Respiratory Syncytial Virus Vaccine

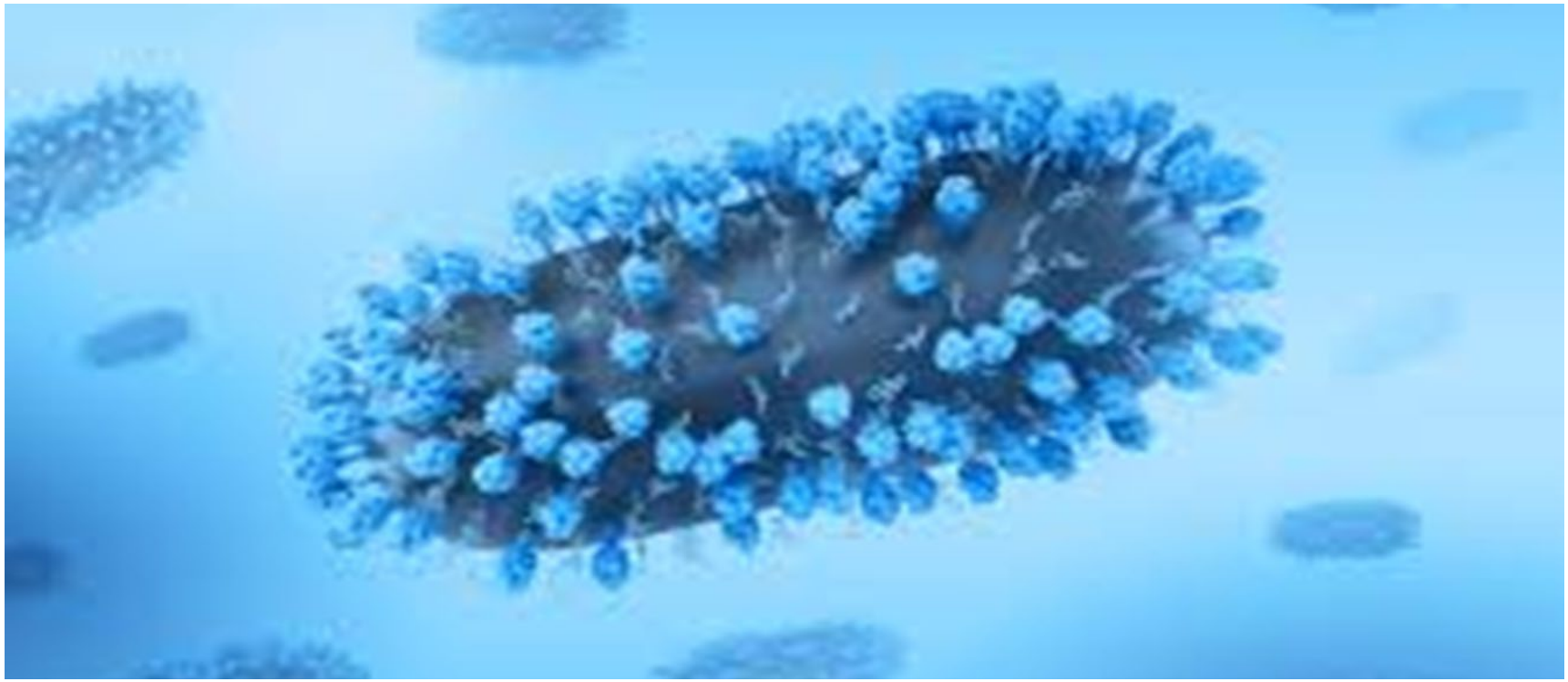


Image from: NIH Celebrates FDA Approval of RSV Vaccine for People 60 Years of Age and Older | NIAID: National Institute of Allergy and Infectious Diseases

October 2024

Introduction

Upon completion of this presentation the learner will understand the clinical information for the introduction of the Respiratory Syncytial Virus (RSV) vaccine into the Alberta Provincial Immunization Program.

Operational questions will NOT be addressed during this presentation (e.g., vaccine distribution specifics).

Always use the online resources for the most up to date information.

Introduction

For more detailed information it is important for providers to refer to other program resources found on the Alberta Health Services (AHS) webpages and orientation presentations such as:

- AHS Vaccine Biological pages
- AHS Vaccine Storage and Handling e-learning modules and Standard
- Guidelines for the reporting of Adverse Events Following Immunization(AEFI)
- Vaccine Administration
- Reporting requirements and data collection guidelines
- Alberta Immunization Policy

Respiratory Syncytial Virus Vaccine (RSV)

2023 – Health Canada approved Arexvy for use in persons 60 years of age and older

2024 – Health Canada approved Abrysvo for use in persons 60 years of age and older and in pregnant individuals

October 2024 - Abrysvo becomes available as a provincially funded vaccine in Alberta

Why is RSV vaccine important?

- RSV is a major cause of lower respiratory infection in infants, children and older adults.
  - Severe infection (involving pneumonia) may develop among elderly patients with underlying respiratory conditions
  - Adults 75 years of age and older, particularly those with certain chronic health conditions are at increased risk of severe RSV disease, hospitalization, intensive care unit (ICU) admission and death. Serious outcomes of RSV infection are also seen in adults 60 years of age and older who are residents of nursing homes and other chronic care facilities.
- RSV causes outbreaks yearly in Canada, usually from late fall to spring.
- Subsequent infections with RSV occur but are normally milder until older adulthood where it can again lead to severe disease.
- Provincially funded RSV vaccine will be provided throughout the year by Public Health and other community partners

RSV burden of disease

Hospitalization related to RSV

- In one Canadian study of adults 50 years of age and older, pooled RSV rates per 100,000 population were:
  - 43.7 in 60-69 year olds
  - 88.6 in 70-79 year olds
  - 282.5 in 80 years of age and older

ICU admission related to RSV:

- Approximately 10% of older adults require ICU admission
- There is an increased risk of ICU admission in older adults with co-morbidities
- Risk of ICU admission and mechanical ventilation is similar to that for influenza infection

RSV burden of disease cont'd

Death related to RSV

- There is limited data available
- Among those admitted to hospital the case fatality rate was approximately 5 to 10% and increases with age and presence of comorbidities
- In a multivariable analysis of a Canadian prospective study among patients hospitalized with acute respiratory illness, adults 75 years of age and older were more likely to succumb to their illness than RSV-negative comparators in the same age group

NACI 2024

RSV vaccine

	ABRYVSO Pfizer Canada
Dosage/Route	0.5 mL/IM
Packaging	Single Dose: vial containing lyophilized RSVpreF vaccine and syringe containing diluent (luer lock needles not included), Single dose packages and 10 doses per package
Indication	Individuals who have not previously received any dose of RSV vaccine and are: • Residents of continuing care homes and senior supportive living accommodations that are 60 years of age and older • Community dwelling seniors 75 years of age and older.

Ingredients	• Lyophilized powder containing 120 mcg of RSV stabilized prefusion F protein
	  ○ 60 mcg Subgroup A
	  ○ 60 mcg Subgroup B
	• Nonmedicinal ingredients

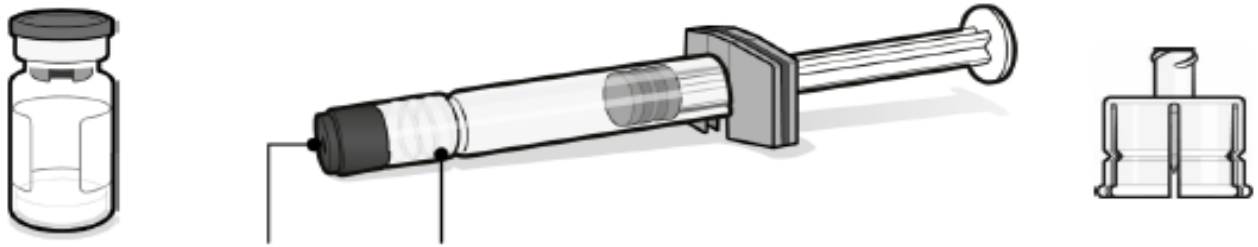
Schedule	1 dose

RSV Vaccine Preparation

Vial containing lyophilized RSVpreF vaccine

Syringe containing diluent

Vial adapter



Syringe cap **Luer lock adapter**

To form Abrysvo, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent Component as described in the panels below.

Step 1. Attach vial adapter

- Peel off the top cover from the vial adapter packaging and remove the flip off cap from the vial.
- While keeping the vial adapter in its packaging, centre over the vial's stopper and connect with a straight downward push. Do not push the vial adapter in at an angle as it may result in leaking. Remove the packaging.

RSV Vaccine Preparation

Step 2. Reconstitute lyophilized vaccine component to form Abrysvo

- For all syringe assembly steps, hold the syringe only by the Luer lock adapter. This will prevent the Luer lock adapter from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adapter. Stop turning when you feel resistance.
- Inject the entire contents of the syringe into the vial. Hold the plunger rod down and gently swirl the vial until the powder is completely dissolved (less than 1 minute). Do not shake.

Step 3. Withdraw reconstituted vaccine

- Invert the vial completely and slowly withdraw the entire contents into the syringe to ensure a 0.5 mL dose of Abrysvo.
- Twist to disconnect the syringe from the vial adapter.
- Attach a sterile needle suitable for intramuscular injection.

Reactions to RSV vaccine

	ABRYSVO
Common	• Pain, erythema, swelling at injection site • Fatigue, headache • Myalgia, arthralgia • Fever • Nausea, diarrhea
Uncommon	• Vomiting
Rare	• Anaphylaxis

Contraindications and precautions

Contraindications:

- People who have experienced anaphylaxis to a previous dose of Abrysvo
- People who have a known severe hypersensitivity to any component of the vaccine

Precautions:

- There are no data on the use of Abrysvo in immunocompromised individuals. Immunocompromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Abrysvo.

Co-administration with other vaccines

- For co-administration with other vaccines, refer to the "Administration With Other Products" section in the RSV vaccine biological page.

Commitment to comfort

Needle Fears

- This can affect people to a degree that they avoid immunization

Commitment to Comfort | Alberta Health Services outlines five principles to improve the immunization experience, health outcomes and satisfaction, and to encourage repeat attendance to healthcare encounters:

- Make a comfort plan
- Use positive language
- Use comfort positions
- Shift attention
- Use numbing cream

AEFI reporting

An adverse event following immunization (AEFI) is defined as a serious or unexpected event temporally associated with immunization.

Local reactions are the most reported event following immunization. A local reaction of pain and/or swelling is ONLY reportable if:

1. the onset of swelling is within 48 hours following immunization;

AND

2. swelling extends past the nearest joint

OR

3. severe pain that interferes with the normal use of the limb lasting greater than 4 days

OR

4. reaction requires hospitalization

AEFI reporting

Any of the following are also reportable adverse events:

- Guillain-Barré Syndrome (GBS)
- Oculorespiratory Syndrome (ORS)
- Anaphylaxis
- Other allergic reactions
- Any reaction outside of what is expected

Consult with AHS Adverse Event Following Immunization (AEFI) Team at AEFI@ahs.ca or 1-855-444-2324 as soon as possible for any case when there is uncertainty as to whether a symptom following immunization is related to the immunization.

Severe reactions (anaphylaxis and death) should be reported within 24 hours and all other reactions within 3 days to the AEFI Team. “Reportable AEFIs” are reported to Alberta Health, and in turn to the National Surveillance Program.

Anaphylaxis

Alberta Health Services employees need to ensure they have completed the Anaphylaxis Management | Insite (albertahealthservices.ca) learning module.

Covenant Health employees need to ensure they have completed Covenant Health Anaphylaxis Learning Module found on CLiC.

All other providers must have Anaphylaxis Management Guidelines in place.

- Additional information available in the Canadian Immunization Guide – Vaccine Safety

Infection Prevention and Control (IPC)

IPC's mandate is to reduce the incidence of healthcare associated infections in patients, residents, and clients by:

- Process and outcome surveillance
- Outbreak identification and management
- Consultation and education
- Guideline, policy, and procedure development
- Research

For more information go to the AHS IPC website at:
https://www.albertahealthservices.ca/info/page6410.aspx

References

Alberta Heath. (2024, October 1). Respiratory Syncytial Virus Vaccine (RSV). In *Alberta Immunization Policy: Biological Products* (2024). Government of Alberta.

National Advisory Committee on Immunization. (2024, July 12). *Statement on the prevention of respiratory syncytial virus disease in older adults. An advisory committee statement.* Public Health Agency of Canada.

Pfizer Canada ULC. (2023, December 21). ABRYSVO Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine. Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00073900.PDF

Public Health Agency of Canada. (2024, August). Respiratory syncytial virus (RSV) vaccines. In *Canadian Immunization Guide: Part 4: Immunizing agents*. Government of Canada.

QUESTIONS & THANKS

Email CDCIMM@ahs.ca or call 1-855-444-2324

Alberta Health Services