

RSV Vaccine Immunization Program

ABRYSVO

October 16, 2024



Reminder:

This videoconference/webinar
will be recorded.

Land Acknowledgement

The FNIHB CDC and Nursing Education Teams respectfully acknowledge we are situated on Treaty 6, 7, & 8 territories, the traditional lands of First Nations and Métis people.

We are thankful to play, work, and live along side First Nations and Métis people.

The FNIHB Alberta Region CDC Team has created this training by using information from:

- Alberta Health
- Alberta Health Services
- Public Health Agency of Canada

Today's Objective

To provide clinical information related to the RSV vaccine available and the publicly funded immunization program.

Respiratory Syncytial Virus (RSV) Infection

- RSV is an RNA virus of the Orthopneumovirus genus and the Pneumoviridae family.
- Human RSV has two antigenic subgroups, A and B, with both often circulating during the same RSV season.
- Susceptibility is universal.
 - Almost all children are infected by RSV at least once by age two and may experience reinfections throughout life.
 - Subsequent infections can occur at any age as infection produces only partial and temporal immunity.
 - However, subsequent infections are usually less severe.

Respiratory Syncytial Virus (RSV) Infection

- Respiratory syncytial virus (RSV) infection is a major cause of lower respiratory tract illness, particularly among infants, young children and older adults.
- Primary infection manifests as pneumonia, bronchiolitis, tracheobronchitis or upper respiratory tract illness (often accompanied by fever and otitis media).
- The infection is very rarely asymptomatic
- In Canada, RSV causes yearly outbreaks of respiratory tract disease, usually starting in late fall and running through to early spring.

Respiratory Syncytial Virus (RSV) Infection

- Although RSV most commonly presents as an upper respiratory tract infection, approximately 20-30% of infants develop lower respiratory tract illness such as bronchiolitis, tracheobronchitis, or pneumonia with the first infection.
- Infants with RSV may present with non-specific signs and symptoms such as lethargy, difficulty breathing, difficulty feeding, and/or irritability, tachypnea, and cyanosis.
- Infants who develop RSV infection in the first weeks of life, especially preterm infants, are at high risk of developing apnea.
- Children under 5 may experience rapid breathing, trouble swallowing, or sepsis.

Respiratory Syncytial Virus (RSV) Infection

- Healthy adults and infants infected with RSV usually do not require hospitalization.
- Some older adults and/or infants younger than 6 months of age may require hospitalization if they are having trouble breathing or are dehydrated; however, in most cases hospitalization lasts a few days.
- Approximately 1-3% of all children under age 1 will be hospitalized because of lower respiratory tract infections caused by severe RSV, with the highest rate of RSV hospitalization occurring in the first six months of life.
- Treatment with antiviral medication is not routinely recommended and most infections resolve within 1 to 2 weeks. Supportive care is recommended for individuals with mild to moderate RSV infection.
- Treatment for severe illness, such as bronchiolitis in hospitalized infants, may include hydration, airway suction, and/or continuous positive airway pressure (CPAP)

How is RSV Spread?

- RSV is spread through particles and droplets released into the air when an infected person coughs, sneezes, breathes or speaks, or via other close contact such as kissing.
- Indirect transmission may also occur by touching surfaces contaminated with RSV and then touching eyes, nose or mouth.
- RSV can survive on surfaces for several hours and on hands for 30 minutes or more.
- RSV is communicable during the period of active disease, and for as long as a month after. Children especially are known to shed virus for long periods even after clinical recovery.

RSV Incubation:

- Time from exposure to developing symptoms ranges from 2 to 8 days, with 4 to 6 days being most common.
- The period of communicability for RSV can begin one to two days prior to symptom onset.
- Viral shedding is typically three to eight days.
- In young infants and immunosuppressed children, viral shedding may last three to four weeks or longer.



Who is at Higher Risk of Developing Complications?

- Some people are at a higher risk for developing more severe illness from RSV, especially:
 - infants
 - older persons (65 years of age or older)
 - individuals who are immunocompromised

Summary of laboratory confirmed RSV cases in Alberta last year (2023-2024)

(The seasons typically go from the last week of August of one year, until the third week of August the following year)

Location	Cases (n)
Alberta	5,046
Calgary Zone	1,674
Central Zone	577
Edmonton Zone	1,707
North Zone	701
South Zone	387
Unknown	0

Source – Alberta Health: <https://www.alberta.ca/stats/dashboard/respiratory-virus-dashboard.htm?data=summary#summary>

Summary of RSV Activity in First Nations 2023-2024

- 9 cases of RSV
 - Less than 2 years of age and adults comprised the cases
- 6 hospitalizations
- >5 deaths
- 2 GeneXpert positive results were submitted
- Co-infections included invasive pneumococcal disease, COVID-19, and group A streptococcus

Statistics from AB FNIHB CDC

RSV Prevention in Alberta

- **Synagis:**
 - A monoclonal antibody.
 - The Alberta Pediatric Respiratory Syncytial Virus (RSV) Prevention Program identifies and coordinates RSV immunoprophylaxis for eligible infants and children residing in Alberta.
 - Once eligible infants are identified, the Synagis is usually administered by public health. Some CHNs in First Nations communities may be assisting with this program to provide the monoclonal antibody during RSV season.
- **Abrysvo:**
 - The RSV adult vaccine program being started in Alberta

Currently in Alberta, there is no infant/child vaccine program.

RSV Vaccine Available in Alberta

- Only publicly funded RSV vaccine available this fall.
 - Pfizer (ABRYSVO)



RSV Vaccine Program Dates

Start Date: October 21, 2024

- Residents of congregate care facilities who are 60 years of age and older
- Individuals residing in community who are 75 years of age and older

Note: Spacing from other vaccines will need to be considered.



AHS Vaccine Biological Page

A biological pages was posted on the RSV Immunization Information webpage at:

<https://www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-ip-sm-rsv-vac-bio-pg-07-316.pdf>

Reminder: For complete and current information, always use the biological pages posted on the AHS website.

Respiratory Syncytial Virus Vaccine (RSV)

BIOLOGICAL PAGE



Section 7	Biological Product Information	Standard # 07.316
Created and approved by	Provincial Immunization Program Standards and Quality	
Approval date	October 7, 2024	Revised

	ABRYSVO
Manufacturer	Pfizer Canada ULC
Classification	Subunit
Indications for Provincially Funded Vaccine	Individuals who have not previously received any dose of RSV vaccine and are: <ul style="list-style-type: none">• 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.

	ABRYSVO
Schedule	1 dose <ul style="list-style-type: none"> If an individual received a previous dose of any RSV vaccine, they are considered up to date and no additional doses are recommended at this time.
Preferred Use	N/A
Dose	0.5 mL
Route	IM

	ABRYSVO
Contraindications/ Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reaction to a previous dose of Abrysvo. <p>Precautions:</p> <ul style="list-style-type: none"> • There is no data on the use of Abrysvo in individuals who are immunocompromised. • Immunocompromised individuals, including those taking immunosuppressant therapy, may have a diminished immune response.

ABRYSVO	
Possible Reactions	<p>Reactions reported in individuals 60 years of age and older.</p> <p>Common:</p> <ul style="list-style-type: none"> • Pain, erythema, swelling at the injection site • Fatigue, headache • Myalgia, arthralgia • Fever • Nausea, Diarrhea. <p>Uncommon:</p> <ul style="list-style-type: none"> • Vomiting. <p>Rare:</p> <ul style="list-style-type: none"> • Anaphylaxis. <p>Unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.</p>

	ABRYSVO
Pregnancy	<p>Not recommended during pregnancy at this time.</p> <ul style="list-style-type: none"> • The National Advisory Committee on Immunization (NACI) does not recommend an immunization program for individuals who are pregnant, even though vaccine is licensed for use in the third trimester (32-36 weeks). • Abrysvo has been studied in pregnant individuals from 24-36 weeks gestation. <p>Note:</p> <p>Monoclonal antibodies are recommended for infants in the prevention of RSV infection.</p>
Lactation	<p>Do not use for people who are breast/chest feeding.</p> <ul style="list-style-type: none"> • There is no data on the excretion of Abrysvo in human or animal milk.

ABRYSVO	
Composition	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> • Lyophilized powder containing 120 mcg of RSV stabilized prefusion F protein: <ul style="list-style-type: none"> ○ 60 mcg Subgroup A ○ 60 mcg Subgroup B. • Non-medicinal Ingredients: <ul style="list-style-type: none"> ○ 22.5 mg mannitol ○ 0.08 mg polysorbate 80 ○ 1.1 mg sodium chloride ○ 11.3 mg sucrose ○ 0.11 mg tromethamine ○ 1.04 mg trometamol hydrochloride ○ sterile water as the diluent.

	ABRYSVO
Blood/Blood Products	Does not contain any human blood/blood products.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	Does not contain latex.
Interchangeability	N/A

	ABRYSVO
Administration with Other Products	<p>Do not give at the same time as other vaccines.</p> <ul style="list-style-type: none"> • Limited efficacy and safety studies have been conducted on giving RSV vaccine at the same time as other vaccines. <ul style="list-style-type: none"> ○ Some studies suggest that giving RSV vaccine and other vaccines at the same time may not produce as strong of an immune response. The clinical significance of this is unknown and more evidence is required to understand if this is a risk. • Space RSV vaccine from other vaccines to adequately monitor vaccine safety and to ensure that adverse events following immunization are not attributed to another vaccine. <p>Spacing recommendations:</p> <ul style="list-style-type: none"> • Prioritize giving seasonal influenza and seasonal COVID-19 vaccines first during respiratory season. • Space RSV vaccine by 2 weeks before or after seasonal influenza and/or seasonal COVID-19 vaccines. <ul style="list-style-type: none"> ○ Space RSV vaccine by 6 weeks before or after any other non-seasonal vaccines. • Consider the dose valid if RSV vaccine is inadvertently administered without the recommended 2-or 6-week spacing interval.

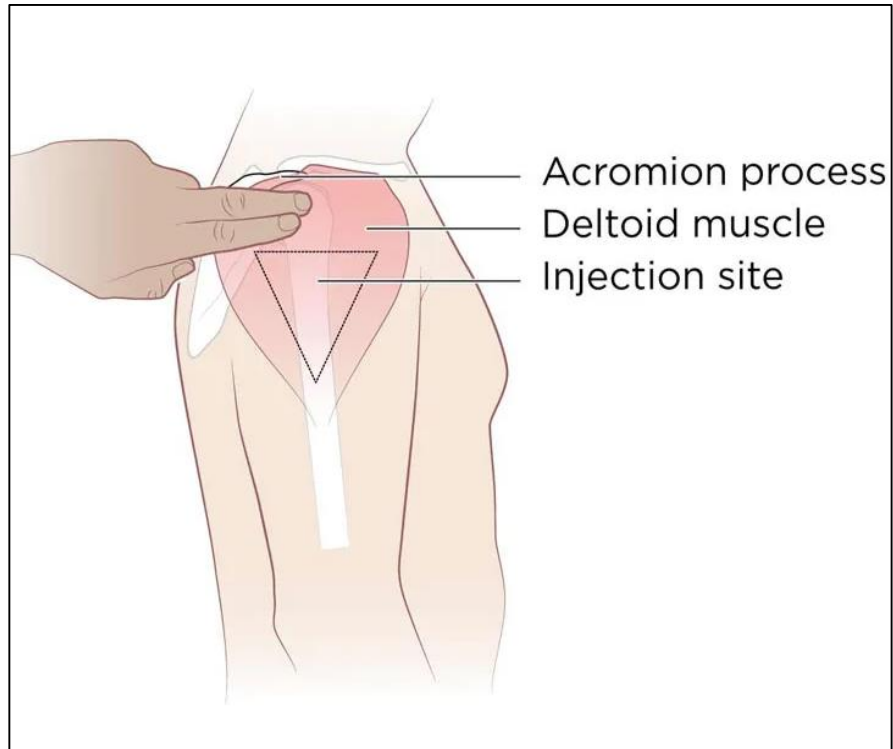
ABRYSVO	
Appearance	Final reconstituted solution is clear and colourless.
Storage	<p>Un-reconstituted vaccine:</p> <ul style="list-style-type: none"> • Store in a refrigerator between 2°C and 8°C. • Store in the original carton to protect from light. • Do not freeze. <p>Reconstituted vaccine:</p> <ul style="list-style-type: none"> • Once reconstituted, administer promptly. <ul style="list-style-type: none"> ○ If a delay in administration, store reconstituted vaccine between 15°C and 30°C and administer within 4 hours. • Do not store under refrigerated conditions (2°C to 8°C). • Do not freeze.

	ABRYSVO
Vaccine Code	RSV
Antigen Code	RSV-F
Licensed for	<ul style="list-style-type: none"> • 60 years of age and older • Individuals who are pregnant in the third trimester (32-36 weeks)
Notes	<ul style="list-style-type: none"> • 2024 October 7: Introduced Respiratory Syncytial Virus (RSV) Vaccine into the routine immunization program for residents of continuing care homes and senior supportive living accommodations that are 60 years of age and older and community dwelling seniors 75 years of age.

ABRYSVO	
Related Resources	Respiratory Syncytial Virus (RSV) Vaccine Information Sheet
References	
<p>Alberta Health. (2024, October 1). Respiratory Syncytial Virus Vaccine (RSV). <i>In Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>National Advisory Committee on Immunization. (2024, July 12). <i>Statement on the prevention of respiratory syncytial virus disease in older adults. An advisory committee statement</i>. Public Health Agency of Canada.</p> <p>Public Health Agency of Canada. (2024, August). <i>Respiratory syncytial virus (RSV) vaccines</i>. <i>In Canadian Immunization Guide: Part 4: Immunizing agents</i>. Government of Canada.</p> <p>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</p>	

Vaccine Administration: Route

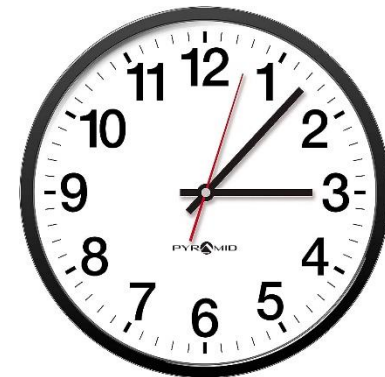
Route: Intramuscular (IM) injection in the deltoid.



Deltoid (injections site noted as the triangle area)

Anaphylaxis

- **All clients are encouraged to wait for 15 minutes after immunization**
- For clients with any known anaphylactic allergies, extend this recommended wait period to **30 minutes**.
- Refer to the FNIHB Anaphylaxis Module on OneHealth.



Vaccine Storage and Handling Principles

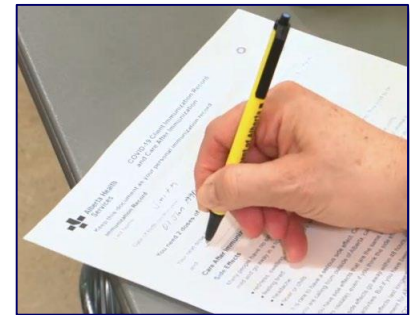
Every immunizer must:

- Understand cold chain excursions and the implications of them
- Identify the key staff members at the clinic responsible for vaccine management
- Understand the specific vaccine storage and handling recommendations for this product
- Understand how to monitor and interpret min/max thermometer readings
- Understand the actions required when a cold chain excursion.

If you have questions about vaccine storage and handling, cold chain breaks, see AB Onehealth ([FNIHB AB Region: Vaccine Management Standards](#) (February 2023) and/or reach out to a member of the **FNIHB CDC Team**.

RSV Vaccine Documentation

- Information required to be recorded on all clients includes:
 - Client demographic information
 - full name, personal health number, date of birth, gender, address including postal code
- Vaccine name & lot number
- Dosage administered
- Site of injection
- Route of administration
- Date of immunization
- Immunizer's first initial and last name, designation & signature



Documentation Reminder:

Immunization reporting to the Alberta Health must be completed.

According to the *Public Health Act: Immunization Regulation*:

- 3(1) A health practitioner who immunizes a patient shall ensure that a report respecting the immunization is submitted to the Chief Medical Officer by electronic means specified by the Chief Medical Officer.
- (2) The health practitioner shall ensure that the report respecting the immunization is submitted as soon as possible and no later than 7 days after the immunization.
- **For health centres in First Nations, reporting to Alberta Health is completed by using the RTI function in CHIP.** Please reach out to the Okaki Help Desk if you are not downloading and uploading immunization records to/from Alberta Health.

Adverse Reaction Reporting

- Use Alberta Health form: “Report of Adverse Reaction following Immunization”
 - speak to FNIHB CDC Team before completing
 - send completed form to FNIHB CDC Team
 - expect written response from FNIHB CDC Team
- Severe reactions are reportable within **24 hours**. All other reactions within one week.

Note: this is a new vaccine, so watching for and reporting adverse events will be important.

Ordering

- Vaccine can be ordered through AVI.
- Reach out to your vaccine depot to discuss when shipments will occur.
- Determine the number of eligible individuals in your community, and if possible, determine how many are interested in receiving the RSV vaccine prior to ordering.
- The RSV vaccine will be available for ordering year-round, it's not just a seasonal vaccine.
- Individuals must meet the age requirement prior to receiving the vaccine.
 - For example: if someone is turning 75 years old in March, they would wait until March to receive the vaccine.

Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing, the immunizer must:
 - Determine that the client is eligible (based on current phase and/or eligibility requirements)
 - Review the disease being prevented
 - Review vaccine

Discuss:

- Risks and benefits of getting the vaccine and not getting the vaccine
- Side effects and after care
- How the vaccine is given
- Provide the opportunity to ask questions
- Affirm verbal consent

7 Rights of Immunization

- ✓ Right product (vaccine)
- ✓ Right client
- ✓ Right dose
- ✓ Right time (date/time, interval between doses, usage expiry of vial)
- ✓ Right route, needle length, site/land marking and technique
- ✓ Right reason (meets eligibility criteria)
- ✓ Right documentation (including reason code)



Commitment to Comfort

Needle Fears

- Up to 25% of adults have needle fears
- Up to 10% of those are significant enough to avoid immunizations
 - This translates to **350,000** Albertans



Solution: The AHS Commitment to Comfort (CTC)

- There is strong evidence that these principles improve immunization experience, health outcomes, satisfaction, and repeat attendance to healthcare encounters

Commitment to Comfort – 5 Core Principles

Make a Comfort Plan

- Establish client preference and offer choice

Use Positive Language

- *Always say:* “you did well”, and leave them with a positive memory “by doing this today, you are saving lives”
- *Avoid:* pain descriptors; focus on what the client can do – to make the immunization feel better (see shift attention)

Use Comfort Positions

- When safe, sit client in an upright comfortable position
- Brief muscle tense and release or lie down if client feels faint

Shift Attention

- Shift client attention to a more pleasant activity or thought (e.g., smartphone game, music, small talk)

Use Numbing Cream

- Needs to be obtained and applied by the person being immunized prior to their appointment
- Numbing cream will not be offered at the immunization sites
- Client needs to talk with a pharmacist to select and obtain a product that is right for them





References

- Alberta health Services (2024). Respiratory Syncytial Virus (RSV) Immunization: Information for Health Professionals <https://www.albertahealthservices.ca/cdc/Page19000.aspx>
- Province of Alberta (2024). Alberta Public Health Disease management Guidelines: Respiratory Syncytial Virus. <https://open.alberta.ca/dataset/f6e6a1cd-6cfa-403c-a8ed-840525590f34/resource/32172f06-43da-463b-907e-684c70cc6fcc/download/hlth-phdmg-respiratory-syncytial-virus-2024-08.pdf> Retrieved October 10, 2024.
- Province of Alberta (2018). Public health act: Immunization regulation. https://kings-printer.alberta.ca/1266.cfm?page=2018_182.cfm&leg_type=Regs&isbncln=9780779806669
- Public Health Agency of Canada(2023). *Respiratory syncytial virus: Infectious substances pathogen safety data sheet* <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/respiratory-syncytial-virus.html>

Questions?
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