RSV Prevention for Infants in Canada: Recommendations for the 2025-2026 RSV Season

FMWC Maternal RSV Task Force White Paper

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FMWC Maternal RSV Task Force

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Summary

The respiratory syncytial virus (RSV) is a common pathogen and a leading cause of respiratory disease among infants and young children. RSV can affect any infant, and healthy, full-term infants represent most cases of severe disease. Infants may develop a range of respiratory illnesses, including bronchiolitis and pneumonia, leading to difficulty breathing and sometimes requiring hospitalization. No curative treatments are available, and therefore, immunization is crucial for prevention. In 2023, two immunizing agents – a maternal vaccine, RSVpreF/ABRYSVO® and an anti-RSV antibody for infants, nirsevimab/BEYFORTUS® – were authorized by Health Canada. Both agents are effective and safe, as shown by large-scale randomized clinical trials and emerging real-world studies.

Many parents, pregnant women, and pregnant people are unaware of RSV disease and the available immunization products and programs. Furthermore, not all HCPs are familiar with the guidelines for the use of preventive options; these guidelines may differ across Canadian regions and practice settings. Therefore, there is a need for increased awareness of RSV disease as well as the options for immunization, the benefits of immunization, and the efficacy and safety of immunizing agents.

In this white paper, the Maternal RSV Task Force of the Federation of Medical Women of Canada (FMWC) presents recommendations to protect infants in Canada from RSV in 2025-2026. The recommendations focus on increasing awareness of RSV disease, education regarding RSV immunization options, and communicating the scientific evidence about RSV prevention to parents, families, pregnant women and pregnant people, and health care professionals (HCPs). Limited access to RSV immunization options is a significant challenge that should be addressed to promote health equity for all people in Canada. We recommend a team approach that involves HCPs with different specialties and practice settings, including pharmacists and other prenatal care providers. Tailored education for HCPs, encouraging vaccine discussions, and a universal immunization registry are key components of our recommendations. In addition, we recommend advocating for public funding for RSV immunization. To align with the Health Canada authorizations for these immunizing

agents, this funding should apply year-round for maternal RSVpreF,[1,2] and during the RSV season for nirsevimab.[3,4]

"Pregnant women and pregnant people" is intended to include people of all gender identities who are pregnant. This language is evolving and the intent is to use language that removes barriers to care.

Introduction

The respiratory syncytial virus (RSV) is a pathogen that causes respiratory infections. RSV is a leading cause of respiratory illness in infants, with 2% of all infants in Canada, or 1 in 50, hospitalized in their first year of life.[5] In some infants and children, RSV disease is associated with long-term complications, such as asthma and reduced respiratory function.[6] In 2023, two immunizing agents, RSVpreF/ABRYSVO® and nirsevimab/BEYFORTUS® were approved by Health Canada after earlier approvals in the UK and EU.[1,3] These agents are expected to have a significant positive impact on public health. The efficacy and safety of these agents has been demonstrated in prospective, randomized clinical trials and emerging real-world studies.[7-12]

However, many health care professionals (HCPs), government representatives, and members of the public are unaware of these options for prevention, as well as RSV disease as a public health problem.[13-15] Access to publicly funded RSV immunization options varies across Canadian provinces and communities, with thousands of infants still unprotected. This is a significant health equity concern. This white paper addresses the **need for increased awareness, education, and communication among HCPs, public health agencies, governments, and the public regarding RSV prevention in infants through immunization.**

Overview of RSV in Canada, challenges, and recent progress in immunization

RSV virology

RSV is an enveloped, single-stranded RNA virus with two subtypes (A and B). The virus causes upper and lower respiratory tract infections (LRTI).[6] RSV is contagious before, during and after infection, and is easily acquired and spread between family members and in the community through droplet, aerosol, and contact transmission.[16,17] An initial infection provides only partial protection against future infections: among children under 5 years of age in the USA, the risk of re-infection within the same RSV season is similar to the risk of initial infection.[18] Historically, RSV infections have followed a seasonal pattern with the highest incidence occurring from November through April, peaking in February.[19] However, this pattern was disrupted by the COVID pandemic, and the incidence of off-season RSV infections is increasing.[20,21]

Disease burden of RSV

RSV infection is challenging to treat, and there are no specific curative treatments available. Symptoms include congestion, cough, fever, wheezing, and decreased appetite; in very young infants, symptoms include irritability, difficulty breathing and/or feeding, apnea, and reduced activity.[22,23] Children may develop bronchiolitis, pneumonia, croup and ear infections (otitis media).[16,24] Supportive care may involve IV fluids, oxygen, or mechanical ventilation.[23]

Individuals who develop LRTI in early childhood have almost double the risk of premature death from respiratory disease relative to unaffected individuals.[25] LRTI before the age of 2 years is associated with lifelong complications such as asthma, recurrent pneumonia, recurrent wheezing, and decreased lung function.[26] Furthermore, RSV co-infection with other pathogens, such as *Streptococcus pneumoniae*, contributes to the severity of childhood LRTI.[25]

RSV is the most common cause of LRTI in children and the leading cause of LRTI-associated hospitalization in infants.[27] In infants, up to 80% of cases of bronchiolitis

and up to 40% of cases of pneumonia are attributed to RSV.[26] In an Ontario study of over 800,000 children, over 12,500 (or 1.4%) were hospitalized for RSV over a period of up to five years.[19] Hospitalization rates of 29.55 per 1000 person-years (PY) among infants 1 month of age and 16.03 per 1000 PY among infants 2-3 months of age were reported.[19] Another Canadian study found that almost half of all RSV-related hospitalizations were of infants under 6 months of age; almost one-quarter of children hospitalized required ICU admission, and most of these children were infants under 6 months of age.[28]

Healthy, full-term infants represent the majority (80%) of cases of severe RSV LRTI,[29] contributing to a significant demand for health care resources, including outpatient resources. However, certain infants are at higher risk. Infants aged <6 months, those born preterm, and those with low birth weight, congenital cardiac or pulmonary conditions, immune deficiency or compromised immune function, or trisomy 21 are at greater risk.[30,31] Males have higher risk than females.[30,31] Maternal risk factors for infant disease include structural and social determinants that increase vulnerability, such as younger maternal age (<25 years), mental health challenges, substance use, limited financial resources, and systemic barriers associated with urban living conditions.

RSV affects families through missed work, emergency department visits, anxiety, and trauma, while also placing a significant burden on the health care system. Surges in cases can overwhelm emergency departments, leading to longer wait times and straining the system's capacity to provide timely care for all. In the winter of 2024-2025, hospitals across Canada reported increasing respiratory illness in children.[32-34] For example, in December 2024, Alberta Children's Hospital was "well over capacity", with its ED, inpatient units, and ICU all full. Healthcare resources had to be redirected to manage this surge in admissions.[35] RSV is a major contributor to hospitalizations of infants and children, and "unprecedented peaks" in child hospital admissions were observed in 2022-2023.[36] The annual direct cost of RSV hospitalization is estimated at $38 million in Ontario alone.[37]

It is also important to note that RSV testing is not widespread and is mainly carried out in hospital; low testing rates are thought to underestimate the incidence of RSV and its contribution to the burden of respiratory disease in Canada, including the need for outpatient care and resources.38 RSV-associated fatalities of infants that

take place at home may be classified as SIDS, further underestimating the contribution of RSV.[39]

RSV impacts entire communities.

RSV impacts entire communities through the cost of hospitalizations, missed work for parents and family members, anxiety and trauma, and impact on the health care system.[40]

Immunization strategies

Three products are available for the immunization of infants. Further details are given in Table 1.

- Maternal vaccine, **RSVpreF/ABRYSVO®** (vaccine; maternal antibodies are transferred to the fetus across the placenta; Health Canada authorized in 2023)[1]
- Monoclonal antibody, **nirsevimab/BEYFORTUS®** (fully human monoclonal antibody; Health Canada authorized in 2023)[3]
- Monoclonal antibody, **palivizumab/SYNAGIS®** (humanized monoclonal antibody; Health Canada authorized in 2002); for infants with certain high-risk conditions only[41]

Nirsevimab and palivizumab are indicated for the prevention of RSV disease **in infants only**. Two other vaccines (RSVPreF[3]/Arexvy[42] and mRNA-1345/mRESVIA™)[43] are indicated **for older adults only**. RSVpreF/ABRYSVO® is also indicated for older adults.[31]

RSVPreF/ABRYSVO® is a vaccine, or active immunizing agent, for pregnant women and pregnant people.[1] After immunization, the mother's antibodies are transferred across the placenta, providing passive immunity to the developing fetus.1 The manufacturer's product monograph states that immunization must be carried out when the pregnant woman or pregnant person is between 32 and 36 weeks' gestation; this is also the indication that is authorized by Health Canada.1 According to the Society of Obstetricians and Gynaecologists of Canada (SOGC), this timing is interpreted as 32 weeks, 0 days (32 +0) through 36 weeks, 6 days (36+6).[44] Correspondingly, the maximum gestation of participants in the MATISSE clinical trial was 36 weeks, 6 days.[7] The Health Canada authorization and the manufacturer's

product monograph do not specify seasonality;[1,2] thus, RSVpreF may be given at any time.[1,2]

Maternal vaccination has several benefits, including protection for the infant starting at birth. An ongoing supply of antibodies can be delivered through breastfeeding, and the polyclonal immune response is thought to provide broader protection against different RSV strains and variations. RSVpreF can be co-administered with influenza, COVID-19, and Tdap vaccines.[40,44,45] Maternal vaccination may be preferred over infant immunization by some mothers and parents.[46-48] Among 723 individuals surveyed across Canada, 77% indicated that they would accept RSV vaccination during pregnancy, whereas 55% would accept immunization of their infants.[46] In another study of 803 individuals in Québec, 88.1% were willing to receive maternal RSVpreF and 92% were willing to have their infants receive nirsevimab; however, 69% preferred maternal RSVpreF.[47,48] However, these preferences may change with increasing awareness and broader access to both RSV immunization options.

Nirsevimab/BEYFORTUS® is a passive immunization agent consisting of a pre-formed monoclonal antibody.[3,49] Nirsevimab is given directly to the infant rather than to the mother/parent. This strategy also has benefits. For instance, nirsevimab may be given regardless of gestational age and provides protection within a few days of birth.[3] Nirsevimab is authorized during the RSV season (for all infants during their first RSV season, and for infants who remain vulnerable to severe disease through their second RSV season).[3]

Palivizumab/SYNAGIS® is a humanized monoclonal antibody directed against a conserved epitope on the RSV F protein.[50] Palivizumab has been authorized in Canada since 2002, but is only indicated for infants with certain high-risk conditions (infants born at ≤35 weeks gestational age and those with bronchopulmonary dysplasia or congenital heart disease).[41] With strict eligibility criteria, only 2% of infants are eligible for palivizumab, which leaves healthy, full-term infants, who represent the majority of RSV cases, unprotected.[51] Nirsevimab has an extended half-life and longer duration of protection, greater neutralizing activity, and simpler dosing than palivizumab: only one dose of nirsevimab is required per RSV season, vs up to five monthly doses of palivizumab during RSV season. Since nirsevimab is also less expensive than palivizumab,[52] nirsevimab is generally preferred. NACI has recommended that nirsevimab replace palivizumab in current

immunization programs, although palivizumab can be used for high-risk infants when nirsevimab is unavailable.[40,49] Therefore, this white paper will focus on nirsevimab and RSVpreF.

Table 1. Characteristics of newer RSV immunizing agents.

	RSVPreF/ABRYSVO®[1]	Nirsevimab/BEYFORTUS®[3]
Mechanism	• Active immunizing agent (vaccine)* consisting of RSV F glycoproteins from strains A and B, stabilized in prefusion conformation; maternal antibodies are transferred across placenta, providing passive immunity to the fetus	• Passive immunizing agent;* pre-formed, recombinant human IgG1k monoclonal antibody directed against conserved epitope of RSV F glycoprotein[53]
Indications	• Pregnant women and pregnant people between 32+0 and 36+6 weeks' gestation, for the prevention of LRTD# caused by RSV in infants from birth through 6 months; also for the prevention of LRTD caused by RSV in individuals ≥60 years of age	• For the prevention of RSV LRTD in neonates and infants during their first RSV season, and in children ≤24 months of age who are vulnerable to severe RSV, through their second RSV season

Dose	• Single IM dose of 0.5 ml	• Infants born during RSV season: administer at birth • Infants born outside RSV season: administer prior to season • Neonates and infants entering first RSV season: single IM dose; 50 mg for body weight <5 kg, 100 mg for body weight ≥5 kg • Children entering second RSV season: single dose of 200 mg, in 2 IM injections
Vaccine efficacy	In MATISSE trial:[7] • 69.4% (97.58% CI: 44.3-84.1%) against medically attended severe RSV-associated LRTI for 6 mo after birth • 56.8% against RSV-associated hospitalization up to 6 mo after birth	Among healthy late-preterm and term infants:[8] • 74.5% (95% CI: 49.6-87.1%) against medically attended RSV-associated LRTI for 5 mo after injection • 62.1% (95% CI: -8.6-86.8%) against RSV-associated hospitalization for 5 mo after injection • 55.8 cases of medically attended RSV-associated LRTI averted per 1000 infants treated

Safety	In MATISSE trial:[7] • No safety signals either in mothers or infants and toddlers up to 24 mo of age • AE incidence similar in vaccine group and placebo group (mothers: 13.8% and 13.1%; infants: 37.1% and 34.5%) AEs included injection-site pain, muscle pain, headache	Among healthy late-preterm and term infants in MELODY trial:[8] • AE incidence similar in both groups (grade ≥3 AEs: 3.6% (nirsevimab), 4.3% (placebo)) • No anaphylaxis or serious hypersensitivity reactions Among infants at higher risk for severe RSV in MEDLEY trial:[54] • Treatment-related AE incidence similar in both groups: preterm cohort, 1.9% (palivizumab), 1.5% (nirsevimab); cohort with heart or lung disease: 2.0% (palivizumab), 1.9% (nirsevimab)

* Active immunization (vaccination) – a killed or attenuated infectious agent, or an antigen derived from an infectious agent, stimulates an individual's immune system to recognize and destroy the infectious agent. Passive immunization – pre-formed antibodies directed against the infectious agent provide immediate protection, without the need for the individual's immune system to produce its own response. # Abbreviations: AE, adverse event; CI, confidence interval; IM, intramuscular; LRTD, lower respiratory tract disease; LRTI, lower respiratory tract infection; mo, months

Challenges and progress in RSV prevention

Potential impact of RSV immunization

Individuals who develop LRTI in early childhood have an increased risk of premature mortality from respiratory disease.[25] Early childhood LRTI is also associated with long-term complications, including asthma, recurrent pneumonia, and decreased lung function.[26] Therefore, preventing RSV disease in infants and young children is

expected to not only reduce their suffering and prevent hospitalization, but also improve health over the long term.[25]

RSV co-infection with other pathogens, such as *Streptococcus pneumoniae*, can contribute to the severity of childhood LRTI.[25] During the COVID-19 pandemic, RSV circulation decreased due to public health measures. During this time, hospital admissions of children for pneumococcal pneumonia or bacteremia decreased, with a 63% reduction in pediatric invasive pneumococcal disease (IPD) noted in France.[55] Because interactions between RSV and other pathogens, as well as the respiratory microbiome and environmental factors, have not been fully explored, it is difficult to estimate the full long-term impact of RSV prevention in infants.[25] However, the possibility of long-term benefits such as a reduction in respiratory disease (including invasive pneumococcal disease (IPD)[55]), reduced respiratory morbidity, and premature mortality, is clear.[25] According to researchers, "**the full public health value of RSV prevention is probably greater than the health effects measured by prevention of acute early severe RSV LRTI alone**."[25]

Nirsevimab/BEYFORTUS®

According to a modeling study, the use of either RSVpreF or nirsevimab could significantly reduce the burden of RSV disease in Canada.[56] The introduction of publicly funded nirsevimab is already having a positive impact in reducing infant hospitalizations. Ontario's Mackenzie Health, which serves the Vaughan and Richmond Hill regions, reported a 67% uptake of nirsevimab for eligible infants in November-December 2024, and the Ontario Ministry of Health reported that 110,000 doses of nirsevimab had been distributed.[57]

RSVpreF/ABRYSVO®

In a modeling study focused on high-income countries, the immunization of pregnant women with RSVpreF was predicted to lead to a 35% reduction in RSV-related hospitalizations of infants in Canada; $8.6 million USD in health care costs would be averted per 100,000 infants in Canada.[10] However, this will depend on enhancing uptake and accessibility.[10] To date, few data are available regarding the uptake of maternal RSVpreF in Canada. The clinical experience of task force members indicates that uptake is variable and dependent on the region and practice setting. To increase uptake, it will be necessary to increase awareness of

this vaccine and to address the logistical challenges of vaccine distribution, such as the need for cold chain facilities and regional variability in access.

"**We need to be much more proactive in making people aware of the vaccine and its effectiveness**. The program went very well in the newborn units, where the acceptance rate was really high, and when I look at what our season was like, there was no closedown of the ER because we were not overwhelmed with RSV like every [previous] January and February. The wards were quiet and the ICU was quiet, so the program was successful."

– John Yaremko, MD, FRCPC, Montréal, QC

Access challenges

Despite these early successes, the public funding of RSVpreF and nirsevimab varies across Canada, representing a health equity challenge. At present, it is estimated that only 60% of infants across the country have access to nirsevimab, and this access is geographically limited, with several provinces having no nirsevimab available.[58] Ontario is the only province that currently funds both RSVpreF and nirsevimab, and both agents are only available just prior to and during the RSV season.[59] The Northwest Territories, Yukon, Nunavut, Saskatchewan, and Québec fund nirsevimab for all infants, but with different age criteria; Nova Scotia and Alberta fund nirsevimab for high-risk infants only. Four provinces (BC, MB, NL, and NB) fund palivizumab for high-risk infants. However, only 2% of infants meet the eligibility criteria for palivizumab;[51] in these provinces, **98% of infants are left unprotected.** In 2024-2025, BC expanded its program by authorizing a limited number of doses of nirsevimab for infants in remote communities and for medically complex children under 2 years of age who do not qualify for palivizumab.[60]

Some communities face additional challenges for RSV prevention and treatment. For instance, northern communities have higher rates of RSV-associated hospitalization than other regions of Canada, and outbreaks may persist for longer periods of time.[61,62] In Indigenous communities, an increased risk of severe RSV disease reflects the long-standing impacts of colonialism and anti-Indigenous racism on housing, access to care, and other social and structural determinants of health. For instance,

in Nunavik, hospitalization rates were reported as 64.8 per 1,000 in healthy term infants and 147.6 per 1,000 in high-risk infants.[63] Infants who contract RSV in northern or remote communities may need to be transported thousands of kilometres for treatment, creating hardships for the family and community.

The availability of nirsevimab is variable, leaving infants unprotected even in jurisdictions where nirsevimab is funded. **In 2024-2025, nirsevimab was unavailable for several months prior to and during the RSV season**, **causing some immunization programs to be delayed. Availability varies by region and is unpredictable,** adding complexity to treatment decisions (e.g., deciding between RSVpreF and nirsevimab). In Québec, nirsevimab is not available in physician offices and can be accessed only in hospitals, midwifery-run birthing centers, CLSCs (*centres locaux de services communautaires*) or vaccine centers.

Current RSV prevention guidelines in Canada and elsewhere

Several medical associations in Canada have issued guidelines and recommendations on preventing RSV. The National Advisory Committee on Immunization (NACI) recognizes the "**significant burden of disease in all infants**" and the impact of RSV on the health care system.[40] NACI recommends building toward a universal immunization program for all infants, which would be seasonal (during or in advance of the RSV season).[40] Nirsevimab is recommended for the universal program, whereas RSVpreF may be considered as an individual decision by each pregnant person together with their HCP.[40] Infants who are at increased risk of severe RSV are to be given higher priority, along with infants who would require complex transportation for treatment and those in Indigenous communities.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommendations are slightly different, emphasizing that both RSVpreF and nirsevimab are effective, and that nirsevimab is preferred only if both options are available.[44] The SOGC also emphasizes the need for HCPs to counsel pregnant women and pregnant people about RSV risks, and the need for equitable access for equity-deserving and remote populations.[44]

As in Canada, the focus on RSV is increasing worldwide, with many nations developing recommendations and instituting national immunization programs (Table

2). For instance, in the USA and France, both RSVpreF and nirsevimab are publicly funded, with nonpreferential recommendations (neither product is preferred over the other); currently, only RSVpreF is being offered as part of the national program.[45,64] The USA's Advisory Committee on Immunization Practices (ACIP) recommends seasonal administration of RSVpreF (from September through January,[45]) whereas the UK's Joint Committee on Vaccination and Immunization (JCVI) recommends year-round availability for both agents.[65] Argentina funds RSVpreF for all pregnant women and pregnant people.[11]

The variability in national and provincial guidelines can lead to confusion among HCPs, making it difficult for them to determine which options to offer to their patients. **As the winter of 2025-2026 approaches, HCPs, public health agencies, and governments will require clear direction to develop programs to increase Canadians' access to RSV prevention.**

Table 2. Summary of programs and recommendations for RSV prevention in Canada and elsewhere.

Country	Recommendation(s) for infant RSV prevention	Seasonality
Canada[40]	• Build toward universal program • Nirsevimab preferred; consider RSVpreF as individual decision • Highest priority for infants with high-risk conditions	• During RSV season

USA[45,66]	• Nonpreferential recommendation; both agents available	• RSVpreF: during RSV season • Nirsevimab: for infants born during or entering their first RSV season and for infants and children 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season
Argentina[11]	• RSVpreF for all pregnant women/pregnant people • Nirsevimab for preterm and high-risk infants	• During RSV season
UK[65,67]	• Nonpreferential; both agents recommended • RSVpreF chosen for current program • RSVpreF to be offered in each pregnancy	• Year-round
France[64]	• Nonpreferential; both agents available • Nirsevimab preferred for infants born to people who received RSVpreF in a previous pregnancy	• During RSV season

Spain[68]	• Nirsevimab	• During RSV season
Australia[69]	• Both agents available • RSVpreF recommended for all pregnant women/people; in addition, nirsevimab recommended for infants born to mothers who were not vaccinated at least 2 wk before delivery or who are at higher risk	• RSVpreF: year-round • Nirsevimab: during RSV season

Efficacy and safety of RSVpreF and nirsevimab in clinical trials and real-world practice

Summary of findings from key clinical trials

Both RSVpreF and nirsevimab are efficacious, as shown in large-scale, randomized, controlled clinical trials. According to NACI, nirsevimab is preferred over RSVpreF, based on nirsevimab's efficacy, duration of protection, and good safety profile[40]

Nirsevimab/BEYFORTUS®

In the phase 3 MELODY trial, nirsevimab demonstrated 74.5% efficacy (95% CI 49.6-87.1%) against medically attended RSV-associated LRTI among healthy late-preterm infants, for up to 5 months after receipt of the injection.[8] The antibody had a favorable safety profile, including in infants with comorbidities;[70] no anaphylaxis or serious adverse reactions occurred. Nirsevimab was also found to be safe for infants at high risk for severe RSV disease, including preterm infants and infants with congenital heart or lung disease.[54]

RSVPreF/ABRYSVO®

In a phase 2b trial, the RSVpreF vaccine led to efficient transplacental transfer and high titers of neutralizing antibodies among infants at birth.[71] Subsequently, the phase 3 MATISSE trial evaluated RSVpreF in over 7,000 pregnant individuals and their infants. RSVpreF had 69.4% efficacy (97.58% CI 44.3-84.1%) against medically attended severe RSV-associated LRTI for up to 6 months after birth.[7] RSVpreF induced robust immune responses and the transplacental transfer of RSV-neutralizing antibodies was efficient.[71] No safety signals were observed either in mothers or in infants and toddlers up to 24 months of age.[7] Adverse events (AEs) were mild or moderate, and included injection-site pain, muscle pain, and headache; AE incidence was similar in the vaccine and placebo groups. Overall, no clinically significant increase in AEs, including preterm birth, low birth weight, or neonatal hospitalization, was observed in the overall analysis.[72]

Summary of real-world/population data

The efficacy and safety of both RSVpreF and nirsevimab have been demonstrated in population studies.

Nirsevimab/BEYFORTUS®

The phase 3 HARMONIE trial, a pragmatic trial of over 8000 infants, demonstrated 83.2% efficacy of nirsevimab against hospitalization for RSV-associated LRTI and 75.7% efficacy against hospitalization for very severe RSV-associated LRTI, among infants <12 months of age in Europe.[73] NIRSE-GAL, a study carried out in Spain, reported 82.0% effectiveness against RSV-related hospitalization and 86.9% effectiveness against severe RSV disease requiring oxygen support.[9] After the introduction of Spain's nirsevimab program, RSV-related hospitalizations decreased by 89.8%; the number needed to immunize (NNI) to avoid one hospitalization was 25. Vaccine uptake of 79-97% was achieved.[9,68] In the USA, a study of 699 infants treated at seven pediatric academic medical centers found that nirsevimab was 90% effective (95% CI 75-96%) against RSV-associated hospitalization with a median time from receipt to symptom onset of 45 days (IQR 19-76 days).[74]

RSVPreF/ABRYSVO®

Argentina has a national maternal RSVpreF vaccination program as its primary strategy for preventing RSV among infants; vaccination is timed to the local RSV

season. The BERNI study was a retrospective, multicenter, case-control study of RSVpreF effectiveness in Argentina.[11,75] Among 505 infants up to 6 months of age, the vaccine effectiveness (VE) of RSVpreF in preventing hospitalization was 78.6% from birth to 3 months of age, and 71.6% from birth to 6 months of age.[11,75] The VE against RSV-associated severe LRTI requiring hospitalization was 76.9% from birth through 6 months of age. In addition, infants with RSV-associated LRTI had more severe illness, required ICU admission more frequently, and had longer hospital stays than those who were RSV-negative.[11,75] Infants whose mothers did not receive RSVpreF had higher rates of progression to severe LRTI and ICU admission, compared with those whose mothers received RSVpreF. Three infants whose mothers did not receive RSVpreF died due to RSV-associated LRTI, whereas there were no deaths among infants whose mothers received the vaccine. Another retrospective study in Argentina reported that RSVpreF vaccination averted 215.71 cases of RSV per 1,000 infants.[76] Again, high VE values were reported: VE against RSV-related hospitalization was 66.1% for infants under 6 months of age and 80.8% for infants under 3 months of age. VE against ICU admission was 87.2%, and VE against extended hospital stays was 88.6%, both for infants under 6 months of age.[76]

In the UK, a prospective, multicenter study of 391 RSV-positive infants and 146 RSV-negative controls reported a VE against hospitalization of 72.4% (for mothers vaccinated >14 days before delivery) and 57.7% (for mothers vaccinated any time before delivery).[12] Among RSV-positive infants, only 18.7% of mothers had received RSVpreF, whereas among RSV-negative infants, 41.1% of mothers had been vaccinated. The investigators concluded that RSVpreF vaccination was effective and equivalent to clinical trial settings in reducing the risk of infant hospitalization.

Taken together, the results of clinical trials and population studies indicate that **both RSVpreF and nirsevimab provide a high level of protection against severe RSV disease and reduce infant hospitalizations. No significant safety concerns have been identified with either immunizing agent,** and most adverse events are mild to moderate.

Summary of FMWC maternal RSV task force recommendations and activities in 2024

The Federation of Medical Women of Canada (FMWC) is dedicated to advocating for health care policies that will benefit women and the entire Canadian population. The FMWC Maternal RSV Task Force is composed of HCPs such as physicians, nurses, public health experts, pharmacists, and RSV prevention advocates. In 2024, the task force published a call for HCPs, the public, and policymakers to act to protect infants from RSV disease.[77] A social media campaign led to over 1.5 million impressions, 525,000 engagements, and 7,000 completed video views, while an article by task force member Darine El-Chaâr, MD, FRCSC, MSc, of the Ottawa Hospital, reached 40,000 HCPs. The FMWC also created a website, RSVprotect.ca, with reliable information for HCPs and patients about RSV and updates on RSV-related topics. Finally, the task force advocated that NACI update its guidance on RSV prevention to reflect the latest evidence and to address inequities. In 2025, the task force is continuing and expanding its campaign for action to improve RSV prevention in Canada.

Recommendations for 2025-2026

The task force's top priorities, both short-term and long-term, are **awareness**, **education**, and **communication** about RSV disease:

- **Awareness** among HCPs (including physicians, nurses, midwives, and pharmacists), pregnant women and pregnant people, the public and policymakers about the burden of RSV disease in infants and the available protective options
- **Education** to address knowledge gaps among HCPs, policymakers, and the public about available options for infant protection from RSV disease
- **Communication** about the options, benefits, efficacy, safety, and availability of immunizations to protect against RSV disease in infants

Short-term recommendations – to be implemented in the next six months to one year

Awareness

The task force recommends:

1. Implementing an awareness campaign that includes a media strategy with clear and simple messaging to inform the public about RSV immunization options.

Currently, many parents and families are unaware of RSV disease and the available vaccine programs. The lack of awareness of RSV and its potential severity has been described as a "**major barrier**" to RSV immunization.[47] Participants in a recent study in Québec expressed a need for more information about RSV and immunization products, preferably from healthcare professionals; they desired a comprehensive understanding of the risks and benefits of RSV immunization, rather than superficial information.[47,48]

An awareness campaign should employ media tailored to specific audiences, including pregnant women and pregnant people, families, providers, and policymakers. The campaign should emphasize that international, prospective, randomized controlled trials have demonstrated high efficacy of both nirsevimab and RSVpreF against RSV, with protection lasting for several months, and that VE has been confirmed in real-world studies.[9,11,12,75,76] Both products are safe, and there is no increased risk of preterm birth with maternal RSVpreF. Infants born pre-term or with other health conditions can receive nirsevimab even if their mother was immunized with RSVpreF.[1,40] Thus, RSVpreF is an effective and safe preventative strategy for protection against infant disease, alongside nirsevimab or palivizumab.

Education

The task force recommends:

2. Offering tailored education regarding the options, benefits, efficacy, safety, and availability of RSV immunization agents to all health care professionals.

HCPs may not have detailed knowledge or hands-on experience with RSVpreF and nirsevimab since they are recently authorized products. HCPs such as family practitioners, maternity clinic practitioners, midwives, pediatricians, pharmacists, nurses, and PAs all require education packages specific to their roles as immunizers and/or health educators. It is important for all HCPs to be aware that RSV immunization is part of their mandate (Castillo, E., et al., unpublished data). Education packages should translate the current scientific knowledge on the burden of RSV in all infants and the urgency of preventing RSV infection in all infants. Packages should include the available data on co-administration of vaccines in pregnancy, the RSV immunization options available to specific patient populations, and that RSVpreF is Health Canada authorized for year-round administration, regardless of the typical RSV season.[1]

Education for HCPs should address knowledge gaps about vaccine access by describing nirsevimab programs and how to procure RSVpreF in their jurisdictions. A list of private insurers that cover RSVpreF and those that do not cover RSVpreF should be included.

Education packages should also include materials to address vaccine hesitancy among HCPs. HCPs who are themselves hesitant do not provide effective counseling.[78] For most HCPs, the details of safety profiles as well as information on the vetting process for immunizing agents, and elements considered by authorities such as NACI, are very helpful in countering hesitancy.

Finally, the information should include answers and evidence to address common questions from patients, such as:

- When is the best time to be immunized?
- Can RSVpreF be given along with other vaccines recommended in pregnancy?
- How long does protection last?
- If a mother has received RSVpreF, is it ever necessary to give nirsevimab to their infant?

3. Supplying HCPs with reliable, evidence-based patient resources that can be accessed during clinic visits and at home.

It is important for patients to have access to evidence-based information about RSV disease and to have time to read, reflect, and ask questions. Ideally, providers could

provide patients with reliable, evidence-based websites for reliable information; QR codes to rsvprotect.ca, vaccinesinpregnancycanada.ca, immunize.ca, or other evidence-based websites can be shared during clinic visits for patients to read at home. Lay language communication tools should be provided to support dialogue with diverse patient groups, especially those with language barriers or health literacy challenges.

The resources should help providers navigate the complexities of discussing RSV prevention with pregnant women and pregnant people. The resources should discuss the available immunization products, benefits and risks, and frequently asked questions. Myth debunking suggestions (e.g., https://www.immunize.ca/debunk-vaccine-misinformation-our-myth-busting-mondays-series) and pre-bunking suggestions should be included, along with suggestions to normalize immunization discussions. A list of private insurers that cover RSVpreF and those that do not cover RSVpreF should be included.

"**Despite two available strategies to prevent RSV in the newborn, still too many providers and pregnant women/pregnant people are unaware of the options**. Avoiding RSV infection is so important that we need to ensure all providers looking after pregnant women/pregnant people have the knowledge to help them make informed choices as to what is best for their newborn."

– Shelley Ross, MD, CCFP, FCFP, Burnaby, BC

4. Involving midwives in RSV immunization and working with the Canadian Association of Midwives to advocate for stronger vaccine recommendations.

Midwives serve a unique population of patients who have potentially greater vaccine hesitancy than other pregnant women and pregnant people. However, midwifery patients also desire evidence-based and nuanced discussions around immunization.[79] Thus, midwives are well positioned to participate in immunization education, support their patients in decision-making, and provide evidence-based, comprehensive informed choice discussions.[79] In some provinces, such as Ontario and Québec, midwives have the authority to administer immunizations such as RSVpreF.[80] At present, midwives in some jurisdictions require a medical directive to

administer nirsevimab since it is a monoclonal antibody rather than a vaccine; this may change in the future.[80]

According to a Canadian study, the currently available tools and methods for communicating with patients about vaccines may not adapt well to the needs of midwives; additional resources are needed.[81] Midwives should have access to resources that are tailored for their profession and patient population, including evidence-based tools for education about the options for RSV immunization.

5. Authorizing pharmacists to administer publicly funded vaccine and engaging pharmacist groups to develop tailored educational strategies and resources.

Pharmacists have the knowledge and training to immunize and often have strong relationships with their patients.[82] Almost all Canadians (about 95%) live within five kilometres of a community pharmacy, and many Canadians have expressed a desire to extend pharmacists' scope of practice to include immunizations.[83] Although Canadian pharmacists are increasingly contributing to immunization efforts, including facilitating access to COVID-19 vaccines during the pandemic,[84] they may not be familiar with recently developed products such as RSV immunizing agents.

According to the Canadian Pharmacists Association, pharmacists have injection authority for RSV vaccines in all provinces and territories except NWT and NU, but they lack access to publicly-funded RSV vaccines.[85] This creates a barrier to vaccine access. In addition, pharmacists may not feel comfortable recommending vaccines that require the patient to pay out of pocket or see a different HCP.[86] Thus, pharmacists should be authorized to administer publicly-funded vaccine.

All pharmacists, including those who are not immunizers, must be familiar with RSV immunization and be able to educate patients using communication strategies specific to RSV prevention. Pharmacists should be provided with evidence-based research on RSV vaccination and patient resources (e.g., a QR code to rsvprotect.ca, vaccinesinpregnancycanada.ca, or other evidence-based websites).

"If [pharmacists] can support us in delivering care and medications and vaccinations, it's another opportunity for us to get the right products in the right patients' hands."

– Shafeena Premji, MHA, MD, CCFP, FCFP, MSCP, Calgary, AB

Communication

The task force recommends:

6. Engaging patient groups to advocate with provincial governments for universal public funding for maternal RSVpreF year-round, and for nirsevimab during the RSV season, for every infant.

All pregnant women/people and their infants should have access to both RSV immunization options with public funding. Easy access to publicly funded RSV immunizing agents during prenatal appointments will be a key factor in increasing immunization rates; out-of-pocket costs or requirements to visit a separate HCP represent barriers. Public funding would promote health equity between provinces, regions, and communities, and provide a motivational incentive for the public. Currently, many HCPs feel conflicted when recommending vaccines that their patients cannot afford, leading to moral injury; public funding would enable them to present stronger recommendations for all eligible patients.

A universal program should make RSVpreF available year-round, not only during RSV season. This is because with increased travel and an increasing incidence of off-season outbreaks, infants will be more vulnerable to RSV throughout the year. Year-round availability would simplify operationalization,[65] help to address disruptions in vaccine availability, and facilitate vaccine counseling and recommendations from HCPs, since it could easily be built into prenatal care counseling workflows. Year-round availability also aligns with the Health Canada authorization and the manufacturer's product monograph, which do not specify seasonality.[1,2] On the other hand, nirsevimab is indicated and authorized for use during the RSV season.[3,4]

To support a universal RSV prevention program, Canadians must share their experiences with RSV disease with policymakers. A strong statement and clear,

simple messaging that aligns with key HCP concerns are needed to support this. A toolkit should be developed to enable patients to easily share their experiences with policymakers via email, social media, and other avenues. Patient groups should also be encouraged to support the creation of a universal immunization registry that would facilitate accurate vaccine record-keeping, improve patient safety, and promote research on vaccine efficacy.

7. HCPs normalize the vaccine discussion and counsel patients using strong recommendations.

Pregnant women, pregnant people, their partners and families may be unaware of RSV disease and its severity and long-term consequences in infants.[13,48] A recommendation from an HCP is highly influential in supporting immunization decisions and helping parents decide what is best for them and their newborn. In Canada, many individuals consider family physicians to be their most trusted sources of information about immunization.[87,88] Therefore, a patient-HCP relationship built on trust is a key factor in RSV immunization uptake.[47] However, it should be noted that ready access to publicly funded RSV immunizing agents will also be an important factor to facilitate easy and convenient transitions from decision to immunization at prenatal visits.

HCPs should offer recommendations early and often, starting even before pregnancy at the family planning stage, and continuing during pregnancy. Repetition is important. HCPs should be aware of vaccine hesitancy and address patient concerns. RSVpreF can be discussed along with other vaccines that are recommended in pregnancy, such as influenza, COVID-19 and Tdap.

When discussing RSV, HCPs should promote immunization to all patients, not just those who are interested in the vaccine, and avoid making assumptions about who will be interested or who will have coverage. HCPs should be clear about the differences between RSVpreF and nirsevimab and the benefits of each strategy; the nature of the discussion may change depending on nirsevimab availability (see recommendation 9). In jurisdictions where no universal nirsevimab program exists, HCPs should increase their efforts to promote the RSVpreF vaccine.

Resources for normalizing vaccine discussions while building rapport and trust are available. For instance, a simulation module for HCPs developed by task force

member Cora Constantinescu, MD, of the University of Calgary, and colleagues is available at: www.can-sim.ca/accessjama/PHAC-RSV-5E/#/.

8. HCPs offer the maternal RSVpreF vaccine to all pregnant women and pregnant people at 32 weeks + 0 days to 36 weeks + 6 days' gestation, year-round.

Offering both RSV immunization options promotes health equity and helps to address potential shortages of nirsevimab. In recent studies of pregnant and postpartum women and people in Canada, some individuals preferred maternal immunization over infant immunization.[46-48] Among 723 individuals surveyed across Canada, 77% indicated that they would accept RSV vaccination during pregnancy, whereas 55% would accept immunization of their infants.[46] In another study of 803 individuals in Québec, 88.1% were willing to receive maternal RSVpreF and 92% were willing to have their infants receive nirsevimab; however, 69% preferred maternal RSVpreF.[47,48] However, these preferences may change with increasing awareness and broader access to both RSV immunization options.

Year-round rather than seasonal availability aligns with the Health Canada indication and the manufacturer's product monograph for RSVpreF.[1,2] Year-round availability would also help to address potential shortages of vaccine and equity issues. Nirsevimab should be offered during RSV season.[3,4]

HCPs should be aware that vaccines recommended in pregnancy can be co-administered. Co-administration of RSVpreF with influenza and Tdap vaccines has been studied and found to be safe[40] and is recommended by the SOGC[44] as well as international working groups such as ACIP[45] and the American College of Obstetricians and Gynecologists (ACOG).[89] Simultaneous administration with other non-live vaccines, including COVID-19, is considered to be safe for pregnant women and pregnant people based on general best practices for immunization.[45,90] As part of routine prenatal care, HCPs 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.[91] RSVpreF is indicated for pregnant women and pregnant people at 32+0 to 36+6 weeks of gestation.[1] For infants, nirsevimab can be administered on the same day, or before or after, routine childhood vaccines.[40]

9. Engaging with manufacturers to clarify the predicted availability of nirsevimab, which influences immunization decisions.

There is a need for transparency and predictability regarding the supply of immunizing agents. When nirsevimab is unavailable, maternal vaccination with RSVpreF becomes even more important. HCPs face difficult decisions on whether to recommend RSVpreF to pregnant people without knowing if nirsevimab will be available when their babies are born. Contingency plans for supply disruptions should be created.

"**All of a sudden there was nothing,** and from a province [Ontario] where we had choices, once the baby was born there was no choice because there was nothing available, and it was in the middle of RSV season. **As a family doctor I'm left with taking a chance with the unknown - if you don't do it now [in spring/summer] and your baby is going to be 6 months old in December, can I depend on availability of vaccine?**"

– Vivien Brown, MDCM, CCFP, FCFP, MSCP, Toronto, ON

Long-term recommendations – to be implemented within the next one to two years

The task force recommends:

10. Implementing a universal, national immunization registry

The need for a national registry has been described by many medical experts, public health officers and advocates, associations, and working groups.[92–95] A universal registry would allow easy access to immunization records for all individuals and providers, helping to avoid missed or duplicate immunizations. Moreover, a universal registry would facilitate studies of vaccine uptake, effectiveness, safety, and access. Canadian pharmacists emphasize that quick and convenient access to accurate vaccination records is critical to their roles as immunizers.[86] Enhancing national approaches to population-specific analysis of vaccine acceptance and uptake,

including immunization registries, is also one of the key objectives of Canada's National Immunization Strategy.[96]

The current system has been described as a "**patchwork of provincial and territorial systems that are unable to communicate with Health Canada or with one another**".[94] The lack of vital information about population-specific vaccine uptake hinders studies of vaccine effectiveness in different populations and against emerging pathogens and prevents efficient surveillance of adverse events.[94]

"**We need to have a surveillance program,** and appropriate monitoring is key. **Why in 2025 do we not have a national vaccine registry in Canada?** We need to continue breaking down the barriers for that."

– Darine El-Chaâr, MD, FRCSC, MSc, Ottawa, ON

11. Involving HCPs and patients in advocating for public funding of RSV immunization agents with their chief public health officers and provincial governments, with a special focus on provinces that do not yet have RSVpreF or nirsevimab programs (BC, MB, NL, NB, PE).

Ontario's example, in which a drop in infant hospitalization is already being observed, demonstrates that public coverage of RSVpreF and nirsevimab can be achieved in advance of national recommendations.[59] As NACI has recently expanded eligibility for RSVpreF among older adults,[97] now is the time to expand eligibility among infants, pregnant women, and pregnant people. Provinces should consider making available RSVpreF doses that have been purchased for older adults but not used.

Each province should be encouraged to develop an advocacy plan or advocacy framework to promote RSVpreF and nirsevimab, as well as other immunizing agents that may be developed in the future. Advocacy plans should engage patient groups early in the process of new product development. Since most HCPs are not trained in advocacy, they should be offered tools to help them promote RSV prevention in their own provinces, such as templates for letter-writing and requesting meetings with representatives.

"**The equity discrepancy is glaring around RSV prevention products: there are provinces of plenty and provinces of nothing.** I come from a province [Alberta] that did not have a nirsevimab program and our RSV vaccine was not covered in pregnancy. It was incredibly frustrating as a frontline physician, and also very confusing for our patients...**our patients were left unprotected."**

– Cora Constantinescu, BSc, MD, FRCPC, MSc, Calgary, AB

12. Engaging with governments and professional societies such as NACI, SOGC, the College of Family Physicians of Canada (CFPC), the Canadian Paediatric Society (CPS), the Canadian Pharmacists Association, and the Canadian Association of Midwives to advocate for strong recommendations for RSV prevention that include maternal vaccination.

The current NACI guideline[40] does not fully convey the urgency of RSV immunization to protect infants or the importance of public funding for both RSVpreF and nirsevimab. Strong recommendations with **clear and simple messaging** are needed to motivate the provinces to develop public funding programs. Public funding for RSV prevention is an important health equity issue that must be addressed as soon as possible for the benefit of all Canadians. Provincial and national associations of HCPs are well placed to promote the needs of their patients and to advocate for improved RSV prevention through networks of HCP advocates.

13. Supporting and encouraging research into open questions regarding RSV immunization.

Although the overall efficacy and safety of the current RSV immunization options are well established, some aspects remain to be investigated. The FMWC emphasizes the importance of continuing and expanding research on RSV prevention. For instance, there are limited data to determine when infants should receive nirsevimab if their mother has been immunized with RSVpreF, and most working groups have not issued specific recommendations, except to state that there are no safety issues associated with receiving both. The question of whether to administer

multiple doses of RSVpreF for women and people who have multiple pregnancies, as is recommended for Tdap,[98] is still open. Additional questions that are still being investigated include:

- How much protection does RSVpreF offer for infants of mothers who are vaccinated before RSV season?
- If an infant born to an immunized mother contracts RSV after the age of 6 months, will the disease be attenuated?
- What is the best strategy for co-administration of vaccines during pregnancy?
- How long do antibodies persist in human milk?
- What is the efficacy of RSVpreF in exclusively human milk fed or breast/chest fed infants?

Along with the above recommendations, the task force also recommends addressing ongoing needs presented in our 2024 white paper,[77] including:

- Partnering with Indigenous elders and other Indigenous community leaders to raise awareness among pregnant women and pregnant Two-Spirit people in Indigenous communities about the burden of RSV disease in infants and the new options available to protect infants from RSV disease
- Improved community-based testing for RSV to derive more accurate estimates of the burden of RSV disease in infants in hospitals and communities
- Collecting real-world data on RSV immunizations
- Research on vaccine hesitancy in pregnant women and pregnant people, and in HCPs

Conclusion

Two effective RSV immunizing agents are now available to help prevent RSV disease in infants. As the 2025-2026 RSV season approaches, the FMWC Maternal RSV Task Force recommends we act now to raise awareness, educate, and communicate the options, benefits, efficacy, safety, and availability of these agents and to prevent RSV disease in infants in Canada.

Appendix 1: FMWC Maternal RSV Task Force Members

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