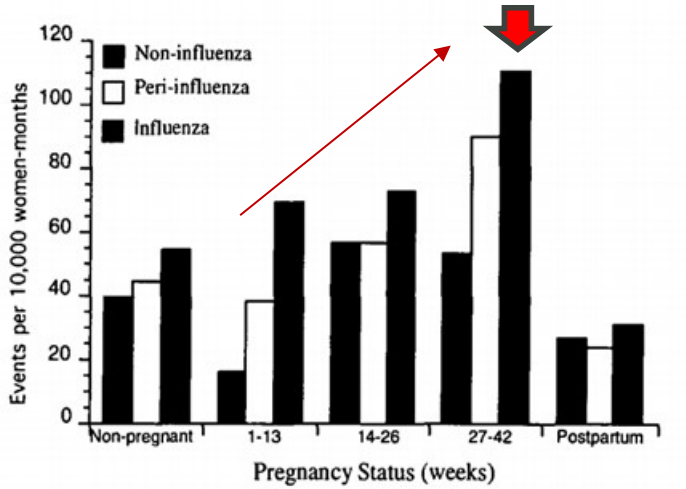


FIGURE 1. Adjusted incidence rates of acute cardiopulmonary events per 10,000 women-months of observation, by medical risk and pregnancy status, among women aged 15–44 years in the Tennessee Medicaid program, 1974–1993. Rates during the three

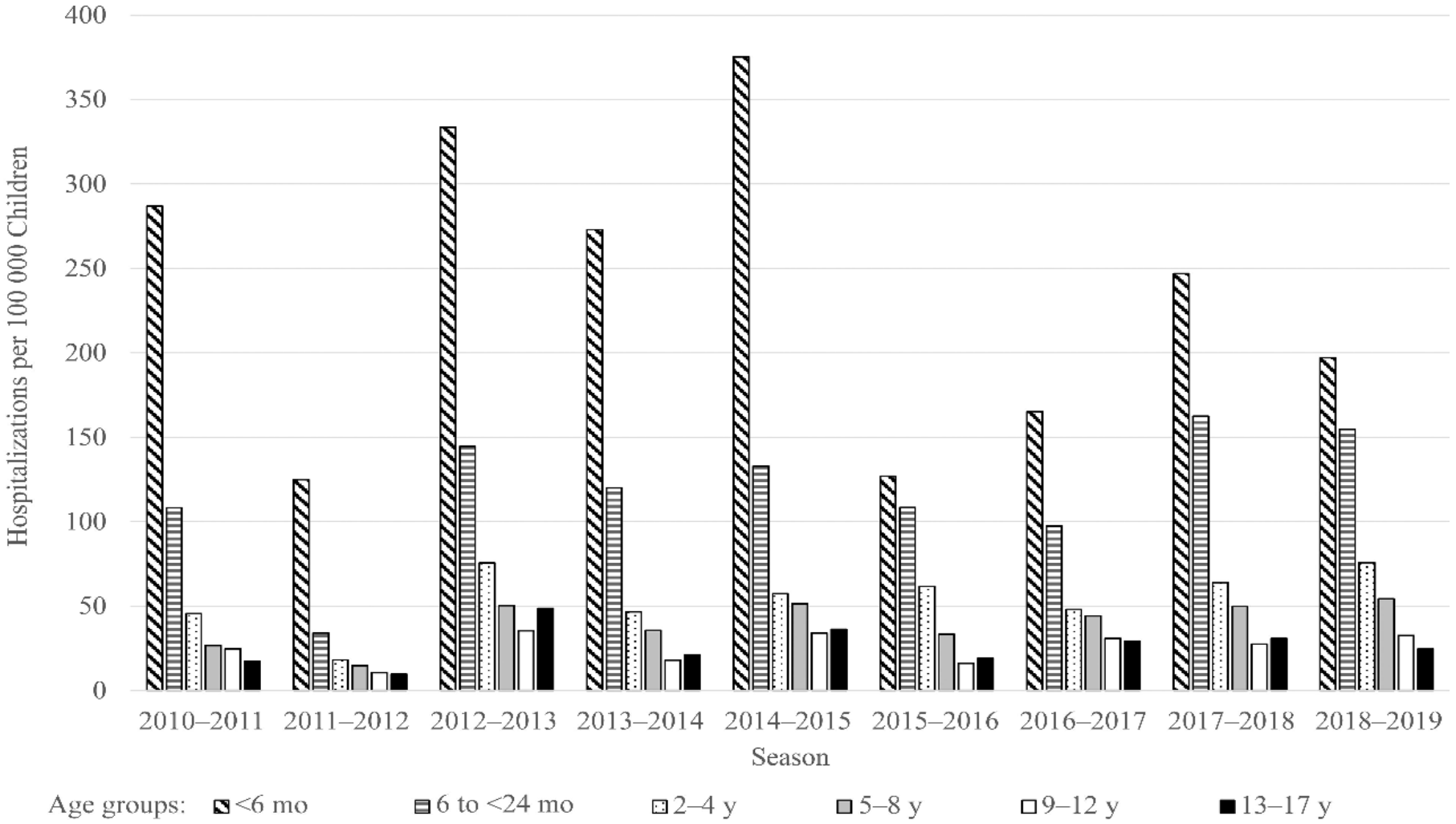
Halsey and Klein D,et al. PIDJ 1990;9:574l
Amino N. et al 1978 Ob Gyn 52: 415
Neuzil KM et al. AJE 1998

Slide adapted from Dr Flor Munoz, Baylor College of Medicine
Texas Children's Hospital

NACI recommends the inclusion of pregnant individuals among those who are particularly recommended to receive influenza vaccination

- Pregnancy associated with increased disease severity with influenza: hospitalization, admission to the ICU, invasive mechanical ventilation, and maternal mortality.
- Higher risk of adverse neonatal outcomes (e.g., premature delivery, low birth weight, NICU admission) with influenza infection during pregnancy.
  - The risks for preterm delivery, low birth weight and admission to the NICU increase with disease severity in the pregnant person.
- Infants under 6 months are at increased risk of hospitalization due to influenza infection compared to children from other ages. However, influenza vaccine is not effective in infants under 6 months; therefore, passive immunization of fetuses through transplacentally transmitted anti-influenza antibodies is currently the best and only available prevention strategy.

Influenza-associated hospitalization rates among children <18 years, by influenza season and age group, from the US Influenza Hospitalization Surveillance Network (FluSurv-NET), 2010–2019.



Clin Infect Dis, Volume 75, Issue 11, 1 December 2022, Pages 1930–1939, https://doi.org/10.1093/cid/ciac296

Influenza-Associated Pediatric Deaths — United States, 2024–25 Influenza Season

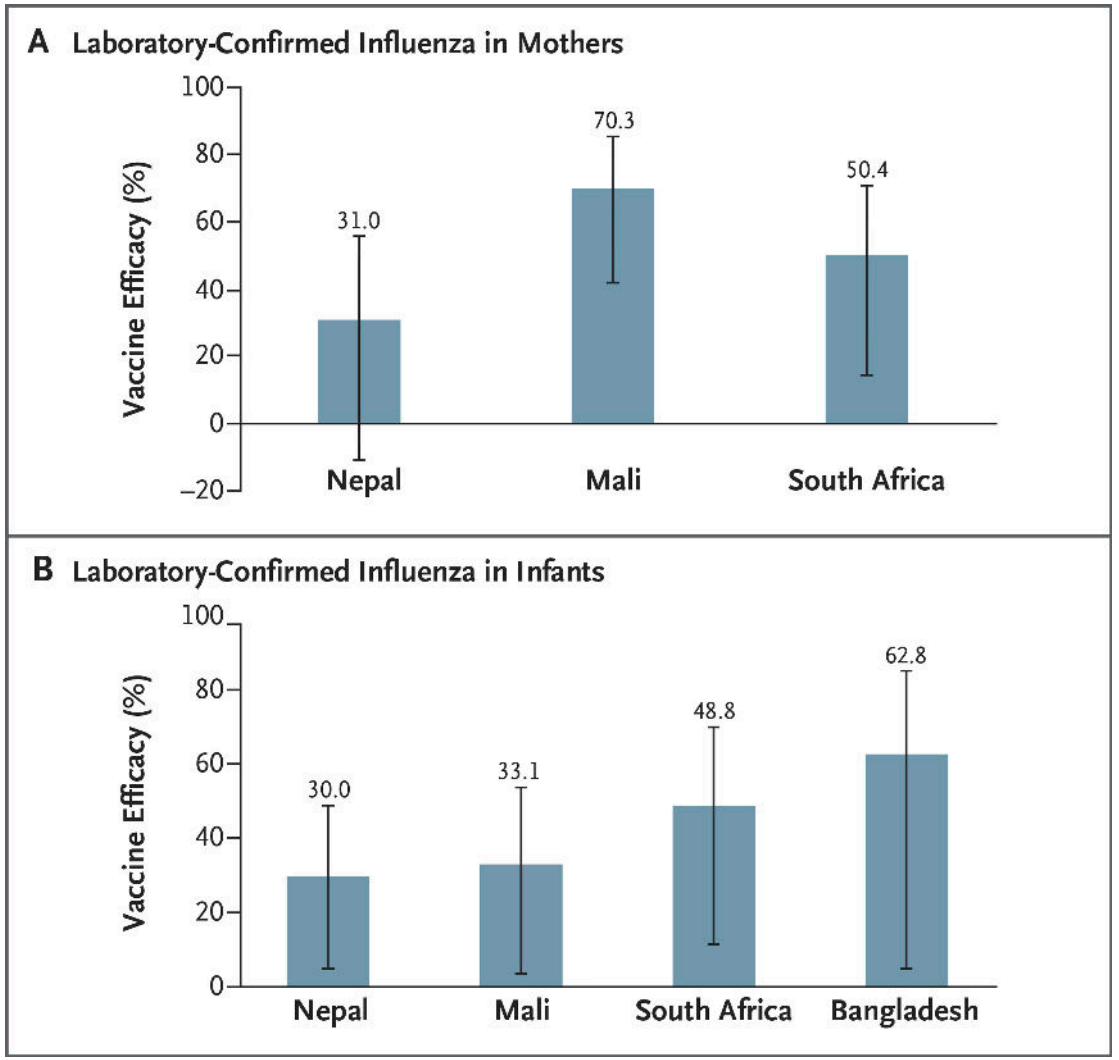
Katie Reinhart, PhD[1]; Stacy Huang, MPH[1]; Krista Kniss, MPH[1]; Carrie Reed, DSc[1]; Alicia Budd, MPH[1]

TABLE 1. Characteristics of children aged <18 years who died from influenza-associated illness and influenza-associated mortality, by selected demographic characteristics — United States, September 29, 2024–September 13, 2025

Characteristic	No. of deaths (%)	U.S. population, no.	Influenza death rate*
Overall	**280 (100)**	**73,132,720**	**3.8**
Age group			
Median age group (IQR)	7 (2–11)	—	—
<6 mos†	20 (7)	1,807,799	11.1
6–23 mos§	41 (15)	5,509,623	7.4
24–59 mos	48 (17)	11,281,892	4.3
5–8 yrs	62 (22)	16,024,708	3.9
9–12 yrs	53 (19)	16,614,665	3.2
13–17 yrs	56 (20)	21,894,033	2.6

https://www.cdc.gov/mmwr/volumes/74/wr/pdfs/mm7436a2-H.pdf

Efficacy of Influenza Vaccination during Pregnancy for Preventing Laboratory-Confirmed Influenza in Infants and Mothers

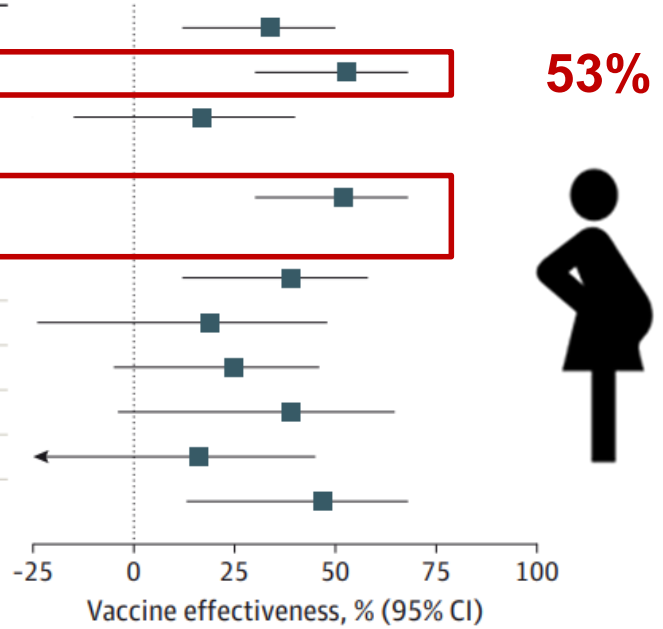


Omer SB. *N Engl J Med* 2017

Effectiveness of maternal influenza vaccination against infant ED visits and hospitalizations, 2016-2020, USA

Figure 2. Effectiveness of Maternal Influenza Vaccination During Pregnancy Against Influenza Hospitalizations and Emergency Department (ED) Visits in Infants

Infants <6 mo of age	Vaccinated mothers, No./total No. (%)		Effectiveness of maternal vaccination against influenza illness in infants, % (95% CI)
	Infants with influenza illness	Control infants	
Overall effectiveness of maternal vaccination	94/223 (42)	1913/3541 (54)	34 (12 to 50)
Infants <3 mo of age	49/106 (46)	1293/2147 (60)	53 (30 to 68)
Mother vaccinated during first or second trimester of pregnancy	59/188 (31)	1009/2637 (38)	17 (-15 to 40)
Mother vaccinated during third trimester of pregnancy	35/164 (21)	904/2532 (36)	52 (30 to 68)
Hospital admission	55/125 (44)	1416/2541 (56)	39 (12 to 58)
ED visit	39/98 (40)	497/1000 (50)	19 (-24 to 48)
Influenza A	70/157 (45)	1913/3541 (54)	25 (-5 to 46)
H1N1	21/53 (40)	1913/3541 (54)	39 (-4 to 65)
H3N2	42/87 (48)	1913/3541 (54)	16 (-29 to 45)
Influenza B	25/67 (37)	1913/3541 (54)	47 (13 to 68)

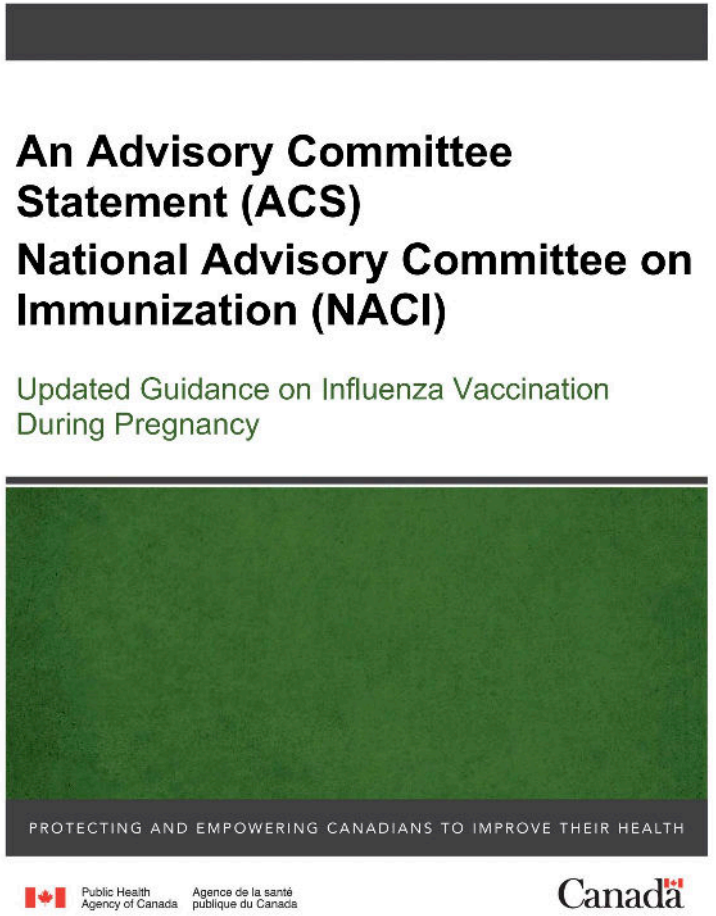


53%

JAMA Pediatr. 2024;178(2):176-184. doi:10.1001/jamapediatrics.2023.5639
Published online December 18, 2023.

Safety

- The safety of influenza vaccination during pregnancy is consistently supported by numerous studies, including clinical trials and observational studies, and routine pharmacovigilance data from safety reporting systems.
- Published data, including currently available **studies of fetal death, spontaneous abortion, and congenital malformations**, **do not report unexpected or concerning patterns**.
- The evidence reaffirms that seasonal influenza vaccination during pregnancy does not appear to be associated with significant safety issues with respect to adverse birth outcomes or maternal non-obstetric SAEs.



https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-updated-guidance-influenza-vaccination-during-pregnancy/naci-statement-2023-12-18.pdf

RSV

NACI Recommendation

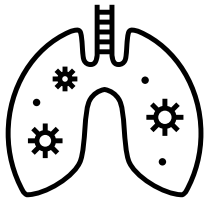
- Nirsevimab preferred
- RSVpreF may be considered as an individual decision by pregnant person together with information from their pregnancy care provider, in advance of, or during, the RSV season
- RSVpreF program NOT recommended

Burden of RSV in infants

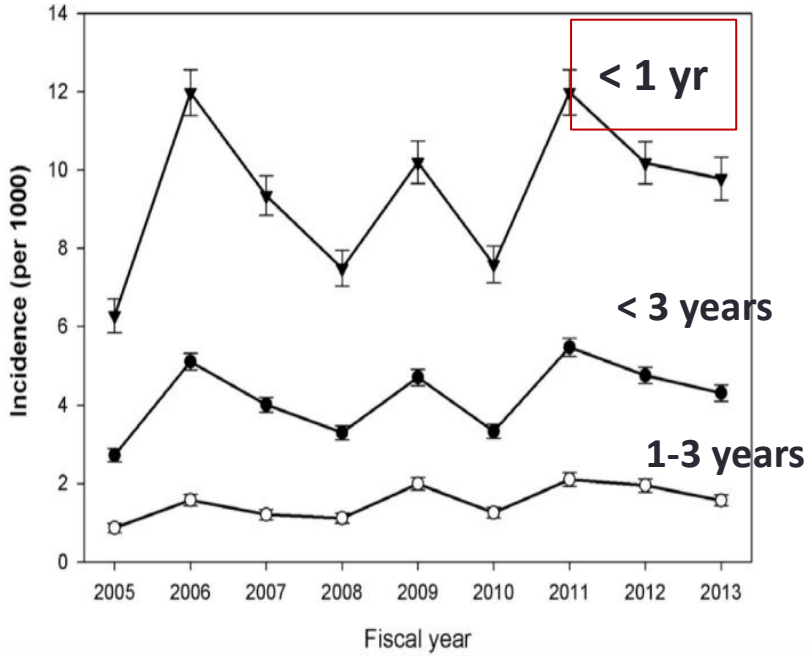
50% of children infected with RSV by 1 year of age

Almost all children infected by 2 years of age

20-40% of primary infections will develop into LRTI, usually **bronchiolitis** or **pneumonia**



Leading cause of hospital admission in the first year of life!



Pisesky A. et al. *PLoS One* 2016

LRTI: lower respiratory tract infection

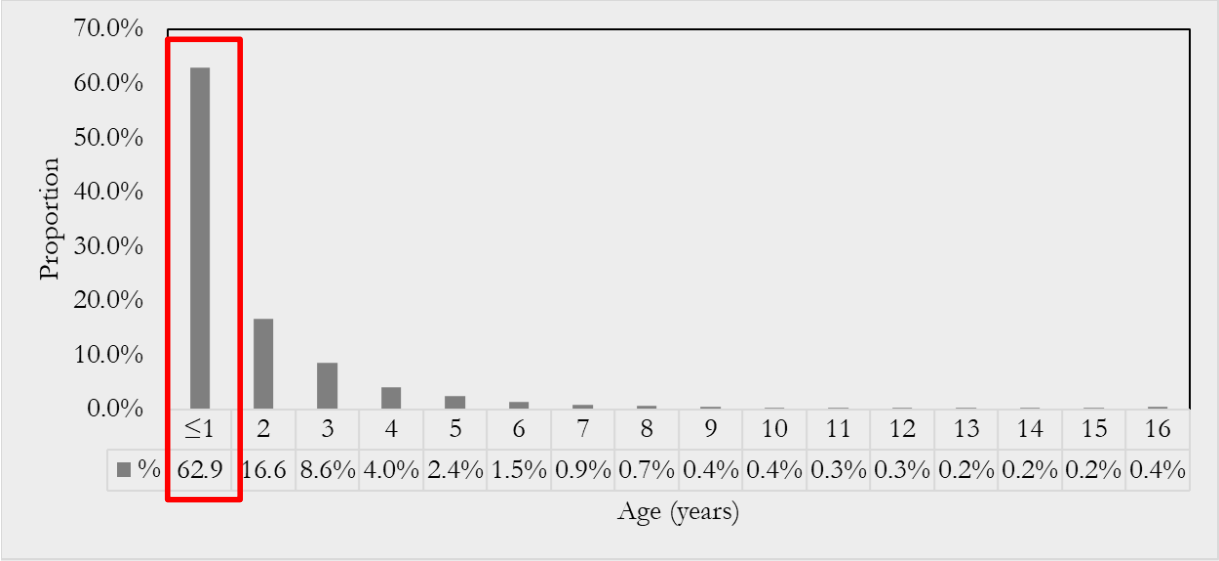
Li et al, *Lancet* 2022; Papenburg and Boivin, *Med Rev Virol* 2010

Pediatric RSV hospitalizations, Canadian Immunization Monitoring Program Active (IMPACT)

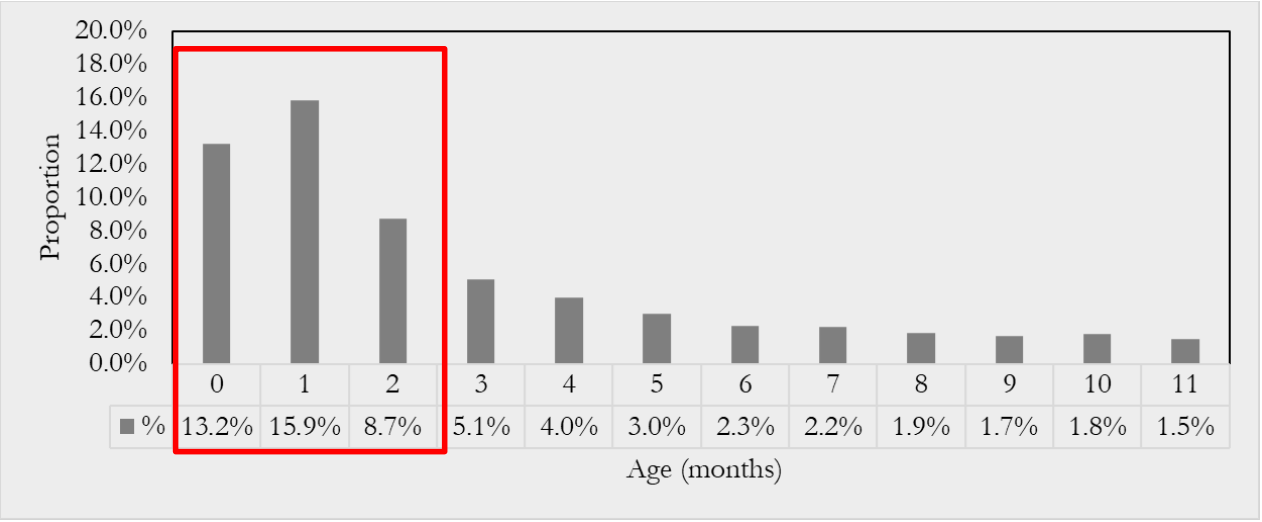
- 5 seasons
  - 2017/18 – 2021/22
- 13 pediatric hospitals
- All RSV+ admissions
  - N=11,014
- 50% < 6 months old
- 23.6% admitted to ICU
  - 60.8% < 6 months old
- Median stay 4 days
  - IQR 2-6

Bourdeau et al.,
JAMA Netw Open 2023

Proportion of RSV-associated hospitalizations by year of life



Proportion of RSV-associated hospitalizations by month of life

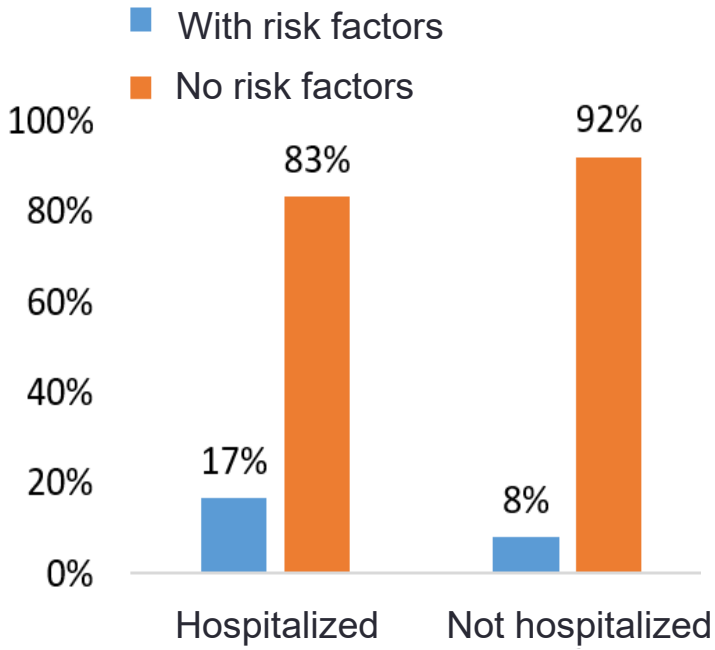


Host risk factors for RSV hospitalization

Table I. RSV hospitalizations per 100 child-years by age and risk group

Age (mo)	Normal	CHD	BPD	≤28 wk GA	29–32 wk GA	33–35 wk GA
0–5	4.4	12.1	56.2	9.4	8.2	8.0
6–11	1.5	6.3	21.4	4.6	5.0	3.5
12–23	0.4	1.8	7.3	3.0	0.9	1.1
24–35	0.1	0.5	1.3	0.0	0.2	0.1

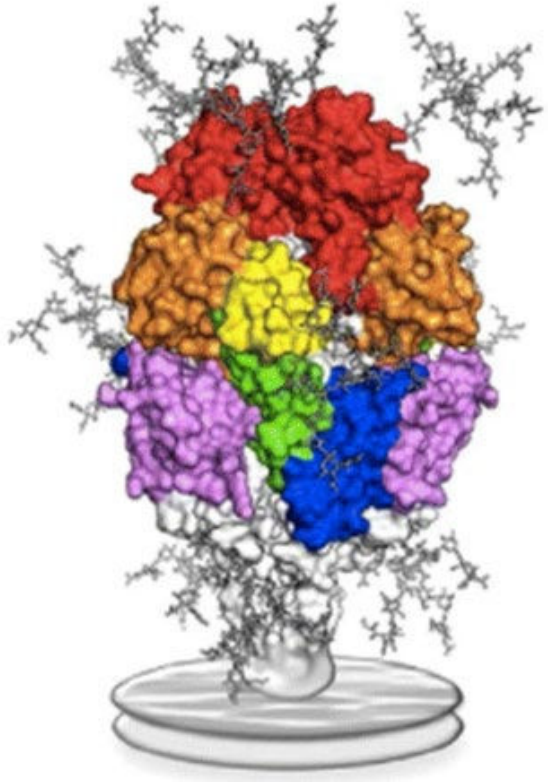
Boyce et al. Rates of hospitalization for RSV Infection among children in Medicaid. *J Pediatr* 2000



Modified from :
Pisesky A. et al. *PLoS One* 2016

Stabilizing the RSV F protein in a pre-fusion (pre-F) state

Vaccines containing stabilized **pre-F** protein are more immunogenic: induce more robust neutralizing **antibodies**



Pre-F

Post-F

Graham B, *Current Opinion in Virology*. 2017.

New RSV maternal vaccine licensed to protect infants, Pfizer (Abrysvo®)

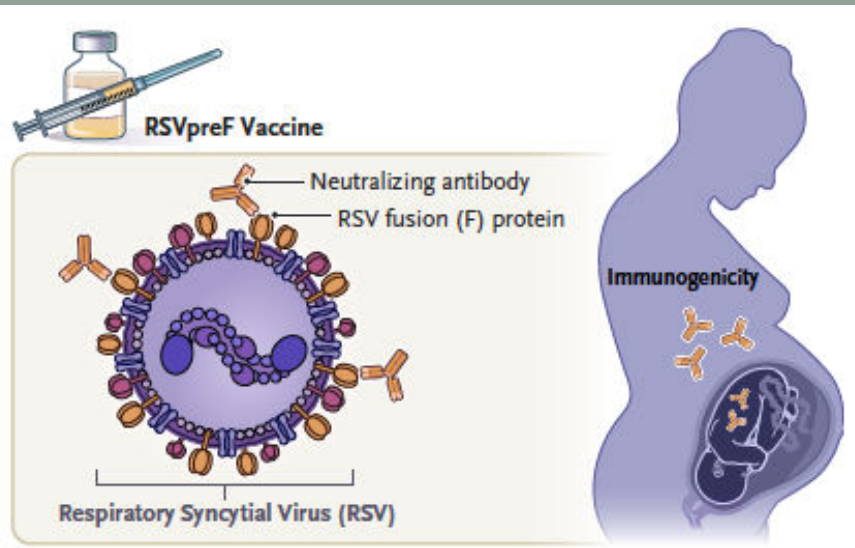
LICENSED	**Health Canada authorization January 2024** Europe, United States, PAHO, other countries
APPROACH	Vaccination in pregnancy to elicit **immune response in the pregnant individual** and increase **transplacental antibody transfer** to baby for protection in early life.
MATERNAL IMMUNIZATION INDICATION	• For immunization of pregnant individuals to help protect their infants from birth through 6 months of age from lower respiratory tract disease due to RSV • Vaccination likely needed with each pregnancy, but *no recommendations yet*
APPROVED GESTATIONAL AGE WINDOWS	• 24 to 36 weeks (Europe) • 28 weeks to birth (UK) • **32 to 36 weeks (Canada, US, PAHO)**
ABOUT THE PRODUCT	• Single dose, IM • Can be given with other maternal vaccines • Lyophilized (freeze-dried) prefilled syringe; single-dose vial • Uses standard cold chain

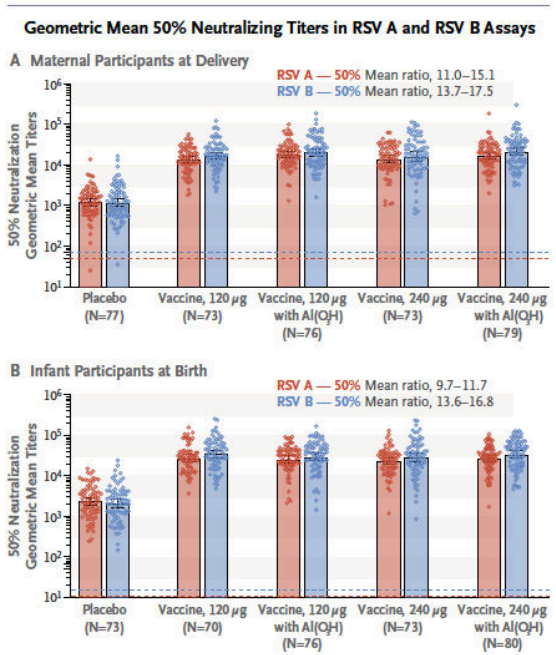
Pfizer Maternal-RSVPreF

Bivalent (A + B) stabilised pre-fusion RSV-F protein

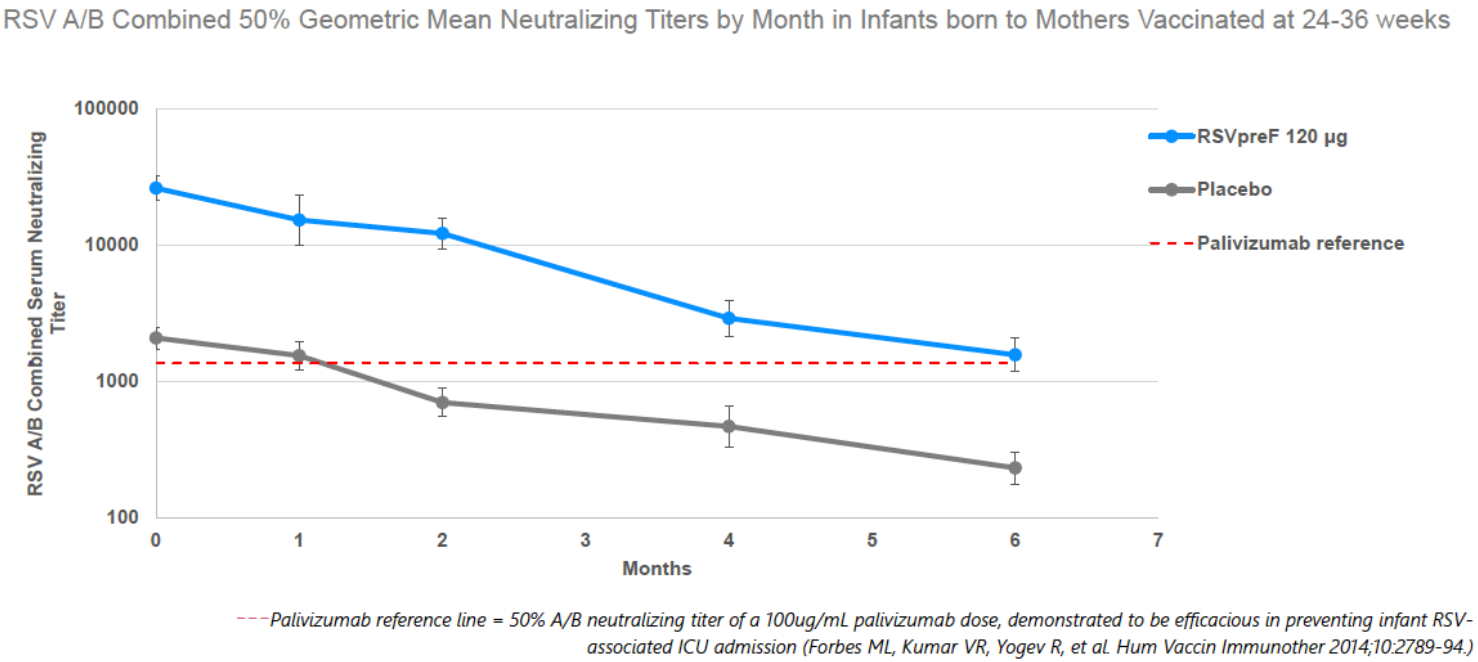
Non-adjuvanted

Pregnant persons ≤49 years between ≥24 and ≤36 weeks gestation





Simoes et al. *N Engl J Med* 2022



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/RSV-Pediatric-06-Munjal-508.pdf

Summary efficacy data for RSV prevention products for protecting infants

PRODUCT / DEVELOPER	PHASE 3 EFFICACY (CONFIDENCE INTERVAL)	OUTCOME MEASURED
Pre-fusion F maternal vaccine* Pfizer	67.7% (15.9% to 89.5%)	Hospitalization for RSV lower-respiratory tract infection (LRTI) from birth through **90 days**
	56.8% (10.1% to 80.7%)	Hospitalization for RSV-LRTI from birth through **180 days**
	57.1% (14.7% to 79.8%)	Medically attended RSV-LRTI from birth through **90 days**
	51.3% (29.4% to 66.8%)	Medically attended RSV-LRTI from birth through **180 days**
Nirsevimab (mAb)** AstraZeneca / Sanofi Pasteur	79.0% (68.5%–86.1%)	Medically attended RSV-associated LRTI through **150 days** after injection
	80.6% (62.3%–90.1%)	Hospitalization for RSV-associated LRTI through **150 days** after injection

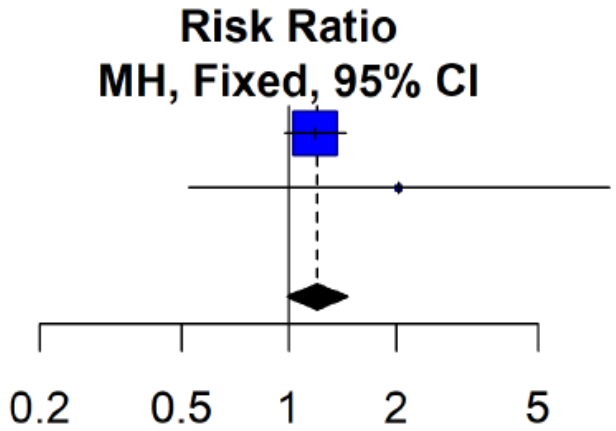
- Kampmann B, et al. *NEJM*, 2023;388. ** CDC Pooled Analysis: https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm.

Outcome: Preterm births (n=2 studies), Pfizer maternal RSVpreF vaccine

Publication	Definition	Events/Vaccine (n/N)	Events/Placebo (n/N)	Relative Risk (95% CI)
Phase 3	<34 weeks	21/3568	12/3558	1.75 (0.86, 3.54)
	<37 weeks	201*/3568	169/3558	1.19 (0.97, 1.45)
Phase 2b	<34 weeks	0/115	1/117	0.34 (0.01, 8.24)
	<37 weeks	6/115	3/117	2.03 (0.52, 7.94)

	Experimental		Control			Risk Ratio
Study	**Events**	**Total**	**Events**	**Total**	**Weight**	**MH, Fixed, 95% CI**
Phase 3, 2023	201	3568	169	3558	98.3%	1.19 [0.97; 1.45]
Phase 2b, 2022	6	115	3	117	1.7%	2.03 [0.52; 7.94]
Total (95% CI)		**3683**		**3675**	**100.0%**	**1.20 [0.99; 1.46]**

Heterogeneity: $Tau^2 = 0$; $Chi^2 = 0.59$, df = 1 (P = 0.44); $I^2 = 0\%$



https://www.cdc.gov/acip/downloads/slides-2023-06-21-23/03-RSV-Mat-Ped-Fleming-Dutra-508.pdf

Outcome: Preterm births (n=2 studies), **Pfizer maternal RSVpreF vaccine**

- Measures of effect
  - Relative risk: 1.20 (0.99, 1.46)
  - Absolute risk*: 9 more per 1,000 (from 0 fewer to 22 more)
- Concerns in certainty assessment:
  - Very serious concern for imprecision due to the width of the confidence interval containing estimates for which different policy decisions might be considered and not meeting optimal information size requirements
- Evidence type: Low

*Absolute risk was calculated using the observed outcomes in the placebo arm during the available clinical trial follow-up. Absolute risk estimates should be interpreted in this context.

RSVpreF: prematurity by dosing interval, RCT vs. FDA

	Trial dosing interval (24–36 weeks gestation)[1]				Approved dosing interval (32–36 weeks gestation)[1,2]			
	RSVpreF vaccine group N=3,568		Placebo group N=3,558		RSVpreF vaccine group N=1,628		Placebo group N=1,604	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Preterm birth (<37 weeks gestation)	202	**5.7%** (4.9%, 6.5%)	169	**4.7%** (4.1%, 5.5%)	68	**4.2%** (3.3%, 5.3%)	59	**3.7%** (2.8%, 4.7%)

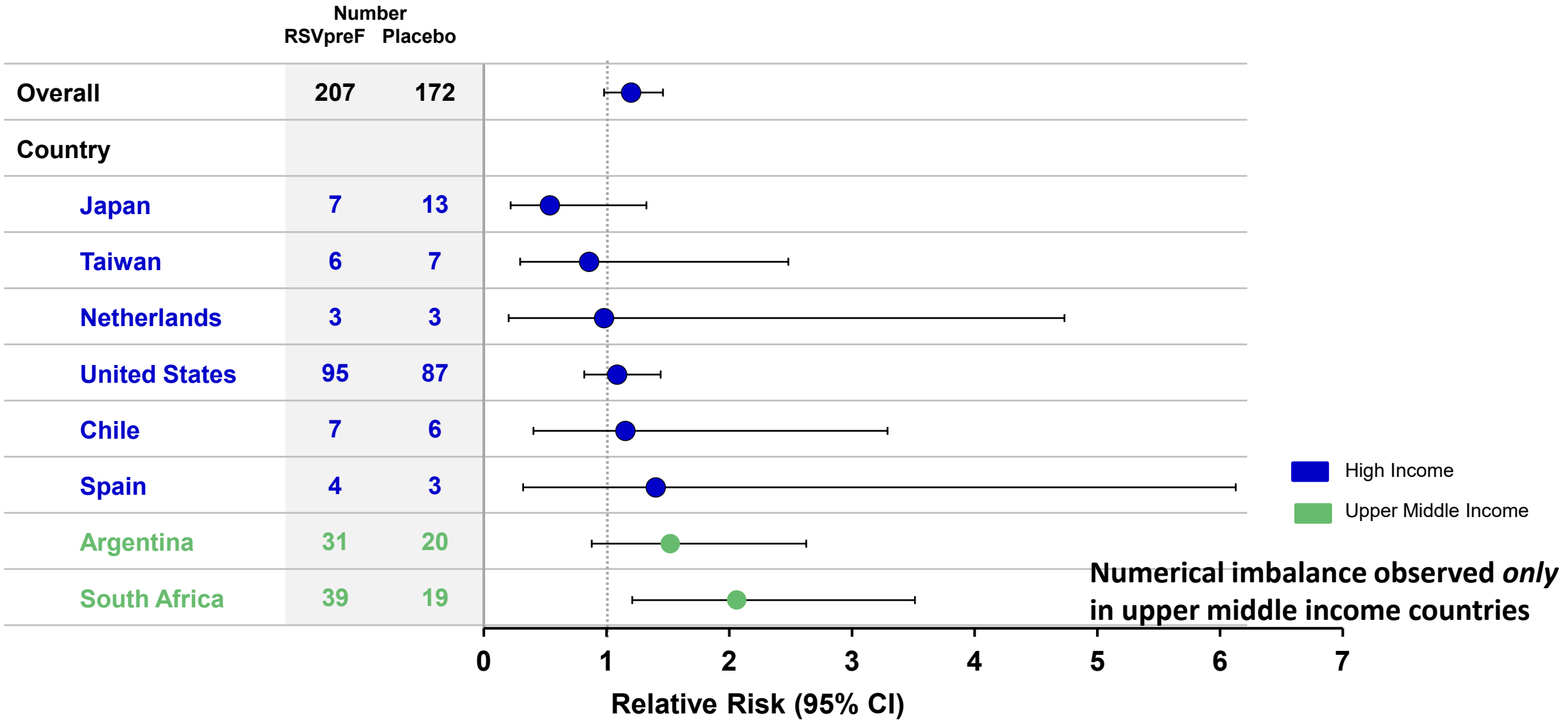
1. Package Insert - ABRYSVO (STN 125768) (fda.gov)

2. Pfizer response to ACIP, unpublished data, August 2023. In package insert, approved dosing interval reported as: 4.2% (68/1,631) in the RSVpreF group and 3.7% (59/1,610) in the placebo group.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-22/06-Mat-Peds-Fleming-Dutra-508.pdf

Final Analysis

RSVpreF: prematurity by country (countries with > 5 preterm births)



Mujal et al. Oral presentation at RSVVW'24. With permission

RSVpreF: time from vaccination to birth

No difference in RSVpreF vs placebo time from vaccination to birth when stratified by pre-term birth status

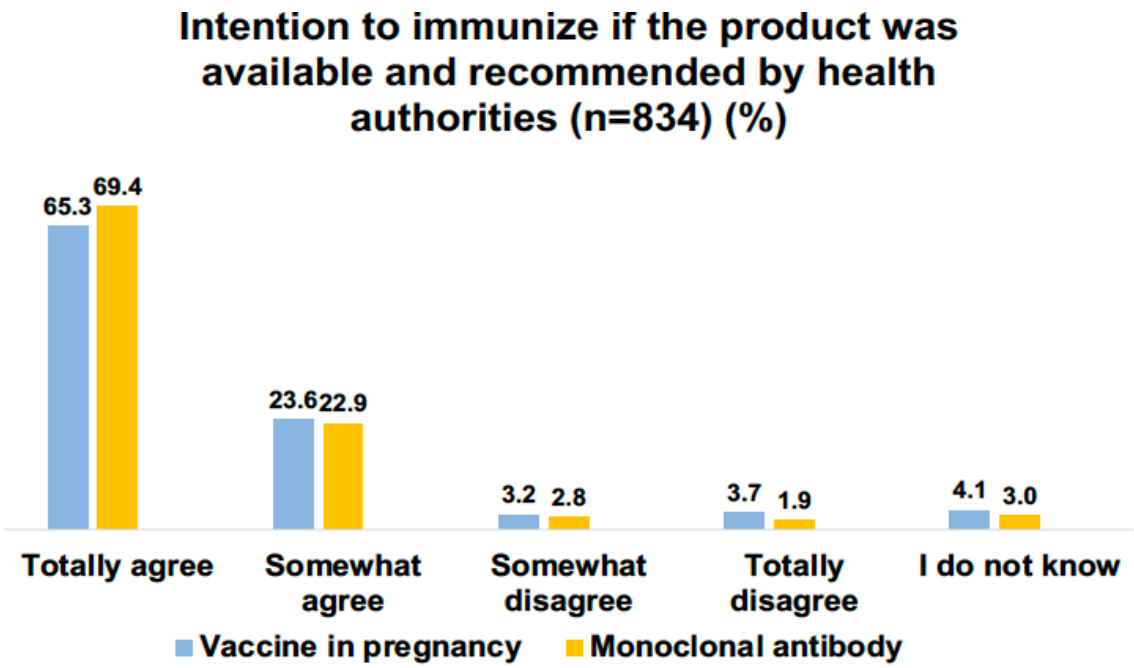
60% of premature births were >30 days after RSVpreF vaccination

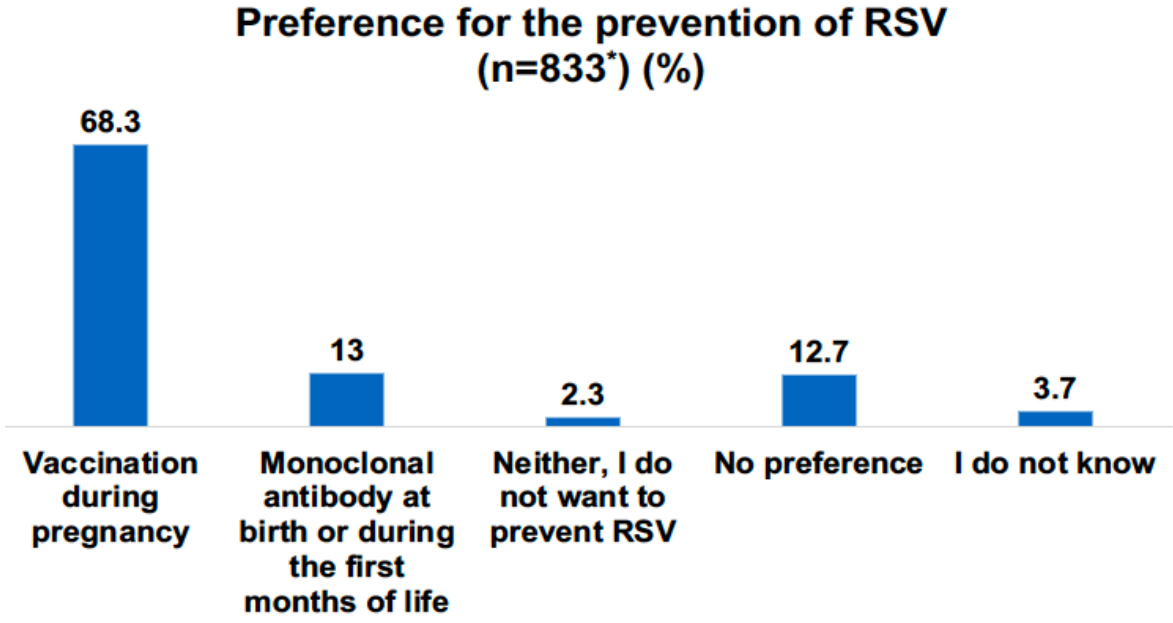
	Preterm		Term	
	RSVpreF 120 µg (N[a]=206)	Placebo (N[a]=172)	RSVpreF 120 µg (N[a]=3450)	Placebo (N[a]=3471)
Relative days of delivery from vaccination	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
≤7 days	8 (3.9)	9 (5.2)	0	2 (<0.1)
>7 days to ≤30 days	72 (35.0)	62 (36.0)	487 (14.1)	473 (13.6)
>30 days	126 (61.2)	101 (58.7)	2963 (85.9)	2996 (86.3)

VRBPAC Pfizer Briefing document

Québec Acceptability Survey

- Anonymous online survey
- Pregnant persons and their partners
- Recruitment via targeted ads on Facebook
- Oct. – Dec. 2023





Gagnon et al., Vaccine 2024

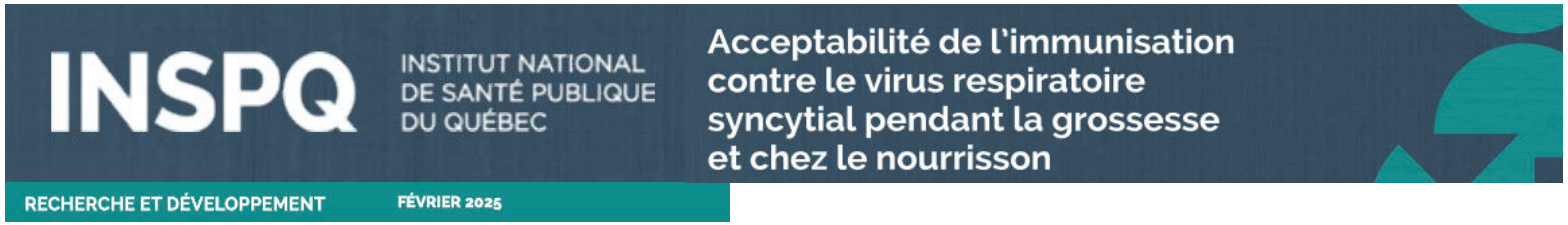
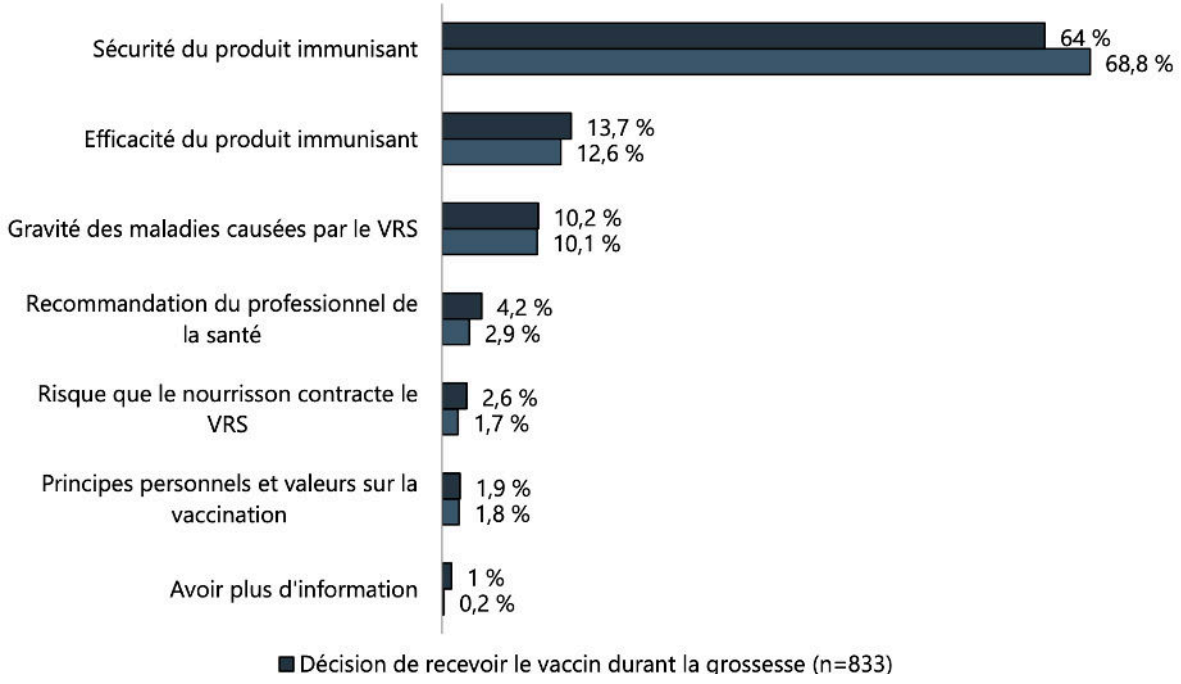


Figure 7 **Facteur le plus important dans la décision de recevoir un vaccin contre le VRS durant la grossesse ou d'administrer un produit immunisant contre le VRS à un nourrisson**



SAFETY = most important factor in decision making

Gagnon, D, *Institut National de Santé Publique du Québec (INSPQ),* 2025.

RSVpreF safety in the field, USA

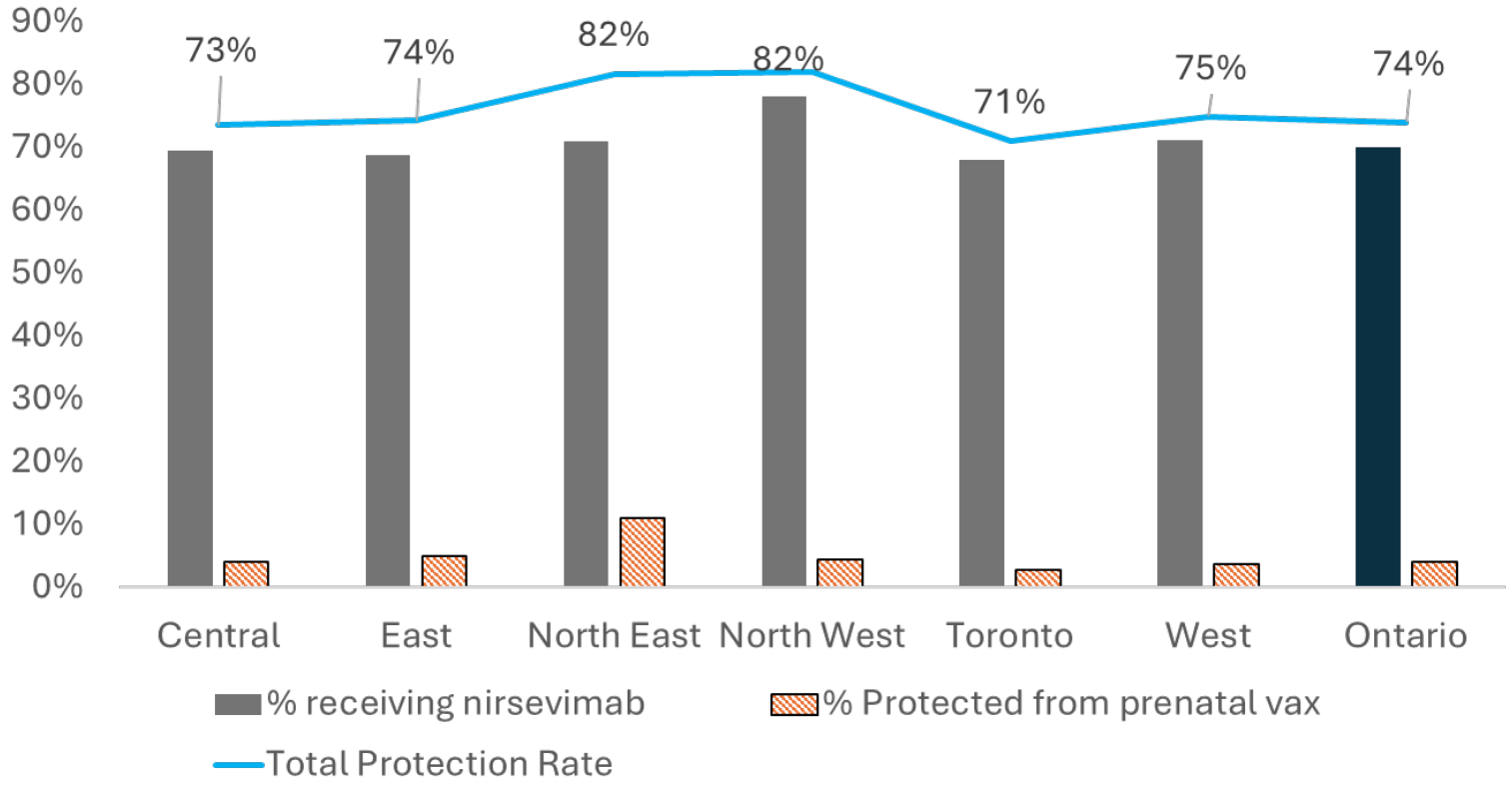
- Safety surveillance from three sources: Vaccine Adverse Event Reporting System (VAERS), V-Safe, and Vaccine Safety Datalink (VSD) :
- Incidence of pre-term births among pregnant individuals who received RSVpreF (4.1%) was within the expected range of incidence of preterm birth at 32-36 wks GA (3.1-6.1%)

https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-RSV-Mat-Peds-Moro-508.pdf

- Cohort study among among 2,973 pregnant individuals in NYC who gave birth during the 2023-24 period when RSVpreF vaccination was recommended.
- Primary outcome: preterm birth (<37 weeks GA)
- 34.5% received the RSVpreF vaccine
- 60 patients (5.9%) who received RSVpreF experienced pre-term vs 131 (6.7%) of those who did not
- Vaccination was not associated with an increase in preterm birth

Son et al. *AMA Network Open.* 2024;7(7):e2419268.

RSV immunization uptake in infants at birth in Ontario by OH region (before discharge from hospital) Nov 24 – Mar 25

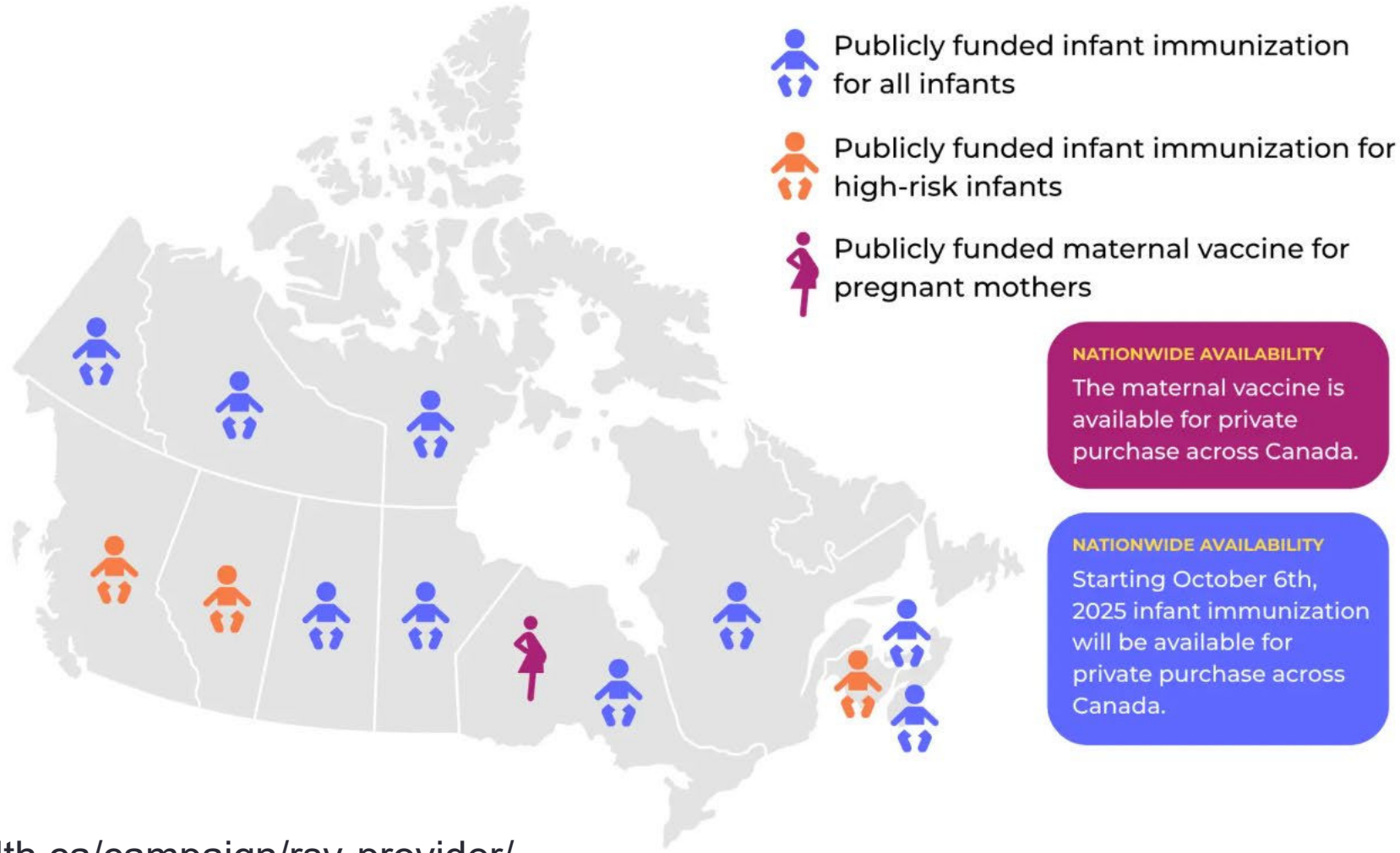


Open dataset – data collection continues: Information derived from data on 34,801 infants born between Nov 2024 and Mar 2025 in Ontario hospitals for whom valid RSV immunization information was reported to BORN by Apr 8, 2025. 82 of 96 birthing centres reporting. Due to missingness (~40%) interpret with caution and curiosity. Note: Missingness is unrelated to RSV immunization practices, but rather timing and completeness of birth record data submission from hospitals.

Courtesy of Dr D. Warsahfsky, Associate CMOH, Ontario
DRAFT FOR DISCUSSION

Ontario

Publicly-funded RSV programs by P/T as of Fall 2025



https://praxushealth.ca/campaign/rsv-provider/

RSV vaccines in pregnancy:

What you need to know

What is RSV?

Respiratory syncytial virus (RSV) is a contagious respiratory virus. While it usually causes mild, cold-like symptoms, RSV can be a **very serious** illness in infants. RSV is common around the world and is most active in Canada during the fall and winter months (when people in Canada are most likely to catch RSV and become sick).

In December 2023, a **vaccine** that protects against RSV – the RSVpreF vaccine – was approved for use in Canada for people **32 to 36 weeks pregnant**.

Why should I get the RSV vaccine if I am pregnant?

Infants younger than six months of age are one of the groups most likely to experience **severe RSV infection**, and severe RSV infection in infants can result in **hospitalization** or **intensive care unit (ICU) admission**. In fact, RSV leads to around **16 times** more hospitalizations in young children than influenza (the flu). RSV is also the leading cause of **bronchiolitis** (inflammation of the small airways of the lungs) and **pneumonia** (a lung infection) in infants

RSV vaccines in pregnancy:
What you need to know

Passing on immunity: How getting the RSV vaccine while pregnant protects your infant

Getting the RSV vaccine allows your body to produce protective proteins called antibodies that specifically protect against RSV infection. When you get immunized against RSV while pregnant, you pass on some of these antibodies to your baby in the womb (*in utero*). These antibodies give your baby protection for up to 6 months against the severe effects of RSV after they have been born.

It is safe to receive the RSV vaccine while pregnant. There is no evidence that the RSV vaccine will harm you or your baby.

Talk to your doctor, nurse, pharmacist, midwife, or local public health office to see if you can receive the RSV vaccine while pregnant.

For more information, please visit https://immunize.ca/respiratory-syncytial-virus-rsv.

References

https://immunize.ca/respiratory-syncytial-virus-rsv

COVID-19

NACI Recommendations (2025-2026)

- NACI recommends a COVID-19 vaccine for previously vaccinated and unvaccinated individuals at increased risk of SARS-CoV-2 exposure or severe COVID-19 disease, which includes
  - Pregnant women and individuals who are pregnant

Table 2. Adverse Pregnancy Outcomes Among Pregnant Persons Diagnosed as Having SARS-CoV-2 During the Pandemic Compared With Pregnant Persons Not Diagnosed as Having SARS-CoV-2 in Canada

Outcomes	No./total (%)		Absolute risk difference (95% CI)	Relative risk (95% CI)	*P* value
	Persons with SARS-CoV-2 diagnosed during pregnancy[a]	Persons without SARS-CoV-2 diagnosed during pregnancy[b]			
Preeclampsia[c]	91/1260 (7.22)	33201/428 813 (7.74)	−0.52 (−1.95 to 0.91)	0.93 (0.75-1.12)	.53
Cesarean delivery	1965/5696 (34.50)	138 918/428 813 (32.40)	2.10 (0.86 to 3.34)	1.06 (1.03-1.10)	.001
Preterm delivery <37 wk[d]	635/5746 (11.05)	28 394/419 937 (6.76)	4.29 (3.48 to 5.10)	1.63 (1.52-1.76)	<.001
Late preterm (34-36 wk)	480 (8.35)	21 638 (5.15)	3.20 (2.48 to 3.92)	1.62 (1.48-1.76)	<.001
Moderate preterm (32-33 wk)	84 (1.46)	2957 (0.70)	0.86 (0.45 to 1.07)	2.08 (1.64-2.53)	<.001
Very preterm (28-31 wk)	41 (0.71)	2269 (0.54)	0.17 (−0.05 to 0.39)	1.32 (0.93-1.74)	.08
Extremely preterm (20-27 wk)	30 (0.52)	1530 (0.36)	0.16 (−0.03 to 0.34)	1.43 (0.95-1.97)	.60
Stillbirth[e]	35/5743 (0.61)	3695/443 184 (0.83)	−0.22 (−0.43 to −0.02)	0.73 (0.50-0.99)	.07

McClymont et al. *JAMA.* **2022**;327(20):1983-1991

Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes, Ontario, 2020-2021

Table 2. Risk of Adverse Peripartum Outcomes Among Individuals Who Received at Least 1 Dose During Pregnancy Compared With Those Who Initiated COVID-19 Vaccine Series After Pregnancy

Outcome	No. (%)		Risk ratio (95% CI)		
	Received ≥1 dose of COVID-19 vaccine during pregnancy	Initiated COVID-19 vaccine series after pregnancy (comparison group 1)	Crude	Adjusted[a]	Adjusted risk difference per 100 (95% CI)[a]
Pregnant individuals with a live birth or stillbirth, No.	22 660	44 815			
Postpartum hemorrhage	677 (3.0)	1351 (3.0)	0.99 (0.90 to 1.09)	0.91 (0.82 to 1.02)	−0.28 (−0.59 to 0.03)
Chorioamnionitis	101 (0.5)	214 (0.5)	0.93 (0.74 to 1.18)	0.92 (0.70 to 1.21)	−0.04 (−0.17 to 0.09)
Cesarean delivery	6988 (30.8)	14 427 (32.2)	0.96 (0.93 to 0.99)	0.92 (0.89 to 0.95)	−2.73 (−3.59 to −1.88)
Emergency cesarean delivery	2829 (15.3)	5943 (16.4)	0.93 (0.89 to 0.98)	0.89 (0.84 to 0.94)	−1.81 (−2.54 to −1.08)
Liveborn infants, No.	22 746	44 943			
NICU admission	2508 (11.0)	5969 (13.3)	0.83 (0.79 to 0.87)	0.85 (0.80 to 0.90)	−1.89 (−2.49 to −1.30)
Low 5-min Apgar score (<7)[b]	403/22 334 (1.8)	894/44 344 (2.0)	0.89 (0.79 to 1.00)	0.84 (0.73 to 0.97)	−0.31 (−0.56 to −0.06)

Abbreviation: NICU, neonatal intensive care unit.

[a] Adjusted using stabilized inverse probability of treatment weights.

[b] The Apgar scoring system is a standardized method to assess the status of newborns immediately after birth. It comprises 5 components (skin color, heart rate, reflexes, muscle tone, and respiration), each of which is given a score of 0, 1, or 2 (with 10 being the highest possible score).

Fell et al. *JAMA.* **2022**;327(15):1478-1487.

The Role of Vaccination in Maternal and Perinatal Outcomes Associated With COVID-19 in Pregnancy

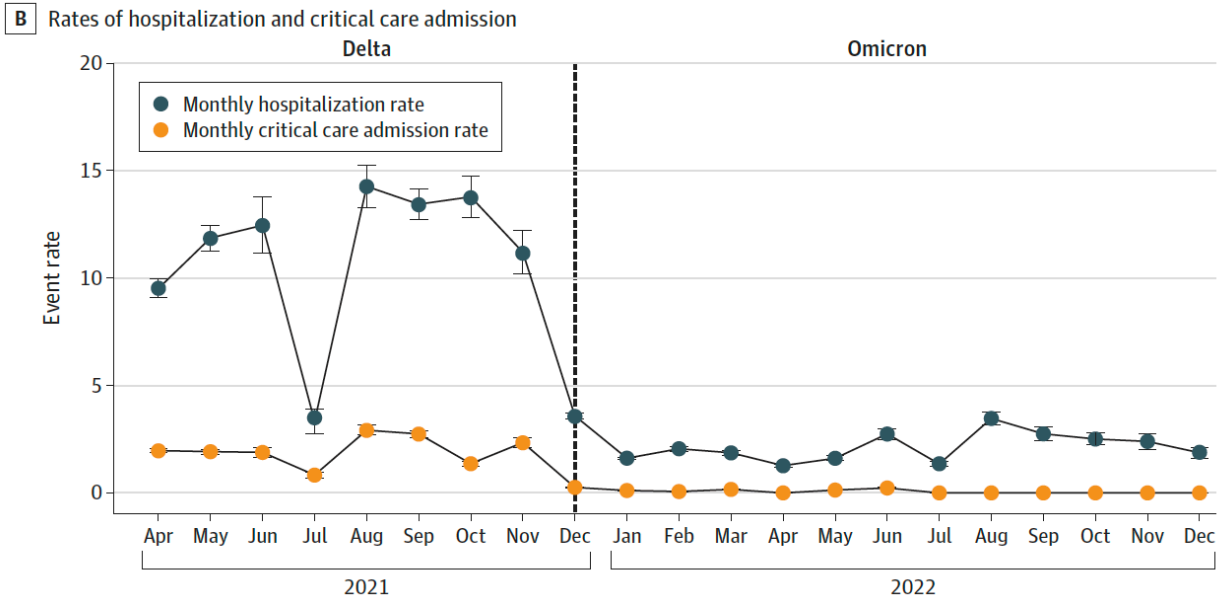
Elisabeth McClymont, PhD; Sandra Blitz, MSc; Lucia Forward, BSc; Sara Cole, BA; Gillian D. Alton, PhD;

Key Points

Question Is COVID-19 vaccination associated with a lower risk of adverse outcomes for cases of SARS-CoV-2 in pregnancy?

Findings This study (n = 19 899) demonstrated that among individuals with SARS-CoV-2 in pregnancy, COVID-19 vaccination was associated with a lower risk of maternal hospitalization (Delta: relative risk [RR], 0.38; Omicron: RR, 0.38) and critical care unit admission (Delta: RR, 0.10; Omicron: RR, 0.10), as well as preterm birth (Delta: RR, 0.80; Omicron: RR, 0.64) in both the Delta and Omicron variant time periods.

Meaning COVID-19 vaccination is associated with a lower risk of severe disease and preterm birth regardless of variant time period.



McClymont et al. *JAMA*. **2025**

First-Trimester mRNA COVID-19 Vaccination and Risk of Major Congenital Anomalies

Clément Bernard, MSc[1,2]; Tom Duchemin, PhD[1]; Lise Marty, PhD[1] ; et al

» Author Affiliations | Article Information

RELATED ARTICLES FIGURES SUPPLEMENTAL CONTENT

Key Points

Question Are messenger RNA (mRNA)–based COVID-19 vaccines teratogenic ?

Findings In this nationwide cohort study of 527564 live-born infants, 130338 (24.7%) were exposed to an mRNA-based COVID-19 vaccine during the first trimester of pregnancy. There was no association with an increased risk for 75 different major congenital malformations, whether examined overall, grouped by organ systems, or individually.

Meaning These findings suggest that mRNA-based COVID-19 vaccines do not appear to have any teratogenic effects.

JAMA Netw Open 2025;8;(10):e2538039. doi:10.1001/jamanetworkopen.2025.38039

Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19–Associated Hospitalization in Infants Aged <6 Months — 17 States, July 2021–January 2022

TABLE 3. Effectiveness* of maternal 2-dose primary mRNA COVID-19 vaccination against COVID-19-associated hospitalization in infants aged <6 months, by timing of maternal vaccination during pregnancy† — 20 pediatric hospitals, 17 states,§ July 2021–January 2022

Timing of maternal vaccination during pregnancy†	No. vaccinated¶/Total (%)		Vaccine effectiveness,* % (95% CI)
	Case-infants	Control-infants	
Any time	28/176 (15.9)	65/203 (32.0)	61 (31 to 78)
Early (first 20 weeks)	17/165 (10.3)	26/164 (15.9)	32 (–43 to 68)
Late (21 weeks' gestation through 14 days before delivery)	9/157 (5.7)	38/176 (21.6)	80 (55 to 91)

SUMMARY

Summary

- Infectious diseases pose a particular risk to pregnant persons, newborns and young infants.
- Vaccines have been shown to be safe and effective during pregnancy
- In Canada it is recommended to offer during pregnancy
  - Tdap
  - Non-live seasonal influenza vaccine
  - COVID-19 vaccine
- RSV vaccine during pregnancy is available but not publicly funded in Canada (with the exception of Ontario)