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Respiratory Season 2024–25 Rounds Part 2: Overview of Influenza, COVID-19, and RSV Immunization

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October 10, 2024

Welcome and Land Acknowledgement

Learning Objectives

By the end of this session participants will be able to:

- Describe the immunization products to be available in Ontario in the Fall of 2024 for COVID-19, influenza and respiratory syncytial virus (RSV)
- Summarize the National Advisory Committee on Immunization's (NACI) recommendations and provincial guidance for Ontario's COVID-19, influenza and RSV programs
- Identify resources to support immunizers in their delivery of Ontario's COVID-19, influenzaand RSV immunization programs in the Fall of 2024

Presenters

- **Dr. Sarah Wilson** is a Public Health Physician at Public Health Ontario where she works with the Immunization and Vaccine-Preventable Diseases team
- **Dr. Richard Mather** is a Public Health Physician at Public Health Ontario where he works with the Communicable Diseases team
- **Dr. Reed Morrison** is a Public Health Physician at Public Health Ontario where he works with the Immunization and Vaccine-Preventable Diseases team and the Communicable Diseases team
- **Dr. Daniel Warshafsky** is an Associate Chief Medical Officer of Health and oversees the immunization portfolio in the Office of the Chief Medical Officer of Health at Ontario's Ministry of Health

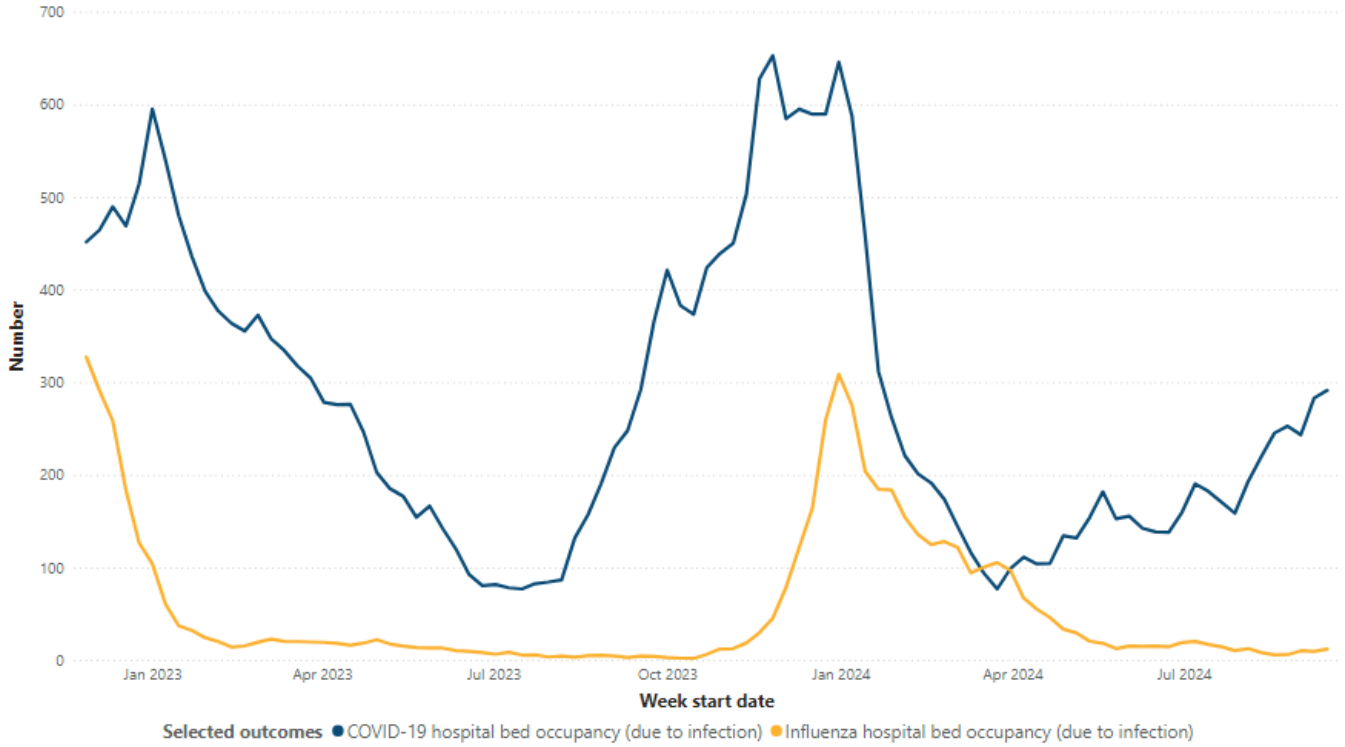
Disclosures

- Dr. Wilson does not have any conflicts of interest to disclose
- Dr. Mather does not have any conflicts of interest to disclose
- Dr. Morrison does not have any conflicts of interest to disclose
- Dr. Warshafsky does not have any conflicts of interest to disclose

COVID-19 Vaccines

COVID-19 Continues to have an Important Burden of Disease

COVID-19 and Influenza Hospitalizations in Ontario: January 2023 to September 2024



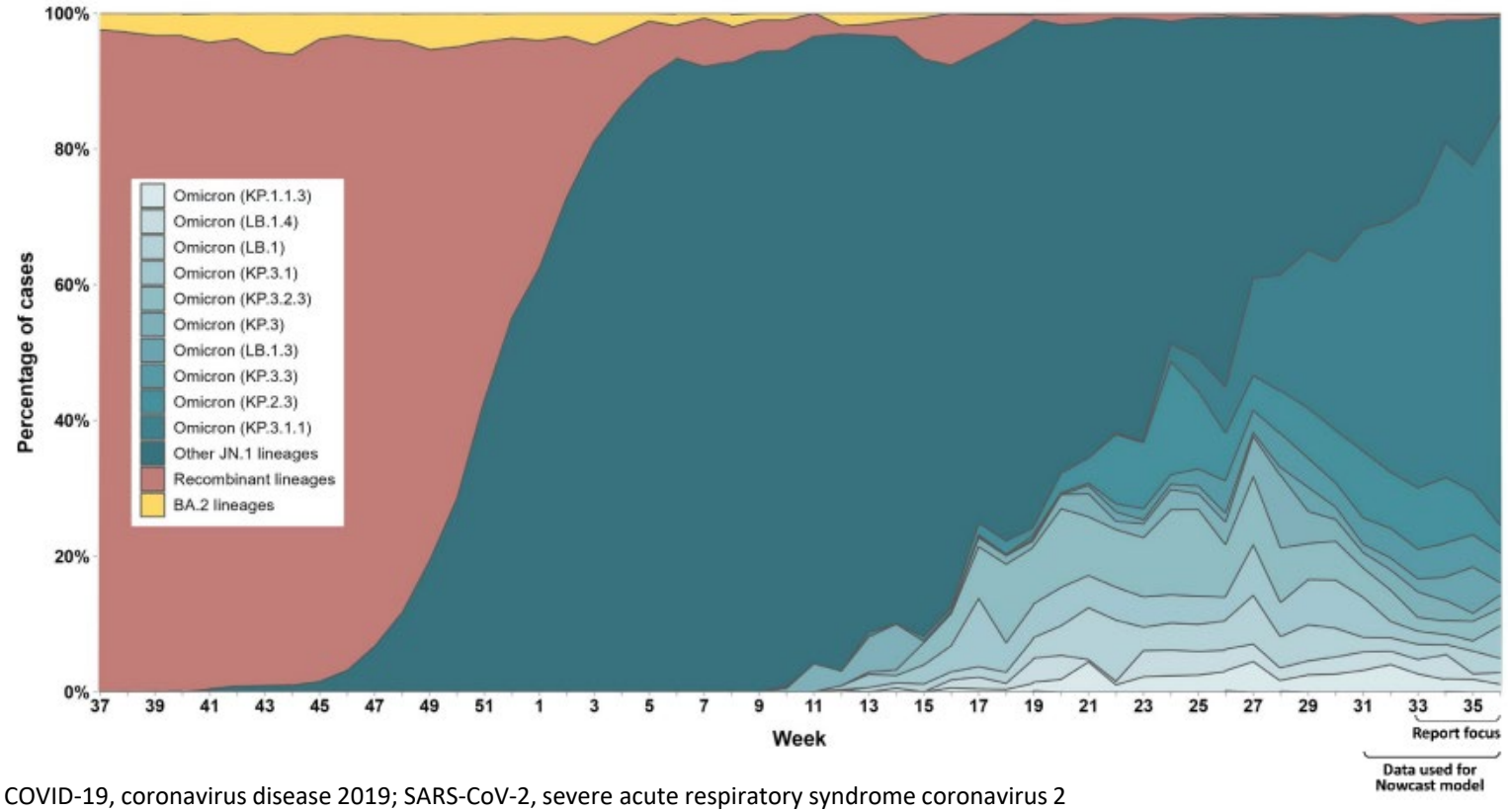
- Although COVID-19 does not yet have a clear seasonal pattern, increased activity in the fall/winter overlaps with circulation of influenza and RSV

COVID-19, coronavirus disease 2019

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Ontario respiratory virus tool [Internet]. Toronto, ON: King's Printer for Ontario; 2024 Sep 22 [extracted 2024 Sep 22]. Available from: https://www.publichealthontario.ca/en/Data-and-Analysis/Infectious-Disease/Respiratory-Virus-Tool

Why is an Updated COVID-19 Vaccine Needed this Fall?

Percentage of SARS-CoV-2 Cases by the Most Prevalent Lineages and Week, Representative Surveillance, Ontario, September 24, 2023 to September 21, 2024



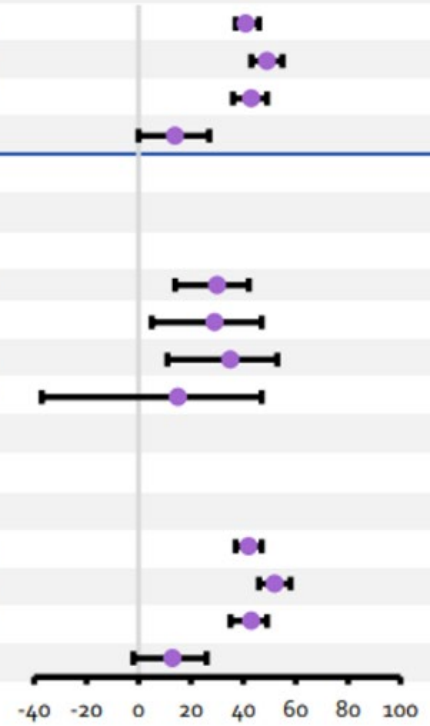
- The SARS-CoV-2 virus continues to evolve over time
- COVID-19 vaccines are updated annually to provide the best protection from currently circulating strains
- Fall 2024 COVID-19 mRNA vaccines will target the KP.2 sublineage

COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). SARS-CoV-2 genomic surveillance in Ontario, September 23, 2024. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 26]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-sars-cov2-whole-genome-sequencing-epi-summary.pdf

How Well did the 2023–24 COVID-19 XBB.1.5 Vaccine Protect Against Hospitalization?

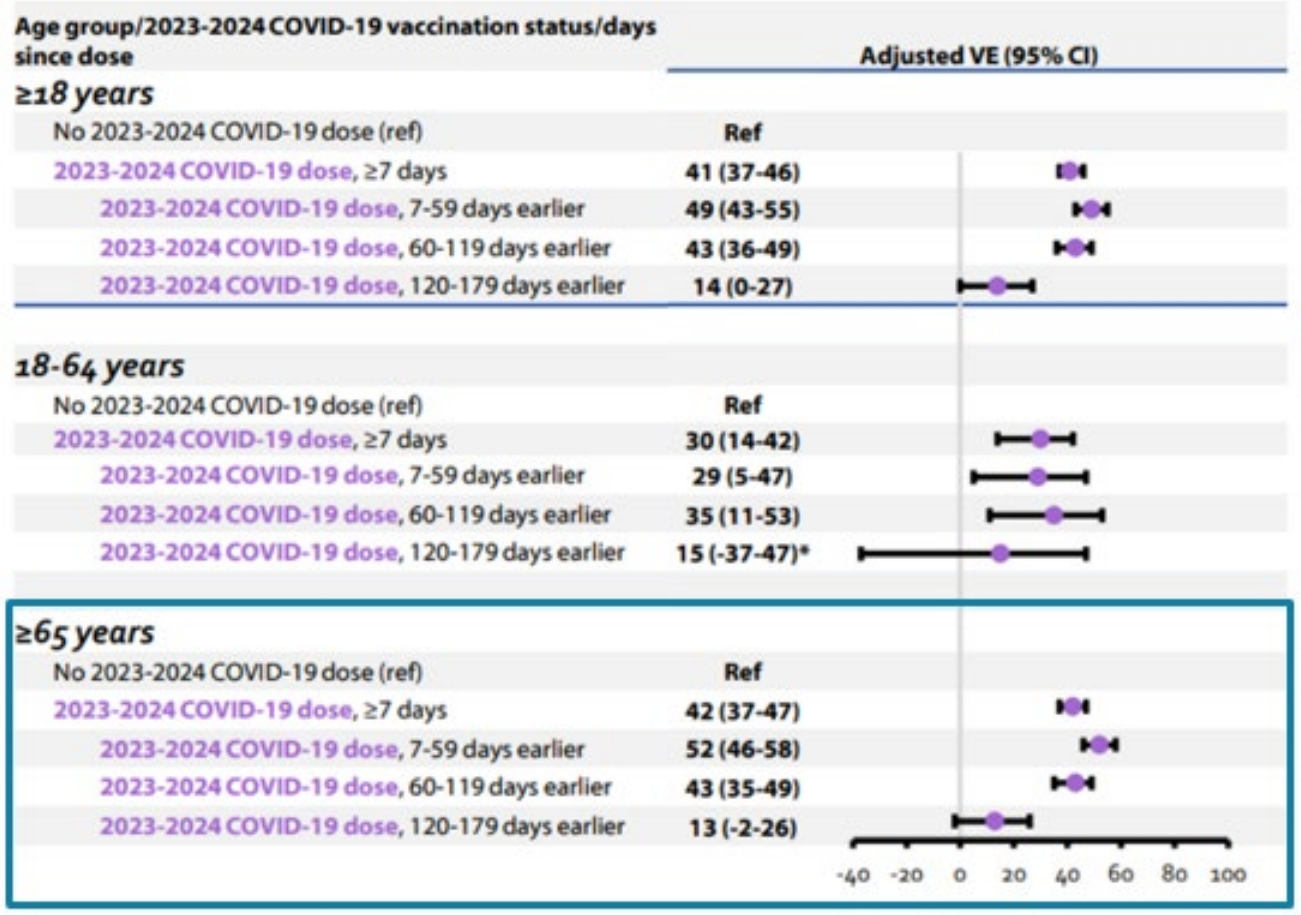
Age group/2023-2024 COVID-19 vaccination status/days since dose	Adjusted VE (95% CI)
≥18 years	
No 2023-2024 COVID-19 dose (ref)	Ref
2023-2024 COVID-19 dose, ≥7 days	41 (37-46)
2023-2024 COVID-19 dose, 7-59 days earlier	49 (43-55)
2023-2024 COVID-19 dose, 60-119 days earlier	43 (36-49)
2023-2024 COVID-19 dose, 120-179 days earlier	14 (0-27)
18-64 years	
No 2023-2024 COVID-19 dose (ref)	Ref
2023-2024 COVID-19 dose, ≥7 days	30 (14-42)
2023-2024 COVID-19 dose, 7-59 days earlier	29 (5-47)
2023-2024 COVID-19 dose, 60-119 days earlier	35 (11-53)
2023-2024 COVID-19 dose, 120-179 days earlier	15 (-37-47)*
≥65 years	
No 2023-2024 COVID-19 dose (ref)	Ref
2023-2024 COVID-19 dose, ≥7 days	42 (37-47)
2023-2024 COVID-19 dose, 7-59 days earlier	52 (46-58)
2023-2024 COVID-19 dose, 60-119 days earlier	43 (35-49)
2023-2024 COVID-19 dose, 120-179 days earlier	13 (-2-26)



- Updated COVID-19 vaccines provided increased protection against hospitalization, compared to those who were not vaccinated with the updated vaccine

Source: Link-Gelles R. Effectiveness of COVID-19 (2023-2024 Formula) vaccines [Internet]. Presented at: Advisory Committee on Immunization Practices (ACIP). 2024 Jun 27 [cited 2024 Oct 08]. ICATT: VE of 2023-2024 COVID-19 vaccine against symptomatic infection among adults aged ≥18 years, by age group and time since dose. Available from: https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-COVID-Link-Gelles-508.pdf

How Well did the 2023–24 COVID-19 XBB.1.5 Vaccine Protect Against Hospitalization?



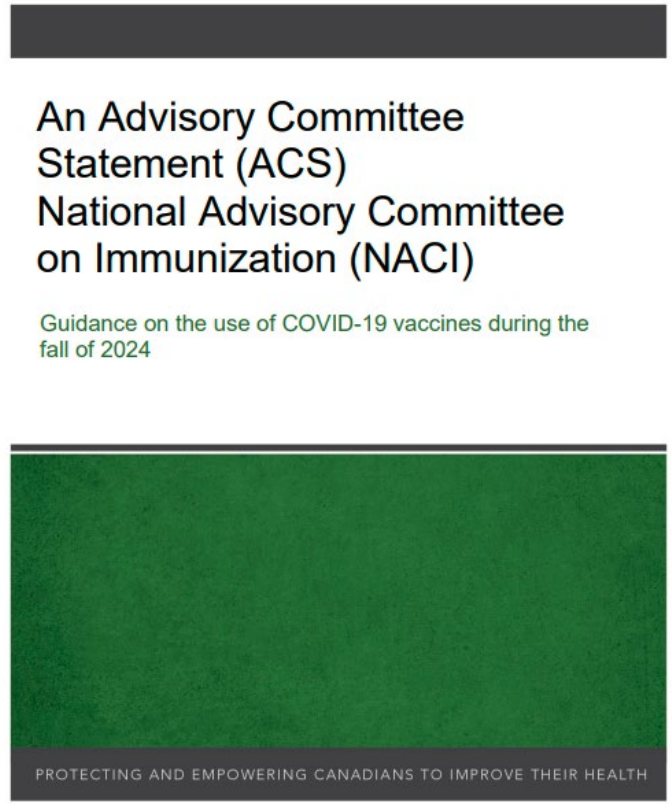
- For adults ≥65 years, VE for hospitalization was **43%** (95% CI 35–49%) at 2 to <4 months and waned to **13%** (95% CI -2–26%) at 4 to <6 months

CI, confidence interval; VE, vaccine efficacy

Source: Link-Gelles R. Effectiveness of COVID-19 (2023-2024 Formula) vaccines [Internet]. Presented at: Advisory Committee on Immunization Practices (ACIP). 2024 Jun 27 [cited 2024 Oct 08]. ICATT: VE of 2023-2024 COVID-19 vaccine against symptomatic infection among adults aged ≥18 years, by age group and time since dose. Available from: https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-COVID-Link-Gelles-508.pdf

NACI COVID-19 Vaccine Recommendations for Fall 2024

- **Only vaccines** containing the latest selected strains should be use in the fall 2024
- COVID-19 vaccination is **strongly recommended** for individuals at increased risk of SARS-CoV-2 infection or severe COVID-19 disease
- All others (≥6 months of age) **may receive** the most recently updated vaccine in the fall of 2024
- Interval after previous COVID-19 vaccine dose:
  - Recommended interval: **6 months**
  - Minimum interval: **3 months**
- Consider delaying COVID-19 vaccination by **3 to 6 months** after test-confirmed infection



NACI, National Advisory Committee on Immunization; COVID-19, coronavirus disease 2019; SARS-CoV-2 , severe acute respiratory syndrome coronavirus-2
Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Guidance on the use of COVID-19 vaccines during the fall of 2024 [Internet]. Ottawa, ON: Government of Canada; 2024 [cited 2024 Oct 08]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024/naci-statement-2024-05-03.pdf

Ontario COVID-19 Vaccine Guidance for Fall 2024

- **Recommended high risk populations for COVID-19 immunization (as soon as vaccine is available)**
  - All adults 65 years of age and older
  - Those 6 months of age and older who are/have:
    - Residents in long-term care homes and other congregate living settings
    - Pregnant
    - From First Nations, Métis and Inuit communities
    - Members of racialized and other equity-deserving communities
    - Underlying medical conditions that place them at higher risk of severe COVID-19, including children with complex health needs
- **To optimize co-administration with influenza vaccine additional groups have been prioritized for COVID-19 vaccine(s)**
  - Children 6 months to <4 years, staff and care providers in in long-term care homes and other congregate living settings, health care workers, first responders, individuals with significant exposure to birds and mammals
- **Starting October 28, 2024, all others (≥6 months of age) are recommended to and may receive an updated COVID-19 vaccine**

COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus-2

Source: Ontario. Ministry of Health. Health care provider fact sheet: COVID-19 vaccine [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 26]. Available from: https://www.ontario.ca/files/2024-10/moh-covid-19-vaccine-fact-sheet-en-2024-10-03.pdf

What COVID-19 Vaccines will be Available in Ontario this Fall?

Vaccine product	Vaccine type	Availability for which age groups	Dosage by age group	Schedule for those previously vaccinated	Interval since last dose
Moderna KP.2	mRNA (monovalent)	≥6 months	• 25 mcg (6 months to 11 years) • 50 mcg (≥12 years)	One dose	≥3–6 months
Pfizer BioNTech KP.2	mRNA (monovalent)	≥12 years	• 30 mcg (≥12 years)	One dose	≥3–6 months

COVID-19, coronavirus disease 2019; mcg, microgram; mRNA, messenger ribonucleic acid

Sources:

Moderna Biopharma Canada Corp. Product monograph (Spikevax) [Internet]. Toronto, ON: Moderna BioPharama Canada Corp; 2024 [modified 2024 Sep 17; cited 2024 Sep 23]. Available from: https://covid-vaccine.canada.ca/info/pdf/spikevax-pm-en.pdf

BioNTech Manufacturing GmbH. Product monograph (Comirnaty) [Internet]. Mainz, GE: BioNTech Manufacturing GmbH; 2024 [modified 2024 Sep 24; cited 2024 Sep 26]. Available from: https://webfiles.pfizer.com/file/fddae31e-ac0e-4bed-83b2-59e7c848d6d7?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6

Public Health Agency of Canada, National Advisory Committee on Immunization. Guidance on the use of COVID-19 vaccines during the fall of 2024 [Internet]. Ottawa, ON: Government of Canada; 2024 [cited 2024 Oct 08]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024/naci-statement-2024-05-03.pdf

COVID-19 Vaccine Schedules for Those Not Previously Vaccinated

Not moderately to severely immunocompromised

Age group	Vaccine product and dosage	Number of doses	Interval *
6 mos to <5 years	• Moderna 25 mcg	2	8 weeks
5 to 11 years	• Moderna 25 mcg	1	N/A
≥12 years	• Pfizer BioNTech 30 mcg • Moderna 50 mcg	1	N/A

Moderately to severely immunocompromised

Age group	Vaccine product and dosage	Number of doses	Interval*
6 mos to <5 years	• Moderna 25 mcg	3	4–8 weeks
5 to 11 years	• Moderna 25 mcg	2 (3 doses may be given)**	4–8 weeks
≥12 years	• Pfizer BioNTech 30 mcg • Moderna 50 mcg	2 (3 doses may be given)**	4–8 weeks

*Same intervals apply to those with recent infection who are receiving doses in primary series.
**Recipients of HSCT and CAR T-cell therapy should receive 3 doses.

CAR chimeric antigen receptor; COVID-19, coronavirus disease 2019; HSCT, Hematopoietic stem cell transplantation; mcg, microgram; mos, months
Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Guidance on the use of COVID-19 vaccines during the fall of 2024 [Internet]. Ottawa, ON: Government of Canada; 2024 [cited 2024 Oct 08]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-guidance-covid-19-vaccines-fall-2024/naci-statement-2024-05-03.pdf

Where can I Find Guidance on COVID-19 Vaccines?

Ontario Ministry of Health (MOH)

- Ontario MOH Health Care Provider Fact Sheet: COVID-19 Vaccines (MOH)

Public Health Agency of Canada (PHAC)

- Guidance on use of COVID-19 vaccines during the fall of 2024 (NACI)
- Canadian Immunization Guide COVID-19 vaccine chapter (PHAC)

Ontario College of Family Physicians (OCFP)

- COVID-19 Vaccines, Treatments and Testing Summary Information for Family Physicians (OCFP)
- COVID-19 Community of Practice (OCFP & University of Toronto Department of Family and Community Medicine)

Influenza Vaccines

Influenza Vaccine Composition for the Northern Hemisphere

Influenza virus type	2023–24 Egg-based vaccines	2024–25 Egg-based vaccines
Influenza A	• A/Victoria/4897/2022 (H1N1)pdm09-like virus • A/Darwin/9/2021 (H3N2)-like virus	• A/Victoria/4897/2022 (H1N1)pdm09-like virus • **A/Thailand/8/2022 (H3N2)-like virus**
Influenza B	• B/Austria/1359417/2021 (B/Victoria lineage)-like virus • B/Phuket/3073/2013 (B/Yamagata lineage)-like virus*	• B/Austria/1359417/2021 (B/Victoria lineage)-like virus • B/Phuket/3073/2013 (B/Yamagata lineage)-like virus*

- B/Yamagata virus no longer recommended by the World Health Organization (WHO) for inclusion in influenza vaccines – not detected globally since March 2020

* Not contained in trivalent inactivated vaccine (TIV) product; TIV, trivalent inactivated vaccine;
Source: World Health Organization (WHO). Recommended composition of influenza virus vaccines for use in the 2024-2025 northern hemisphere influenza season [Internet]. Geneva: WHO; 2024 [cited 2024 Sep 24]. Available from: https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2024-2025-northern-hemisphere-influenza-season

Universal Influenza Immunization Program (UIIP) Vaccines for 2024–25

Age group	Type of product	Product name	Composition
6 months and over	Standard-dose quadrivalent (QIV)	• FluLaval Tetra • Fluzone® Quadrivalent • **Flucelvax® Quad**	• 15 mcg per strain
65 years and over	High-dose quadrivalent (QIV-HD)	• Fluzone® High-Dose Quadrivalent	• 60 mcg per strain
65 years and over	Adjuvanted trivalent (TIV-adj)	• Fluad®	• 15 mcg per strain • MF59 adjuvant

- The influenza vaccine is the best defence against getting and spreading the influenza virus
- Protection against infection and illness from the influenza virus through influenza vaccination may provide added benefits in protecting against other diseases or worsening of existing chronic illnesses

QIV, quadrivalent inactivated vaccine; QIV-HD, high-dose quadrivalent inactivated vaccine; TIV-adj, adjuvanted trivalent inactivated vaccine
Source: Ontario. Ministry of Health. Universal influenza immunization program (UIIP) [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 24]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/default.aspx

Influenza Vaccine Schedule

Age	Immunization status	Number of doses recommended for current season
6 months to < 9 years of age	Not previously immunized with any influenza vaccine in their lifetime	2 doses at least 4 weeks apart
6 months to < 9 years of age	Previously immunized with at least one dose of any influenza vaccine in their lifetime	1 dose
9 years of age and older	Any	1 dose

- No change in dose recommendations for 2024–25 influenza vaccine

Source: Ontario. Ministry of Health. Health care provider fact sheet: influenza immunization for individuals 6 months to 64 years of age [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 24]. Available from: https://www.ontario.ca/files/2024-09/moh-uiip-24-25-6mo-64-fact-sheet-en-2024-09-25.pdf

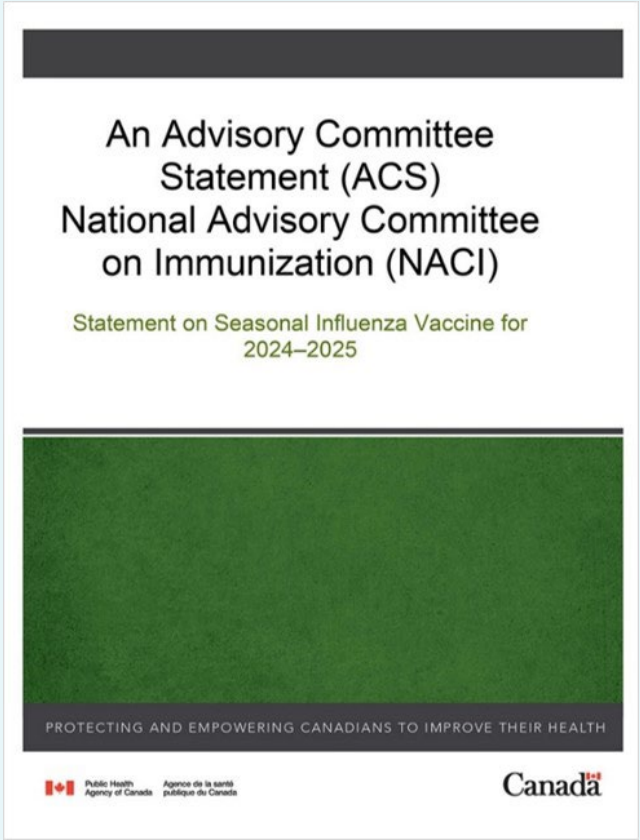
NACI Seasonal Influenza Vaccine Recommendations for 2024–25

Recommendation for individual-level decision making

Influenza vaccine should be offered annually to anyone 6 months of age and older who does not have a contraindication to the vaccine

Influenza vaccination is particularly important for:

- People at high risk of influenza-related complications or hospitalization
- People capable of transmitting influenza to those at high risk
- People who provide essential community services; and
- People who are in direct contact with poultry infected with avian influenza during culling operations



NACI, National Advisory Committee on Immunization;
Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on seasonal influenza vaccine for 2024-2025 [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 Jul 25 [cited 2024 Sept 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2024-2025.html

NACI 2024–25 Recommendations for Adults 65 Years and Older

- Evidence supports high-dose inactivated influenza vaccine (IIV-HD), adjuvanted inactivated influenza vaccine (IIV-Adj) and recombinant influenza vaccine (RIV), as having **increased benefit as compared to standard-dose** inactivated influenza vaccine (IIV-SD), with no difference in safety
- **No definitive conclusion can be reached regarding the superiority of IIV-HD, IIV-Adj or RIV over one another** as there is a limited number of studies directly comparing these vaccines against each other

- NACI recommendation for individual-level and public health program-level decision making:
  - **High-dose inactivated influenza vaccine (IIV-HD), adjuvanted inactivated influenza vaccine (IIV-Adj) or recombinant influenza vaccine (RIV) should be offered, when available, over other influenza vaccines for adults 65 years of age and older**

IIV-Adj, adjuvanted inactivated influenza vaccine; IIV-HD, high-dose inactivated influenza vaccine; QIV, quadrivalent inactivated vaccine; RIV, recombinant influenza vaccine; UIIP, Universal Influenza Immunization Program; NACI, National Advisory Committee on Immunization; RIV, recombinant influenza vaccine

Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Supplemental guidance on influenza vaccination in adults 65 years of age and older [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sept 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-supplemental-guidance-influenza-vaccination-adults-65-years-older.html

Ontario Influenza Vaccine Guidance for 2024–25 UIIP

1. **Recommended priority populations for influenza immunization (as soon as vaccine is available)**
   - Residents, staff and care providers in congregate living settings (e.g. chronic care facilities, retirement homes)
   - Individuals at high-risk of complications or hospitalization due to influenza
     - All adults 65 years of age and older
     - **All children 6 months to 4 years of age**
     - All pregnant people
     - Individuals in or from First Nations, Métis or Inuit communities
     - Members of racialized and other equity-deserving communities
     - Individuals 6 months of age and older with specified underlying medical conditions
   - Health care workers, first responders and **individuals with significant exposure to birds or mammals**

UIIP, Universal Influenza Immunization Program

Source: Ontario. Ministry of Health. Universal influenza immunization program (UIIP) [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 24]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/default.aspx

Ontario Influenza Vaccine Guidance for 2024–25 UIIP

2. General population (starting October 28, 2024)

- **All individuals 6 months of age and older without contraindications, in particular:**
  a. Individuals capable of transmitting influenza to either infants under 6 months of age or those prioritized to receive the influenza vaccine as soon as it is available
  b. People who provide essential community services

UIIP, Universal Influenza Immunization Program
Source: Ontario. Ministry of Health. Universal influenza immunization program (UIIP) [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 24]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/default.aspx

Ontario Influenza Vaccine Guidance for Older Adults

- Seniors, especially those in congregate settings such as long-term care homes, hospitals, and retirement homes, should get immunized as soon as the influenza vaccine is available for them
- The **high dose quadrivalent (QIV-HD) or adjuvanted trivalent (TIV-adj) vaccines should be offered, when available, over standard dose QIV influenza vaccines** for adults 65 years of age and older
- If a preferred product is not available, any of the available age-appropriate influenza vaccines (including QIV) should be used
- The most important thing is for older adults to be vaccinated—**do not delay vaccination to wait for a particular product**

QIV, quadrivalent inactivated vaccine; QIV-HD, high-dose quadrivalent inactivated vaccine; TIV-adj, adjuvanted trivalent inactivated vaccine; UIIP, Universal Influenza Immunization Program
Source: Ontario. Ministry of Health. Universal influenza immunization program (UIIP) [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Sep 24]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/default.aspx

Where can I Find Guidance on Influenza Vaccines?

Ontario Ministry of Health (MOH)

- Health Care Provider Fact Sheet: Influenza Immunization Information for the 2024/2025 Influenza Season
- Health Care Provider Fact Sheet: Influenza Immunization for individuals 6 months to 64 years of age
- Health Care Provider Fact Sheet: Influenza Immunization for Individuals ≥65 years of age

Public Health Agency of Canada (PHAC)

- Statement on seasonal influenza vaccine for 2024–2025 (NACI)
- Addendum to the statement on seasonal influenza vaccine for 2024-2025: Transition from quadrivalent to trivalent influenza vaccines (NACI)
- Supplemental guidance on influenza vaccination in adults 65 years of age and older (NACI)

World Health Organization (WHO)

- Recommended composition of influenza virus vaccines for the 2024-2025 northern hemisphere influenza season (WHO)

RSV Prevention

RSV Vaccines for Older Adults

- Two vaccines are available for adults aged ≥60 years to prevent RSV lower respiratory tract disease (LRTD)[1]:

Parameter	RSVPreF3 (Arexvy, GlaxoSmithKline)	RSVpreF (Abrysvo™, Pfizer)
Date of authorization	August 4, 2023	December 21, 2023
Vaccine type	Adjuvanted recombinant protein subunit	Bivalent recombinant protein subunit
Dose	1 dose (0.5 mL)	1 dose (0.5 mL)
Route of administration	Intramuscular	Intramuscular
Indication	• Adults ≥60 years of age	• Adults ≥60 years of age • Pregnant individuals from 32–36 weeks gestational age to prevent LRTD in infants

LRTD, lower respiratory tract disease; RSV, respiratory syncytial virus

1. Ontario. Ministry of Health. Older adult high-risk respiratory syncytial virus (RSV) vaccine program [Internet]. Version 4.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-older-adult-high-risk-rsv-fact-sheet-v4-0-health-care-providers-en-2024-08-16.pdf

Safety and Effectiveness of RSV Vaccine in Older Adults

- Both vaccines have high efficacy in preventing LRTD caused by RSV in clinical trials[1]
- Vaccination **reduces the risk of hospitalization due to RSV by 75%** among adults ≥60 years[2]

- Side-effects are typically mild and last only a few days[1]
- Common side effects include[1]:
  - Pain, redness and swelling at injection site
  - Fatigue
  - Fever
  - Headache
  - Nausea
  - Diarrhea
  - Muscle or joint pain
- Early safety data from the US suggest a potentially increased rate of Guillain-Barré syndrome in older adults; however, events are rare and available data cannot confirm the association at this time[3, 4]

LRTD, lower respiratory tract disease; RSV, respiratory syncytial virus; US, United States

1. Ontario. Ministry of Health. Older adult high-risk respiratory syncytial virus (RSV) vaccine program [Internet]. Version 4.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-older-adult-high-risk-rsv-fact-sheet-v4-0-health-care-providers-en-2024-08-16.pdf
2. Surie D, Self HS, Zhu Y, Yuengling KA, Johnson CA, Grijalva CG, et al. RSV vaccine effectiveness against hospitalization among US adults 60 years and older. JAMA. 2024;332(13):1105-7. Available from: https://doi.org/10.1001/jama.2024.15775
3. Patricia L. Evaluation of Guillain-Barré Syndrome (GBS) following Respiratory Syncytial Virus (RSV) vaccination among adults 65 years and older [Internet]. Presented at: Meeting of the Advisory Committee on Immunization Practices. 2024 Jun 26-28. Available from: https://stacks.cdc.gov/view/cdc/157862
4. Hause AM, Moro PL, Baggs J, Zhang B, Marquez P, Melgar M, et al. Early safety findings among persons aged ≥60 years who received a respiratory syncytial virus vaccine - United States, May 3, 2023-April 14, 2024. MMWR Morb Mortal Wkly Rep. 2024;73(21):489-94. Available from: https://doi.org/10.15585/mmwr.mm7321a3

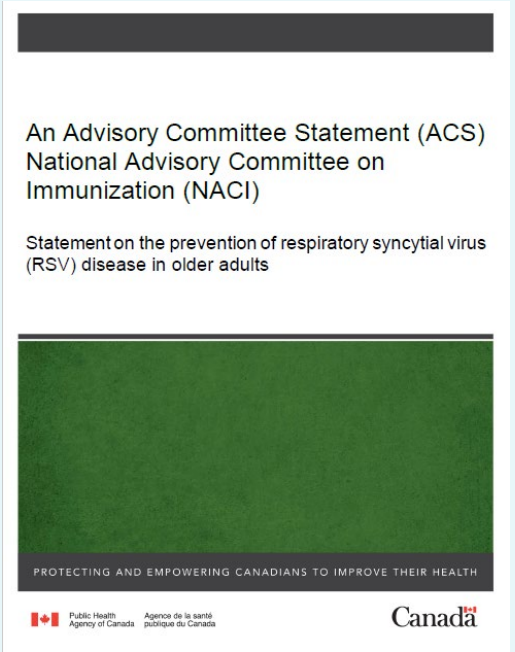
NACI Statement on the Prevention of RSV Disease in Older Adults

Recommendations for public health program level decision-making

1. RSV immunization programs for adults ≥75 years of age, particularly for those who are at increased risk of severe RSV disease* (*Strong recommendation*)
2. RSV immunization programs for adults ≥60 years of age who are residents of nursing homes and other chronic care facilities (*Strong recommendation*)

Recommendations for health care providers advising individual clients

3. An RSV vaccine may be considered as an individual decision by adults 60 to 74 years of age in consultation with their health care provider (*Discretionary recommendation*)



- NACI did not make any preferential recommendations on RSV vaccine products; a single dose of either vaccine may be used

*Clinically significant chronic health conditions for which RSV vaccination is particularly important include: Cardiac or pulmonary disorders, diabetes mellitus and other metabolic diseases, moderate and severe immunodeficiency, chronic renal or liver disease, neurologic or neurodevelopmental conditions, and class 3 obesity.

NACI, National Advisory Committee on Immunization; RSV, respiratory syncytial virus

Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on the prevention of respiratory syncytial virus disease in older adults [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sept 24]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-rsv-disease-older-adults/naci-statement-2024-07-12.pdf

Ontario's Publicly Funded RSV Prevention Program for Older Adults

Ontario's publicly funded RSV program includes individuals aged ≥60 years who are also:

- Residents of long-term care homes, Elder Care Lodges, or retirement homes
- In hospital receiving ALC and similar settings (e.g., complex continuing care, hospital transitional programs)
- Receiving hemodialysis or peritoneal dialysis
- Recipients of solid organ or hematopoietic stem cell transplants
- Experiencing homelessness
- Identify as First Nations, Inuit, or Métis

- One dose of the RSV vaccine offers multi-year protection. Individuals who received the vaccine during the 2023–24 season do not need another dose this season

ALC, alternate level of care; RSV, respiratory syncytial virus

Source: Ontario. Ministry of Health. Older adult high-risk respiratory syncytial virus (RSV) vaccine program [Internet]. Version 4.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-older-adult-high-risk-rsv-fact-sheet-v4-0-health-care-providers-en-2024-08-16.pdf

RSV Prevention Products for Infants

- 3 products are authorized to prevent RSV lower respiratory tract infections (LTRI) in infants[1,2]:

2 monoclonal antibody immunizing agents:
nirsevimab (Beyfortus™) and palivizumab (PrSynagis®)

Administered to infants to provide direct and immediate protection against disease

RSV vaccine: RSVpreF (Abrysvo)

Administered to pregnant individuals to protect infants from severe RSV illness

LTRI, lower respiratory tract infection; RSV, respiratory syncytial virus

1. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Beyfortus® (Nirsevimab) [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-guidance-hcp-en-2024-08-28.pdf
2. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Abrysvo™ [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-abrysvo-guidance-hcp-en-2024-08-28.pdf

Comparison of RSV Prevention Products for Infants

- Nirsevimab (Beyfortus) and RSVpreF (Abrysvo) will be offered as a part of Ontario's publicly funded infant RSV prevention program[1,2]

Parameter	Monoclonal Antibody Provided to Infants[1,3]	Vaccine Provided to Pregnant Individuals[2,4]
Immunizing agent	Nirsevimab (Beyfortus)	RSVpreF (Abrysvo)
Indication for use	Infants and high-risk children up to 24 months of age*	Pregnant individuals between 32–36 weeks gestation who will deliver during the RSV season
Type of immunity for infant	Passive immunity	Passive immunity
How it works	Provides ready-made antibodies against RSV for immediate protection of the infant	Stimulates production of antibodies against RSV in the pregnant individual. Antibodies are transferred to the infant through the placenta and breastfeeding.
Timing of administration	Before or during RSV season	Before or during RSV season
How long it takes to be effective	Immediate protection	~2 weeks following administration
Duration of protection	Up to 6 months from date of administration	Up to 6 months from birth

*May include but is not limited to children with: chronic lung disease of prematurity, hemodynamically significant congenital heart disease, immunocompromised states, Down syndrome, cystic fibrosis, neuromuscular disease, congenital airway anomalies.

RSV, respiratory syncytial virus

Sources: 1. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Beyfortus® (Nirsevimab) [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-guidance-hcp-en-2024-08-28.pdf
2. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Abrysvo™ [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-abrysvo-guidance-hcp-en-2024-08-28.pdf
3. AstraZeneca Canada Inc. Product monograph (Beyfortus™). Mississauga, ON: AstraZeneca Canada Inc.; 2023 [cited 2024 Oct 08]. Available from: https://pdf.hres.ca/dpd_pm/00070439.PDF
4. Pfizer Canada ULC. Product monograph (Abrysvo™). Kirkland, QC: Pfizer Canada ULC; 2023 [cited 2024 Oct 08]. Available from: https://pdf.hres.ca/dpd_pm/00073900.PDF

Safety and Effectiveness of RSV Products for Infants

Nirsevimab (Beyfortus)[1,2, 3]

- **81%** and **90%** efficacy at 150 days against RSV LRTI requiring hospitalization and ICU admission, respectively; similar results observed in real-world settings
- Most common side-effects: rash, fever and injection site reactions
- Rates of systemic adverse events (e.g., bronchiolitis, pneumonia, LTRI) were comparable between nirsevimab and placebo groups

RSVPreF (Abrysvo)[4,5,6]

- **57%** and **69%** efficacy at 6 months against hospitalization due to RSV and severe RSV LRTI (e.g. ICU admission), respectively
- Most common side-effects: pain/redness/swelling at injection site, fatigue, headache, muscle soreness, and nausea
- Slightly higher rate of pre-term births in the vaccine group vs. placebo (not statistically significant); current data cannot definitively establish or dismiss the potential association

ICU, intensive care unit; LTRI, lower respiratory tract infection; RSV, respiratory syncytial virus

Sources: 1. AstraZeneca Canada Inc. Product monograph (Beyfortus™). Mississauga, ON: AstraZeneca Canada Inc.; 2023 [cited 2024 Oct 08]. Available from: https://pdf.hres.ca/dpd_pm/00070439.PDF

2. Drysdale SB, Cathie K, Flamein F, Knuf M, Collins AM, Hill HC, et al. Nirsevimab for prevention of hospitalizations due to RSV in infants. N Engl J Med. 2023;389(26):2425-35. Available from: https://doi.org/10.1056/nejmoa2309189

3. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Beyfortus® (Nirsevimab) [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-guidance-hcp-en-2024-08-28.pdf

4. Kampmann B, Madhi SA, Munjal I, Simões EAF, Pahud BA, Llapur C, et al. Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. N Eng J Med. 2023;388(16):1451-64. Available from: https://doi.org/10.1056/nejmoa2216480

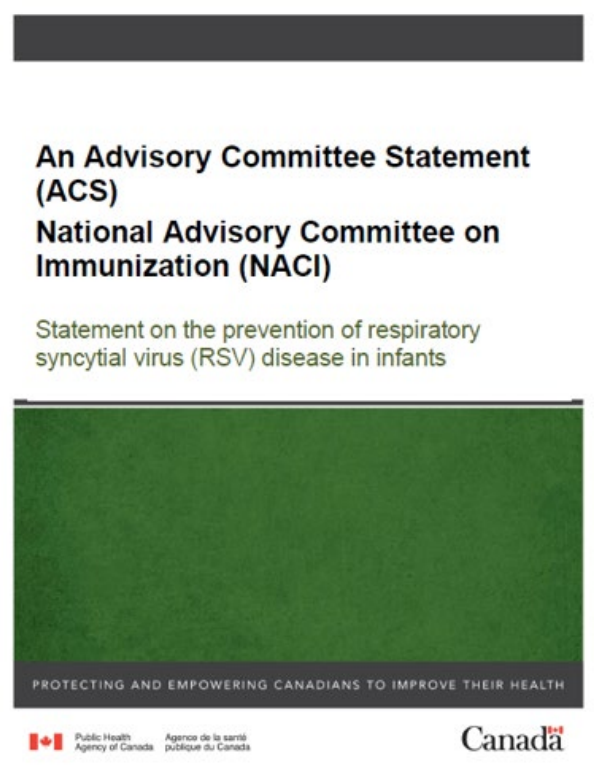
5. Pfizer Canada ULC. Product monograph (Abrysvo™). Kirkland, QC: Pfizer Canada ULC; 2023 [cited 2024 Oct 08]. Available from: https://pdf.hres.ca/dpd_pm/00073900.PDF

6. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Abrysvo™ [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-abrysvo-guidance-hcp-en-2024-08-28.pdf

NACI Statement on the Prevention of RSV Disease in Infants

Recommendations for public health program level decision-making

1. Building towards a universal RSV immunization program for all infants
2. Use nirsevimab in RSV immunization programs to prevent severe RSV disease in infants
   - Priority should be given to infants at increased risk of severe RSV disease in their 1st or 2nd RSV season
   - Program expansion to all other infants entering/born during their 1st RSV season when possible
   - Should be offered to infants entering/born during their 1st RSV season whose transportation for severe RSV disease treatment is complex, and/or at risk of severe disease due to social and structural health determinants (e.g., First Nations, Métis and Inuit populations)



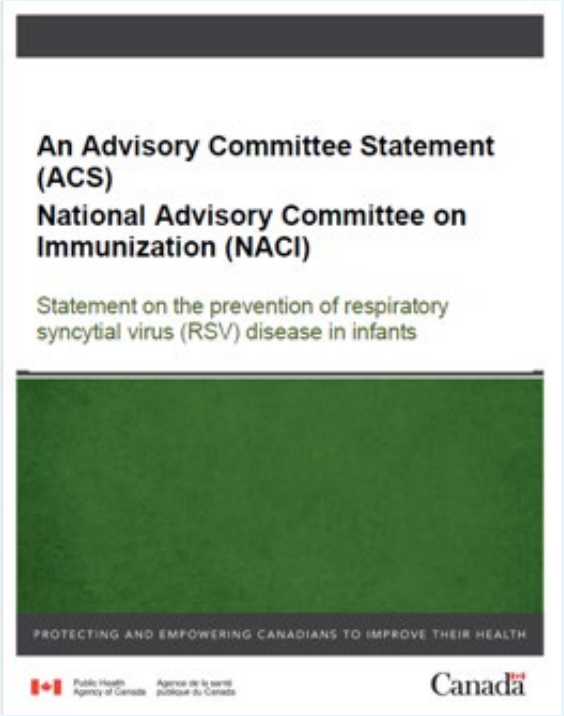
NACI, National Advisory Committee on Immunization; RSV, respiratory syncytial virus

Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on the prevention of respiratory syncytial virus disease in infants [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sep 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants.html

NACI Statement on the Prevention of RSV Disease in Infants

Recommendations for health care providers advising individual clients

1. RSVpreF may be considered as an individual decision by a pregnant individual together with information from their pregnancy care provider in the context of informed consent



NACI, National Advisory Committee on Immunization; RSV, respiratory syncytial virus

Source: Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on the prevention of respiratory syncytial virus disease in infants [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sep 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants.html

Eligibility for the Ontario RSV Infant Monoclonal Antibody Program

Infants and children who are Ontario residents and meet the following criteria will be eligible for nirsevimab:

- Born in 2024 prior to the RSV season or during the 2024–25 RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their 2nd season:
  - Chronic lung disease, including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of RSV season
  - Hemodynamically significant congenital heart disease requiring corrective surgery or are on cardiac medication for congestive heart failure or diagnosed with moderate to severe pulmonary hypertension
  - Severe immunodeficiency
  - Down syndrome/Trisomy 21
  - Cystic fibrosis with respiratory involvement and/or growth delay
  - Neuromuscular disease impairing clearing of respiratory secretions
  - Severe congenital airway anomalies impairing the clearing of respiratory secretions

GA, gestational age; RSV, respiratory syncytial virus

Source: Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Beyfortus® (Nirsevimab) [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-guidance-hcp-en-2024-08-28.pdf

Eligibility in Ontario for RSV Vaccine During Pregnancy

- To be eligible for RSVPreF, individuals must be:
  - A resident of Ontario
  - Pregnant in their 32nd – 36th week of gestation
  - In consultation with their health care provider

NACI recommends nirsevimab over the vaccination of pregnant individuals based on its efficacy, duration of protection, and favourable safety profile.

Nirsevimab is recommended for infants aged <8 months entering or born during their 1st RSV season. Pregnant individuals and their health care providers should discuss the use of the vaccine in cases where nirsevimab would not be agreed to or available (e.g., not giving birth in Ontario).

- If it is anticipated that nirsevimab will be administered to a healthy infant, then RSVpreF in pregnancy may not provide added benefit

NACI, National Advisory Committee on Immunization; RSV, respiratory syncytial virus

Source: Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Abrysvo™ [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-abrysvo-guidance-hcp-en-2024-08-28.pdf

Nirsevimab Use When the RSV Vaccine is Given During Pregnancy

Nirsevimab should be administered to the following infants whose parent received the RSV vaccine in pregnancy[1,2]:

- Infants born less than 14 days after administration of the RSV vaccine*
- Infants who meet the medical criteria for increased risk from severe RSV disease:
  - All premature infants born <37 wGA*
  - Chronic lung disease, including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the 6 months prior to the start of RSV season
  - Hemodynamically significant congenital heart disease requiring corrective surgery or are on cardiac medication for congestive heart failure or diagnosed with moderate to severe pulmonary hypertension
  - Severe immunodeficiency
  - Down syndrome/Trisomy 21
  - Cystic fibrosis with respiratory involvement and/or growth delay
  - Neuromuscular disease impairing clearing of respiratory secretions
  - Severe congenital airway anomalies impairing the clearing of respiratory secretions

*First season only for those who do not have other medical condition(s) placing them at high risk of severe RSV disease in their 2nd season

GA, gestational age; RSV, respiratory syncytial virus

Source: 1. Ontario. Ministry of Health. Infant and high-risk children Respiratory Syncytial Virus (RSV) prevention program guidance for health care providers – Beyfortus® (Nirsevimab) [Internet]. Version 1.0. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Oct 08]. Available from: https://www.ontario.ca/files/2024-08/moh-infant-high-risk-children-rsv-beyfortus-guidance-hcp-en-2024-08-28.pdf

; 2. Ministry of Health. Vaccines Operations Touchpoint. Presented October 1, 2024.

Where can I Find Guidance on RSV Immunization Products?

Ontario Ministry of Health (MOH)

- High-Risk Older Adult RSV Fact sheet for health care providers
- Infant RSV Guidance for Health Care Providers – Beyfortus
- Infant RSV Guidance for Health Care Providers – Abrysvo

Public Health Agency of Canada (PHAC)

- Statement on the prevention of respiratory syncytial virus in older adults (NACI)
- Statement on the prevention of respiratory syncytial virus disease in infants (NACI)
- Canadian Immunization Guide RSV chapter (PHAC)

Centre for Effective Practice (CEP)

- 2024-2025 RSV Prevention Program for infants in Ontario

Provincial Council for Maternal and Child Health (PCMCH)

- Fact Sheet for Healthcare Providers

Reporting AEFIs in Ontario

- Ontario conducts surveillance of vaccine safety data in collaboration with local, provincial, territorial, and national partners
- AEFI reporting by health care providers is mandated under the Health Protection and Promotion Act (HPPA) Section 38 and Reg. 569
- Reports are sent to the local PHU using the Ontario AEFI reporting form
- Some common/mild events or events clearly attributed to other causes do not need to be reported

AEFI, adverse event following immunization; HPPA, Health Promotion and Protection Act; PHU, public health unit

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Report of adverse even following immunization (AEFI) [Internet]. Toronto, ON: King's Printer for Ontario; 2021 [cited 2024 Sept 24]. Available from: https://www.publichealthontario.ca/-/media/documents/a/2020/aefi-reporting-form.pdf?la=en

Reporting Adverse Events Following Administration of Nirsevimab

- As nirsevimab is a monoclonal antibody and not a vaccine, s.38 of the HPPA requiring provider reporting of suspected AEFIs to PHUs does not apply
- Incidents should be managed as per practices and organizational policies for other medicines and therapeutics
- To report a side effect of nirsevimab, please see the Health Canada Side Effect Reporting Form
  - Form may be completed online, downloaded, faxed, or mailed

AEFI, adverse event following immunization; HPPA, Health Promotion and Protection Act; mAb, monoclonal antibody; PHU, public health unit

Co-Administration of Seasonal and Non-Seasonal Vaccines and RSV Monoclonal Antibodies

- In general, inactivated vaccines may be administered concurrently with, or at any time before or after, other inactivated or live vaccines[1-3]
  - The RSV, COVID-19, and influenza vaccines can be co-administered
  - Due to the absence of direct clinical trials, it is unknown how the adjuvants in Fluad® and Shingrix® may interact when co-administered
- Nirsevimab can be administered on the same day or any time before or after routine childhood vaccines, including influenza; no interval between nirsevimab and live vaccines (such as MMR and Varicella) is necessary[2]

MMR, measles, mumps, rubella vaccine; RSV, respiratory syncytial virus

Sources: 1. Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on the prevention of respiratory syncytial virus disease in older adults [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sept 24]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-rsv-disease-older-adults/naci-statement-2024-07-12.pdf
; 2. Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on the prevention of respiratory syncytial virus disease in infants [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 [cited 2024 Sep 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants.html
; 3. Public Health Agency of Canada, National Advisory Committee on Immunization. Statement on seasonal influenza vaccine for 2024-2025 [Internet]. Ottawa, ON: His Majesty the King in Right of Canada, as represented by the Minister of Health; 2024 Jul 25 [cited 2024 Sept 24]. Available from: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2024-2025.html

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