



Summary of the National Advisory Committee on Immunization (NACI) Statement of May 17, 2024

Statement on the prevention of respiratory syncytial virus
(RSV) disease in infants



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Résumé de la Déclaration du Comité consultatif national de l'immunisation (CCNI) du 17 mai 2024 Déclaration sur la prévention de la maladie causée par le virus respiratoire syncytial (VRS) chez les nourrissons

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Overview

- On May 17, 2024, the Public Health Agency of Canada (PHAC) released the National Advisory Committee on Immunization's (NACI) updated guidance on The Prevention of Respiratory Syncytial Virus (RSV) disease in infants. This guidance is based on current evidence and NACI expert opinion.
- Health Canada has recently authorized two new products to protect infants and children from RSV:
 - Nirsevimab (BEYFORTUS™, Sanofi), a monoclonal antibody, was authorized on April 19, 2023 to protect infants in their first RSV season and children under 24 months of age who remain vulnerable to severe RSV disease in their second RSV season.
 - RSVpreF (ABRYOVO™ Pfizer) is a vaccine authorized on December 21, 2023 to protect infants through vaccination of pregnant women and pregnant people in their third trimester (32 through 36 weeks gestation).

Following a thorough review of the evidence provided by nirsevimab and RSVpreF, NACI makes the following recommendations for public health and individual decision-making:

- Considering the significant burden of disease in all infants from RSV and the impacts of RSV on the Canadian health system, **NACI recommends building towards a universal RSV immunization program for all infants. Program introduction could occur in stages depending on access, cost-effectiveness, and affordability of available options.**
- **NACI recommends that RSV immunization programs use nirsevimab to prevent severe RSV disease in infants.**
 - **Priority for immunization programs should be given to infants who are at increased risk of severe RSV disease in their first or second RSV season. When possible, the program should be expanded to all other infants entering or born during their first RSV season.**
 - **Nirsevimab should be offered to infants entering, or born during, their first RSV season whose transportation for severe RSV disease treatment is complex, and/or whose risk of severe RSV disease intersects with established social and structural health determinants such as those experienced by some Indigenous communities across First Nations, Métis and Inuit populations.**
- **NACI recommends 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.**

NACI will continue to monitor the evolving evidence and will update guidance as needed.

For more information on which groups are considered to be at increased risk of severe RSV disease, please see [List 1](#) in the NACI Statement.

For the full statement, including supporting evidence, rationale, and a list of infants considered to be at increased risk of severe RSV disease, please see NACI's [Statement on the Prevention of Respiratory Syncytial Virus \(RSV\) disease in infants](#).

What you need to know

- Respiratory syncytial virus (RSV) is one of the most common respiratory viruses in infants and young children, infecting almost all children by the age of two years old.
- RSV can cause serious respiratory disease in infants and young children. Although the risk of severe RSV disease is higher in infants with certain medical conditions, infants who are not at increased risk account for the largest proportion of infants with severe RSV disease each year.
- Consistent with many other respiratory viruses, RSV is seasonal, with infections being more common in the winter. Jurisdictions are encouraged to define their RSV season based on local epidemiology within Canada to determine the right time for their immunization programs.
- While there is not yet a vaccine that can be offered directly to infants to protect them from RSV, we now have three products that can temporarily protect infants during the first months of life through “passive immunization”. Two are monoclonal antibodies (nirsevimab and palivizumab), and the third is a vaccine provided during pregnancy (RSVpreF).
- The introduction of nirsevimab and RSVpreF in Canada provides an opportunity to expand RSV programs and protect more infants against this disease. Palivizumab (SYNAGIS[®]), a relatively expensive monoclonal antibody given as four to five doses, has been authorized in Canada since May 2002 to protect against severe RSV disease but only in infants with underlying health conditions at highest risk.
- At this time, nirsevimab is the preferred immunization option based on its efficacy, duration of protection, and good safety profile. This preference will be revisited as needed based on emerging evidence. However, if nirsevimab is not available, other options can be considered for an RSV immunization program.
- As a priority, nirsevimab should replace palivizumab in current immunization programs for infants at highest risk of RSV severe disease. RSV immunization programs can then build and expand over time depending on access to supply, cost-effectiveness, and affordability of available options.

- RSVpreF is a vaccine given during pregnancy. Antibodies against RSV are transferred across the placenta to the fetus so that a newborn infant will have temporary protection against RSV in the first months of life. This same immunization strategy is also used to prevent pertussis (whooping cough) in infants via the Tdap vaccine when provided in pregnancy.
- 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. NACI will continue to carefully monitor the evidence on the safety of RSVpreF vaccine and will update guidance accordingly.
- There is no expected additional benefit to using both RSVPreF and nirsevimab for healthy infants. However, if RSVpreF was received during pregnancy and an infant is at increased risk for severe RSV disease or is born less than 2 weeks after RSVPreF was given, nirsevimab should still be provided.
- At the present time, NACI does not recommend a universal immunization program for RSVpreF. More data and information are expected to emerge over time and NACI will reconsider this recommendation in the future. Infants who are identified as having medical risks for severe RSV disease (e.g., certain lung and heart conditions) should be considered eligible to receive a monoclonal antibody (nirsevimab or palivizumab). NACI recommends availability of a monoclonal antibody through publicly funded programs in provinces and territories.
- RSVpreF is also authorized to prevent RSV in older adults 60 years of age and over, as is a similar vaccine from GSK (RSVPreF3, Arexvy[®]). Recommendations for the use of these vaccines to protect adults are under development and will be published soon.

For more information on NACI's recommendations on the use of RSV immunization for infants, please refer to the RSV chapter in the [Canadian Immunization Guide \(CIG\)](#), as well as additional statements on the [NACI web page](#).

Quotes

“NACI’s new recommendation to build toward a universal RSV immunization program will create more opportunities to protect infants against severe RSV disease. We recognize that moving towards this goal will take time and that it will involve implementing change across many levels of our health care system. However, we strongly believe that a universal RSV program will have a significant impact on the health of infants. NACI encourages people to discuss available immunization options in their setting with a healthcare provider in advance of childbirth. NACI’s recommendations are grounded in the best available scientific evidence. We will update our guidance as needed, as evidence continues to accumulate and as advancements are made on the best ways to protect infants.”

- Dr. Robyn Harrison, NACI Chair

“Respiratory syncytial virus (RSV) is one of the most common respiratory viruses in infants and young children, infecting almost all children by two years of age. Severe RSV disease is most common in young infants in their first months of life during the RSV season, generally from late fall to early spring. Canada has two new options to help protect infants against severe RSV disease – Beyfortus (nirsevimab) and Abrysvo (RSVpreF). NACI’s new guidance provides a foundation for a future universal immunization program for all infants. Moving toward a universal RSV program will provide an additional tool to protect infants in Canada during the respiratory virus season, when influenza and COVID-19 can also co-circulate in our communities and contribute to stress on our healthcare systems. I thank NACI for continuing to provide timely, expert advice to help protect the health of people in Canada.”

- Dr. Theresa Tam, Chief Public Health Officer