



The Federation of Medical Women of Canada (FMWC) Maternal RSV Task Force

Respiratory Syncytial Virus (RSV):
Recommendations for the Prevention of Disease in
Infants for the 2024 - 2025 RSV Season

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The FMWC Maternal RSV Task Force

Respiratory Syncytial Virus (RSV): recommendations for the prevention of disease in infants for the 2024 - 2025 RSV season

Introduction

The Federation of Medical Women of Canada (FMWC) convened a Maternal RSV Task Force to develop recommendations to prevent Respiratory Syncytial Virus (RSV) disease in infants during the 2024 - 2025 RSV season. We need to act now to **educate**, **communicate** and bring **awareness** to the new preventative measures recently approved by Health Canada to protect infants against RSV.

The recommendations in this white paper serve as a call to action for healthcare providers, the public and policymakers to protect infants from RSV-associated morbidity and mortality, reduce the strain of RSV illness on Canadian pediatric healthcare systems and society, and alleviate the psychological trauma families endure when caring for an infant with RSV. We aim to **inspire action and equip healthcare providers and pregnant women and pregnant people with the knowledge required for informed, shared decision-making** on how to best protect their newborn infants from RSV disease in the 2024 - 2025 RSV season.

Informed, shared decision-making.

Who Are We?

The FMWC is a national organization recognized for its leadership and advocacy for women's evolving health. We are committed to promoting the well-being and health of women and women-identifying individuals both within the medical profession and society at large. The FMWC has a 100-year history in Canada, is a member of the non-

governmental organization (NGO) section of the Department of Global Affairs at the United Nations (UN) and is a member of the Medical Women’s International Association (MWIA), making us a part of the Economic and Social Council of the UN (ECOSOC). In the Spring of 2024, the FMWC convened a Maternal RSV Task Force to identify practical recommendations for the prevention of RSV disease in infants 0-6 months for the 2024 – 2025 RSV season. The task force included national healthcare leaders and immunizers practicing in various healthcare settings across Canada.

What is RSV?

Respiratory syncytial virus (RSV) is a prevalent and highly contagious RNA virus that causes lower respiratory tract disease (LRTD) and upper respiratory tract disease.^{1,2} While most people infected with RSV have mild to moderate flu-like symptoms and recover in a week or two, in infants, it can be a cause of severe morbidity, including severe LRTD, bronchiolitis, and pneumonia, leading to hospitalization, and in some cases death.^{1,2} With grandparents and infants, it is important to consider the transmission of RSV within families; adults over the age of 60, especially those with co-morbidities, are also at an increased risk of hospitalization from RSV, placing an extra strain on families and increased risk of infecting infants 0-6 months.

Over half of RSV-related hospitalization cases in children are in patients under six months of age.³

Quick Facts - RSV Incidence and Impact in Canada

- o RSV causes seasonal epidemics, with RSV in infants more common in late fall, winter, and early spring.¹ While there is a seasonality with RSV, according to the Public Health Agency of Canada, in recent years, surveillance data have shown an earlier onset of RSV cases starting in as early as August in some provinces.⁴
- o RSV can cause serious complications in infants, and the high number of RSV-associated hospitalizations and intensive care unit admissions during the RSV season can put a substantial strain on healthcare resources.⁵ While infants with

certain medical conditions are at a higher risk of severe RSV disease, healthy-term infants account for the largest proportion of infants with severe RSV disease each year.^{2,6,7}

- o Over half of RSV-related hospitalizations in children are in patients under six months of age with the highest rate of hospitalization occurring in the first three months of life.^{3,8}
- o 23.6% of RSV-related hospitalization cases required intensive care unit admission with over 60% of ICU admissions occurring in children under six months of age.³
- o The economic impact of RSV-associated hospitalizations is considerable, with estimated costs exceeding \$9,000 per case in Ontario.⁹
- o RSV burden is not fully accounted for without community-based RSV testing and without considering the burden of disease in infants not hospitalized, such as missed days of work for parents, caregiving challenges, and the cost of outpatient appointments.

What Does this Mean to Our Patients?

“Our son had zero risk factors, was born completely healthy and at term (38.5 weeks, 7.5lbs). The fact he got so sick and so fast is a mystery. That’s what RSV can do in infants, even those born completely healthy.”

- Mom Jessica sharing her experience when her one-month-old son contracted RSV disease

Parents who have experienced an infant with RSV recount the trauma of seeing their small child appear limp and struggling to take a breath. Ottawa-based mother Jessica Cohn continues to experience the trauma RSV can cause after her second child was diagnosed at just one month old. She recounts crumbling to the floor when a team of doctors told her that her son’s health was deteriorating, and he would need to be intubated. It’s a trauma she carried through her third pregnancy and still feels fresh today.

“Our son had zero risk factors, was born completely healthy and at term (38.5 weeks, 7.5lbs). The fact he got so sick and so fast is a mystery. That’s what RSV can do in infants, even those born completely healthy.”

Discussing the new protective measures now available for infants, Ms. Cohn shared “I’m just so happy this is all coming to fruition. As my doctor can attest, I was begging

for this type of vaccine when I was pregnant with my 3rd child (my pregnancy after my son who was sick with RSV).”

“I hope pregnant moms will hear my story and take action to prevent it from happening to them. It’s not just the babies with preexisting conditions RSV can affect...it can affect any baby. It’s that scary.”

What New Options Do We Have Available to Prevent Infection?

Health Canada has recently approved two new products nirsevimab (Beyfortus™, Sanofi) and RSVpreF (Abrysvo™, Pfizer) that provide vital protection against RSV in infants during the critical early months of life. The approval of these new products provides an opportunity to expand protection from RSV disease to all infants, not just those at high risk for RSV, as has been the case until now with the previous generation monoclonal antibody palivizumab (Synagis®, AstraZeneca, first marketed by Abbvie in 2002). Until the approval of these two new products, we had only one resource to protect infants against RSV disease which was part of a narrowly targeted program for the highest risk infants with certain high-risk conditions.⁵ The approval of these new products offers healthcare providers with additional prevention resources and offers families the choice to protect their infants from RSV disease.

1. Nirsevimab (Beyfortus™, Sanofi), is a monoclonal antibody, indicated for the prevention of RSV LRTD in neonates and infants during their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.¹⁰
2. RSVpreF (Abrysvo™, Pfizer), is a maternal RSV vaccine, indicated for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age through active immunization of pregnant women and pregnant people from 32 through 36 weeks gestational age.¹¹

The National Advisory Committee on Immunization (NACI) released a statement on the prevention of RSV disease in infants which recommends:

- building towards a universal RSV immunization program for **all infants**⁵

- a phased RSV immunization program using nirsevimab, initially focusing on high-risk infants who are at increased risk of severe RSV disease⁵
- program introduction in stages depending on access to supply, cost-effectiveness, and affordability of available options⁵
- RSVpreF may be considered as an individual decision by a pregnant woman or pregnant person together with information from their pregnancy care provider, in advance of, or during, the RSV season, to prevent severe RSV disease in their infant in the context of informed consent.⁵

What Does the FMWC Maternal RSV Task Force Recommend?

Education | Communication | Awareness

The task force's top priorities, both short-term and long-term, are **Education**, **Communication** and **Awareness**.

1. **Education** to address knowledge gaps among healthcare providers about available options for infant protection from RSV disease.
2. **Communication** about the efficacy, safety, availability and benefits of immunizations to protect against RSV disease in infants.
3. **Awareness** among healthcare providers, pregnant women and pregnant people, the public and policymakers about the burden of RSV disease in infants and the available protective options.

Short-Term Recommendations (to be implemented in the next six to twelve months)

The short-term recommendations include providing urgent **education** support to healthcare providers, community leaders and vaccinators on the recently approved options for infant protection from RSV disease and raising **awareness** among providers, pregnant women and pregnant people, the public and policymakers about the burden of RSV disease in **all infants** and the impacts on the Canadian pediatric healthcare system, society and families. While we eagerly await the provinces to build towards possible universal programs for all infants aligned with NACI's recommendation at this time where

nirsevimab is preferred over RSVpreF, there are many considerations including availability of supply, timing, cost effectiveness and logistics for implementation of these programs.⁵ NACI will continue to carefully monitor the scientific developments related to passive immunizing products for RSV and will update recommendations as evidence evolves. In the meantime, the upcoming RSV season is approaching and since RSVpreF is currently available for sale in Canada through pharmacies and other health care providers who offer vaccination services, we see an opportunity to offer protection from RSV to **all infants** through active immunization of pregnant women and pregnant people between 32 and 36 weeks gestational age. The short-term recommendations include providing **communication** tools to help providers explain the protective options available and aim to help prevent RSV disease in **all infants** for **the 2024-2025 RSV season**.

These recommendations will evolve as new evidence emerges, and market conditions change.

“The time is now. We have new options, we have the luxury of learning from other countries’ experiences, and we need to act now to protect infants, and we will.”

– Dr. Vivien Brown, Family Physician, Toronto, Co-Chair FMWC Maternal RSV Task Force

Education

The task force recommends:

1. **Educating healthcare providers about the burden of RSV disease and the newly approved options available to protect infants from RSV disease.** Healthcare providers need educational tools to fully understand the current paradigm in RSV prevention strategies. NACI’s new recommendation is to move towards a universal RSV immunization program for all infants, at this time with nirsevimab preferred over RSVpreF, possibly in stages starting with the high risk infants and depending on access to supply, cost-effectiveness and affordability.⁵ As NACI indicated and we know from experience as healthcare providers, this goal will take time and involve implementing change across many levels of our healthcare system.⁵ With the 2024 - 2025 RSV season quickly approaching, we must now begin counselling and offering options to pregnant women and pregnant people to protect their newborn infants against RSV this year. While the provinces

formalize, evaluate and consider implementing universal programs, we need to **act now to educate healthcare providers**. Our recommendation aligns with NACI's position **encouraging people to discuss available immunization options in their setting with a healthcare provider in advance of childbirth**¹², and even in jurisdictions where nirsevimab might be available, RSVpreF may be recommended using shared decision-making for those families that would prefer an immunizing product during pregnancy versus the neonatal period. Since RSVpreF is currently available with supply in Canada to protect **all infants** from RSV through active immunization of pregnant women and pregnant people between 32 and 36 weeks gestational age, the task force recommends **urgent education** for providers about the efficacy, safety, availability and benefits of the maternal RSV vaccine. The educational tools must emphasize **the timing of administration of RSVpreF and follow Health Canada's approval for the use of the vaccine**. As per NACI's summary, from studies the RSVpreF pregnancy vaccine is shown to be effective at preventing severe RSV disease in infants during the first months of life and administration during the authorized dosing interval of 32 through 36 weeks of gestation was not associated with safety concerns.¹² **The task force recommends a very clear message in educational tools for healthcare providers** to share accurate and easy to understand information with their pregnant patients to allow for informed shared decision-making. For that reason, we include the data from the clinical trials as summarized below.

Clinical Trial Data Summary:

When RSVpreF was given to pregnant women and pregnant people outside of the approved window for use (outside of the 32 – 36 weeks gestational age window) there was a non-statistically significant imbalance in preterm births observed among the RSVpreF recipients versus the placebo recipients, most pronounced in the 28 through 31 weeks' gestation subgroup.¹¹ The majority of this imbalance came from investigational sites in South Africa and Argentina with no imbalance seen in the aggregate incidence among participants from high income countries such as Canada, as per World Bank Group categories.¹¹ Additionally, no increase in overall infant mortality was observed (5 in RSVpreF, 12 in placebo), and no differences were observed in neonatal hospitalization / prolongation of hospitalization in infants overall (391[11%] in RSVpreF, 353 [9.9%] in placebo), or in those born premature (83 [2.3%] in RSVpreF, 80 [2.2%] in placebo).¹¹ Available

data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF.¹¹ As a precaution, the indication for RSVpreF is currently limited to 32 through 36 weeks' gestation.¹¹ NACI will continue to carefully monitor the evidence on the safety of RSVpreF vaccine and will update guidance accordingly.¹²

Our recommendations call for **clear and consistent educational messaging** for providers and their patients to allow for informed, shared decision-making so each pregnant woman and pregnant person is empowered to make the best choice to protect their baby from RSV disease.

2. **Developing and disseminating tailored education packages for providers** that recognize and meet the unique needs of their patient populations considering social and structural determinants of health, diversity, equity and inclusion for all pregnant women and pregnant people in Canada. The tailored education packages should easily translate knowledge on the burden of RSV in **all infants**, the urgency of combating RSV infection in **all infants**, and the RSV immunization options available to their specific and unique patient populations. These education packages should be widely disseminated to all healthcare providers practicing prenatal care. This includes family physicians, obstetricians and gynecologists, pharmacists, nurses, midwives, doulas, elders, community leaders, and all other pregnancy care providers.

Urgent education is needed for providers on the efficacy, safety, availability, and benefits of the recently approved options for infant protection from RSV disease for this RSV season.

3. **Providers offer the maternal RSV vaccine for eligible pregnant women and pregnant people as an option to be considered on an individual basis as aligned with NACI's recommendation** which states that RSVpreF may be considered as an individual decision by a pregnant woman or pregnant person together with information from their pregnancy care provider, in advance of, or during, the RSV season, to prevent severe RSV disease in their infant in the context of informed consent,^{5,12} especially in jurisdictions where a universal provincial program for all infants is not yet implemented. Given that a

recommendation for vaccine is strongest coming from a trusted healthcare provider, we recommend that providers must have sufficient knowledge to know when to discuss maternal RSV immunization with their pregnant patients, and how to explain and understand the benefits and safety data, and the different options for RSV protection currently available in Canada and how they work to protect newborn infants. As part of routine prenatal care, healthcare providers currently recommend the Tdap vaccine to all pregnant women and pregnant people between 27 and 32 weeks of gestation to protect infants against tetanus, diphtheria, and pertussis.¹³ Additionally, this year, the RSVpreF vaccine should be offered as an option to eligible patients between 32 and 36 weeks of gestation to protect their infants against RSV from birth until 6 months of age. Providers should communicate that vaccines recommended in pregnancy can be co-administered at the same time.⁵ Providers must clearly and effectively communicate the benefits, safety profile and the choices available for infant protection from RSV disease to allow for informed, shared decision-making with their patients.

- 4. Collaborating with organizations whose members provide pregnancy care to ensure a broad reach of the educational assets developed for healthcare providers.** This is an opportunity to more quickly and broadly disseminate the information. FMWC, task force members and other collaborating organizations should work together to synergistically share all educational tools developed.
- 5. Educating pregnancy care providers about vaccine access.** Healthcare providers practicing prenatal care in all parts of Canada should be provided with educational tools informing them if, when and what universal programs with nirsevimab are available in their jurisdiction. To be prepared for those patients who chose maternal vaccination with RSVpreF, providers should be given educational resources on when and how to procure the maternal RSV vaccine and have it available when eligible patients come in. If they cannot vaccinate the patient, they should refer their patient to a vaccinator. Providers should be given educational tools explaining the vaccine costs, insurance coverage options, and patient support programs to help those who cannot afford the vaccine and do not have insurance coverage.

“We see our pregnant patients on a regular basis and offer other routine vaccines. To give every infant the chance for protection from RSV this 2024 - 2025 season, we have the ideal opportunity to educate, inform and offer the option for maternal RSV vaccination between 32 and 36 weeks’ gestation.

– Dr. Shelley Ross, Family Physician, Burnaby, Co-Chair FMWC Maternal RSV Task Force

Communication

The task force recommends:

6. **Equipping healthcare providers with patient communication tools.** A communication kit should be provided to all healthcare providers including physicians, pharmacists, nurses, midwives, doulas, elders, community leaders, and all other pregnancy care providers to help them navigate the complexities of discussing the new RSV protective options for infants with pregnant women and pregnant people. The communication kit must include the complexities of discussing the available RSV immunizations, vaccination timeline for the 2024 - 2025 RSV season, benefits and risks, frequently asked questions, and suggestions to help start the conversation about the available options with patients.
 - A factual **one-page handout available in print and digital** format in multiple languages is an essential part of this communication kit. Sharing the information and adding it to already existing **digital pregnancy apps** is also recommended as an effective method to communicate the information with pregnant patients.
 - Aligning and adding the communication tools to other collaborating organizations’ communication kits will also be useful in this regard. A coordinated and unified message should be communicated.

Trusted pregnancy care providers should dispel misinformation, explain benefits and risks, and inform and empower patients for shared decision-making.

- 7. The task force recommends an informed, shared decision-making approach when discussing preventative options for RSV disease with pregnant women and pregnant people.** Pregnant women and pregnant people may not be aware of the severity and life-threatening consequences of this vaccine-preventable disease in infants. Healthcare providers are one of the primary sources of vaccine education. Providers should explain the benefits and risks of the options available to protect infants from RSV disease, dispel misinformation, and empower their patients by giving them the correct information in an easily understood and relatable fashion, thus paving the way to informed shared decision-making. With respect to RSVpreF, pregnant women and pregnant people continue to experience paternalism during medical decision-making.¹⁴ Therefore the autonomy of pregnant women and pregnant people in making informed decisions based on clear information communicated in a way that is easily understood, regarding accepting vaccines for themselves to protect their infants must be prioritized.⁵

Awareness

The task force recommends:

- 8. Employing a public relations firm to develop a media strategy to educate the public about the new options available to protect infants from RSV disease.** A coordinated and broad effort to raise awareness about the significance of RSV disease in infants and the new options available to protect against it is crucial for increasing vaccine acceptance among the public at large and specifically pregnant women and pregnant people, providers, policymakers and key partners. The public awareness campaign should use various forms of media tailored to specific audiences where they are most likely to see, understand and accept the information. This could include earned media, social media and traditional media like TV, radio, billboards.
- 9. Partnering with Indigenous Elders and other Indigenous community leaders to raise awareness among pregnant women and pregnant people in Indigenous communities about the burden of RSV disease in infants and the new options available to protect infants from RSV disease.** Tailored

messaging and means of raising awareness should be created to allow autonomous decisions to be made by Indigenous pregnant women and pregnant people with the support of healthcare and public health partners in accordance with the United Nations Declaration on the Rights of Indigenous Peoples.¹⁵ Tailored messaging and mechanisms to communicate the messaging should also take in account the geographic setting where the pregnant woman or pregnant person in an Indigenous community resides (e.g., urban, rural, on-reserve, off-reserve).

23.6% of RSV-related hospitalization cases required intensive care admission where greater than 60% of ICU admissions were in children under six months of age.³

Long-Term Recommendations (to be implemented in the next twelve to twenty-four months)

In keeping with our short-term recommendations, our long-term recommendations focus on the same three key areas: **education, communication and awareness**. In the next twelve to twenty-four months, we recommend improved understanding and knowledge through education developed from data collection and research, communication to address vaccine hesitancy and awareness leading to equitable vaccine access for **all pregnant women and pregnant people and all infants**.

The task force recommends:

- 1. Improved community-based testing for RSV to have a more accurate estimate of the burden of RSV disease in infants in hospitals and communities.** Provincial health units should encourage routine testing to differentiate RSV from other viruses that cause respiratory illness. Viral testing facilitates disease management and provides critical surveillance data. As more RSV immunizations become available to prevent RSV in infants, the surveillance data will help inform RSV prevention policies.

2. **Collecting real-world data on RSV immunizations.** Healthcare providers and provincial health units must collect real-world effectiveness and safety data on RSV immunizations. Education on the real-world data collected must be provided to healthcare providers and policymakers. This data will help inform future RSV immunization policies, funding, and recommendations.
3. **Research on vaccine hesitancy in pregnant women and pregnant people.** Public health and/or other medical organizations should conduct quantitative and qualitative research with pregnant women and pregnant people and new parents to understand attitudes toward vaccines. Study results from different provinces should be compared to better understand the factors influencing vaccine hesitancy and uptake. Public health units and health professionals should implement practical communication strategies to address maternal vaccine hesitancy and increase vaccine confidence. Options such as vaccine passports and mobile applications to increase vaccine uptake should be explored.
4. **Engaging with key partners and provincial governments across Canada to lobby for publicly funded provincial RSV immunization programs to protect all infants.** Public funding will help achieve equitable access to the new options for infant RSV protection. While the provinces formalize, evaluate and consider implementing provincial RSV programs, healthcare leaders, experts, partners and providers should coordinate action and engage with members of the provincial legislatures across all parties and provinces to increase awareness on the importance of RSV prevention in **all infants** and the importance of community-based RSV testing to gain a deeper understanding of the RSV burden of disease.

“I want all patients/pregnant individuals to know the best options to protect their infant from RSV based on availability, cost, location and their personal choices. Patient decision making is key.”

- Dr. Darine El-Chaâr, Maternal Fetal Medicine, Ottawa
FWMC Maternal RSV Task Force Member

Conclusion

We now have two new RSV protective measures in our armamentarium to help prevent RSV disease in infants. Given that RSV season in Canada is quickly approaching, the FMWC Maternal RSV Task Force recommends **we act now** to **educate, communicate** and **increase awareness** on the available new protective measures to prevent RSV disease in infants **this RSV season**.

“RSV has plagued us for years; this is the year we can prevent this disease.”

- Dr. Cora Constantinescu, Pediatric Infectious Disease, Calgary, FMWC Maternal RSV Task Force Member



Appendix 1: FMWC Maternal RSV Task Force Members

Dr. Vivien Brown - Family Physician - Toronto – Co-Chair

Dr. Shelley Ross - Family Physician - Vancouver – Co-Chair

Jen Belcher – Pharmacist - Vice President, Strategic Initiatives & Member Relations - Ontario Pharmacists Association - Kingston

Dr. Tali Bogler - Family Physician - Toronto - family medicine obstetrics provider

Dr. Cora Constantinescu - Pediatric Infectious Disease - Calgary

Dr. Shelita Dattani – Pharmacist - Senior Vice President, Pharmacy Affairs and Strategic Engagement - Neighbourhood Pharmacy Association of Canada - Ottawa

Dr. Darine El-Chaâr - Maternal Fetal Medicine (MFM) Physician - The Ottawa Hospital

Dr. Milena Forte - Family Physician - Toronto - family medicine including full-scope maternity care

Dr. Sherilyn Houle – Pharmacist - Associate Professor School of Pharmacy - U of Waterloo

Dr. Jia Hu - Co-Founder, 19 to Zero - Calgary - Public Health Physician - Family Physician

Dr. Unjali Malhotra - Family Physician - Vancouver - Medical Director Women's Health First Nations Health Authority

Dr. Christine Palmay - Family Physician - Toronto - preventative medicine and women's health

Dr. Charissa Patricelli - FIR (Families in Recovery) Physician - Vancouver - perinatal addiction services

Dr. Shafeena Premji - Family Physician - Calgary - women's health, low-risk obstetrical care

Antonella Pucci - Manager, Immunization Initiatives at Canadian Public Health Association (CPHA) - Immunize Canada - Ottawa

Dr. Chloe Rozon - OB GYN - PGY5 Resident - The Ottawa Hospital

Theresa Tang - Co-Chair & CEO, 19 to Zero – Calgary

Observers:

Lauren Douglas – Veritas

Sheri Fitzpatrick-Poulain – FMWC Maternal RSV Lead - FleurishMD

Joyce McCaffrey – Atlas

Krithika Muthukumaran – Medical Writer - Purple Elephant Medical Communications

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