Association of Ontario Midwives

Delivering what matters.

Tuesday October 1, 2024

INFANT AND HIGH-RISK CHILDREN RESPIRATORY SYNCYTIAL VIRUS (RSV) PREVENTION PROGRAM

Your Webinar Will Begin Momentarily

Infant RSV Prevention Program 2024/25

Association of Midwives

Ministry of Health

September 26, 2024

Ontario

RSV - Background

- RSV is a severe lower respiratory illness that impacts infants, young children, and older adults, often resulting in hospitalization. Highest rates of RSV are seen in infants 3 months and younger, decreasing with age, with risk decreasing as the infant ages (usually around 8 months).
- The disease burden of RSV, influenza, and COVID-19 has strained hospital capacity in Ontario during recent respiratory seasons. **The 2022 - 23 RSV season saw:**
    - **3,850 Hospitalization admissions of children under 2 years**
    - **539 ICU admissions of children under 2 years**
- There are two types of products that can prevent severe RSV infection:
    - vaccines, which stimulate the immune system to produce antibodies (Abrysvo™ – Pfizer), and
    - prophylaxis drugs, which offer antibodies for protection (Synagis® - AstraZeneca; Beyfortus™ – Pfizer)
- Up until 2023, no RSV vaccine had been approved in Canada, and only Synagis® was utilized in Ontario's program for high-risk infants.
    - The previous program was only for high-risk infants and children and required an adjudication process for eligibility.

Infant RSV Prevention Program: 2024-25 Season

	Beyfortus™	Abrysvo™
Manufacturer	Sanofi	Pfizer
Product Type	Monoclonal Antibody	Stabilized subunit vaccine
Eligibility	• Born in 2024 before current RSV season • Born during the 2024/25 RSV season • Children 12 months and up to 24 months of age who remain vulnerable from severe RSV disease (see Table 1)	Pregnant individuals from 32 to 36 weeks gestational age Delivering during RSV season
Dosing	1 dose Age and Weight-based dosing **Infants born during the current RSV season** < 5kg: 50 mg in 0.5 mL ≥ 5 kg: 100 mg in 1.0 mL	1 dose: 0.5 mL (120 mcg) Requires reconstitution
Route	Intramuscular	Intramuscular (deltoid preferred)
Timing (tentative)	October through to end of March	September through to end of March

Infant RSV Prevention Program: 2024-25 Season

Table 1: High-risk Infants for RSV Disease During Second RSV Season (up to 2 years of age)
• Chronic lung disease of prematurity, including bronchopulmonary dysplasia/chronic lung disease **Note:** Children who were < 12 months of age and approved for coverage in the previous RSV season for chronic lung disease and bronchopulmonary dysplasia remain eligible.
• Hemodynamically significant congenital heart disease
• Severe immunodeficiency
• Down Syndrome / Trisomy 21
• Cystic fibrosis with respiratory involvement and/or growth delay
• Neuromuscular disease
• Severe congenital airway anomalies impairing clearing of respiratory secretions

NACI Statement and Recommendations

- Only one of these products is recommended to protect infants from RSV, and using both is unnecessary except in certain circumstances.
    - Only one product is publicly funded in Ontario (i.e., parents need to decide between vaccination during pregnancy or antibody administration for their infant)
    - Some exceptions to this (see slide 18)
- The National Advisory Committee on Immunization (NACI) recommends Beyfortus as it has the strongest evidence for infant protection and fewer side effects than the vaccine.
- **Nirsevimab** has been shown to **reduce hospital admission associated with RSV by 81 to 83%.** It also has shown an **80% reduction** in medically attended RSV respiratory tract infection in healthy infants.
- **Abrysvo** vaccine administered to pregnant women and pregnant people results in a **reduction in RSV associated hospital admission in their infants by 57%.** It also reduces medically attended RSV respiratory tract infection in their infants by 51% in their first RSV season.

Immunity

- There are two types of immunity:
  - **Active Immunity** involves stimulating the immune system to produce antibodies against a specific pathogen.
  - **Passive Immunity** involves directly transferring antibodies to an individual, protecting a specific antigen.

	Active	Passive
Mechanism	1. **Natural Immunity** through exposure to and recovery from disease 2. **Vaccine-induced immunity** through vaccination to create an immune response	1. Antibodies passed from pregnant individual to baby during pregnancy and through breast milk. 2. Antibodies administered through medications such as monoclonal antibodies and immune globulins
Protection	• Provides long-term protection • Effective about 10 days to 2 weeks after administration • Helps build immune memory for faster and stronger responses for future exposures	• Provides protection immediately after administration • Short-term protection, typically lasting up to 6 months • Beneficial for individuals who need quick immunity or cannot produce their own antibodies
Examples	• Natural infection with diseases like chicken pox or measles • Vaccines for diseases like measles, polio, influenza	• Monoclonal antibodies used to prevent diseases like RSV and COVID-19 • Antibodies passed from pregnant individuals to their babies for early life protection

Comparison of the Monoclonal Antibody and Vaccine for Infant RSV Prevention

	Monoclonal Antibody Provided to Infant	Vaccine Provided to Pregnant Individuals
Immunizing Agent	Beyfortus (Nirsevimab)	Abrysvo
Indication for Use	Infants and high-risk children up to 24 months of age (to be administered during RSV season)	Pregnant individuals between 32-36 weeks gestation who will deliver during RSV season
Type of Immunity for Infant	Passive	Passive
How it Works	Through injection, provides ready-made antibodies for immediate protection	Stimulates the pregnant individual's immune system to produce antibodies. Antibodies are transferred to the infant through the placenta and breastfeeding.
Timing of Administration	Before or during RSV season	Before or during RSV season (September to February)
How long it takes to be effective	Protection immediately after administration	Approximately 2 weeks following administration
Duration of Infant Protection	Short-term, up to 6 months	Up to 6 months from birth

Beyfortus Administration Guidelines for Infants and Children

Category	Weight	Dose	Timing
Infants born during the current RSV season∞	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Administered from birth
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Administered from birth
Infants born in 2024 before the current RSV season starts (up to 12 months of age)*	< 5 kg	50 mg in 0.5 mL (100 mg/mL)	Shortly before the start of the RSV season∞
	≥ 5 kg	100 mg in 1 mL (100 mg/mL)	Shortly before the start of the RSV season∞
Children over 12 months and up to 24 months of age and at continued high-risk from RSV infection	N/A	200 mg (two 1 mL injections of 100 mg/mL)†	Shortly before the start of their second RSV season∞

∞ Due to the seasonality of the RSV virus, Beyfortus should be administered shortly before and during the active RSV season. The RSV season is generally from November to April, peaking in December, with variations in various regions in Ontario and between years.

*NACI recommends Beyfortus especially for infants less than 8 months of age due to risk of severe outcomes in younger infants.

†If a child weighs less than 10 kg entering their second RSV season, consideration can be given to administering a single dose of 100 mg at the clinical discretion of the provider.

Administration Considerations for Beyfortus

Co-administration with other Vaccines	• May be administered on the same day or any time before or after routine childhood vaccines, including influenza. • No interval between Beyfortus and live virus vaccines is necessary.
Contraindications and Precautions	• Those with known hypersensitivity or a history of a severe allergic reaction (e.g., anaphylaxis) to any product ingredients, including non-medicinal ingredients or materials in the product's packaging. • Caution for individuals with bleeding disorders. • Individuals who have a moderate or severe acute illness, with or without fever, should delay immunization until they have recovered before receiving Beyfortus. The ministry will make this change in the next guidance version revision.
Administration after RSV Infection	• Generally, not necessary or recommended for an infant who has had a confirmed RSV infection during the current season. • Additional benefit after recovery is unknown and expected to be low, as the risk of rehospitalization in the same season is very low. • Consideration may be given to severely immunocompromised infants who may not mount an adequate immune response to the RSV infection.

Excipient List

Ingredient	50 mg/0.5 mL dose	100 mg/mL dose	Purpose in Product	Common Uses
Arginine Hydrocholoride	8 mg	17 mg	Stabilizer	Dietary supplements, protein shakes
L-histidine hydrochloride monohydrate	1.6 mg	3.3 mg	Acidity regulator	Antacids, food preservatives
Polysorbate 80	0.1 mg	0.2 mg	Emulsifier	Ice cream, cosmetics, salad dressings
Sucrose	21 mg	41 mg	Stabilizer	Table sugar, candies, soft drinks
Water for injection	USP	USP	Diluent (volume)	Purified water used in medical and pharmaceutical products
Does **NOT** contain gelatin (some individuals may be concerned about potential porcine or bovine origin).				

Nirsevimab: Safety Profile Across a Broad Infant Population

	Phase 2b[1] 29 to <35 wGA		MELODY[2] All Subjects ≥35 wGA		MEDLEY[3] Season 1 Preterm		MEDLEY[3] Season 1 CHD/CLD		MEDLEY[4]* Season 2 CHD/CLD		
	Placebo (n=479)	Nirsevimab (n=968)	Placebo (n=996)	Nirsevimab (n=1998)	Palivizumab (n=206)	Nirsevimab (n=406)	Palivizumab (n=98)	Nirsevimab (n=208)	Pali/Pali (n=42)	Pali/Nirs (n=40)	Nirs/Nirs (n=180)
Serious adverse events	16.9%	11.2%	7.4%	6.3%	5.3%	6.9%	20.4%	19.2%	0.0%	10.0%	9.4%
Adverse events of Grade 3 or higher	12.5%	8.0%	3.8%	3.1%	3.4	3.4%	13.3%	14.4%	2.4%	10.0%	7.8%
Adverse events of special interest	0.6%	0.5%	0%	0.2%	0.0%	0.2%	0.0%	0.5%	0.0%	0.0%	0.0%
Deaths	3	2	0	4	0	2	1	3	0	0	0

- None of the serious adverse events or deaths were considered related to nirsevimab
- Overall, incidence of nirsevimab anti-drug antibody was low across studies with no safety concerns
- Nirsevimab had a favorable safety profile with similar types and frequencies of adverse events compared with the placebo or palivizumab arms

*Groups labels indicate which product the participants received in both seasons (Season 1 / Season 2)
CHD, congenital heart disease; CLD; chronic lung disease; Nirs, nirsevimab; Pali, palivizumab; wGA, weeks gestational age.

References: 1. Griffin MP, et al. *N Engl J Med*. 2020;383(5):415-425. 2. Muller WJ, et al. *N Engl J Med*. 2023;388:1533-1534. 3. Domachowske J, et al. *N Engl J Med.* 2022;386(9):892-894.
4. Domachowske JB, et al. *J Pediatric Infect Dis Soc*. 2023;12(8):477-480.5. Hammitt LL, et al. N Engl J Med. 2022;386(9):837-846.

Slide courtesy of Sanofi

The safety profile of nirsevimab was consistent with data from previous trials

In the clinical development program, the 3 most frequent AEs were *rash* (0.7%), *pyrexia* (0.5%) and *injection site reaction* (0.3%)[1]

HARMONIE STUDY

Treatment-related AEs occurred in 2.1%of patients. Most adverse events in the two trial groups were grade 1or 2 in severity[2]

In Spain, >200,000 doses of nirsevimab have been administered with no new safety signals identified[3]

Around 2 million doses of nirsevimab have been distributed through the end of February 2024.[3-5]

In post-marketing surveillance, hypersensitivity reactions have been reported following the use of nirsevimab, including serious hypersensitivity reactions.* At time of initial approval, the Product labeling already included a warning relating to hypersensitivity reactions, including anaphylaxis, having been observed with other monoclonal antibodies. In response to the post-marketing reports, the Product labeling was updated with a warning relating to the occurrence of serious hypersensitivity reactions following the administration of Beyfortus and the inclusion of hypersensitivity in the adverse reactions section. To date, no other risks have been identified based on data reported from post-marketing surveillance.

References: 1. Beyfortus. Summary of product characteristics. Accessed 29 March 2024. 2. Drysdale SB, et al. *N Engl J Med.* 2023;389(26):2425-2435. 3. Ministerio de Sanidad. Accessed 9 April 2024. https://www.sanidad.gob.es/areas/promocionPrevencion/vacunaciones/comoTrabajamos/docs/Nirsevimab.pdf 4. Sanofi Beyfortus™ (nirsevimab-alip) Injection Update. Press release. Sanofi. 14 December 2023. Accessed 1 May 2024. https://www.news.sanofi.us/2023-12-14-Sanofi-Beyfortus-TM-nirsevimab-alip-Injection-Update 5. Sanofi to release 230,000 additional doses of RSV immunization nirsevimab. News release. AAP News. 14 December 2023. Accessed 1 May 2024. https://publications.aap.org/aapnews/news/27504/Sanofi-to-release-230-000-additional-doses-of-RSV?autologincheck=redirected 5. VAERS - Data Sets (hhs.gov) Last updated: April 5, 2024

Slide courtesy of Sanofi

Beyfortus – Adverse Events Following Immunization (AEFI)

Nirsevimab is a fully-humanized monoclonal antibody, which tends to be more tolerable and less reactogenic than previous-generation antibodies.

Observation Post-administration: Recipients should be observed for at least 15 minutes after immunization. A 30-minute observation period is preferred should concerns regarding possible allergies arise.

Common side effects during clinical trials included:

- Rash
- Pyrexia
- Injection site reactions within seven days

- Some clinical trial participants experienced systemic adverse events, such as:
  - Bronchiolitis
  - Pneumonia
  - Bronchitis
- As Beyfortus is a new drug product, its safety and tolerability will continue to be monitored in post-market safety surveillance.
- Unlike vaccines, monoclonal antibodies are not reportable under s.38 of the *Health Protection and Promotion Act*
  - Adverse Events Following Immunization (AEFI) with Beyfortus should be managed as per practices and organizational policies for other medicines and therapeutics
  - Report any AEFIs to Health Canada, using the Side Effect Reporting Form.

Administration Considerations for Abrysvo

Co-administration with other Vaccines	**Concurrent administration to pregnant persons with tetanus, diphtheria, and acellular pertussis (Tdap), COVID-19, and influenza vaccines can be considered. Different vaccines should always be given at different vaccination sites.**
Contraindications and Precautions	• Those with known hypersensitivity or a history of severe allergic reaction (e.g., anaphylaxis) to any product ingredients, including non-medicinal ingredients or materials in the packaging. • Caution for individuals with bleeding disorders • Individuals with moderate or severe illness, with or without fever, should wait until they have recovered
Administration after RSV Infection	• Those with severe acute illness should wait until symptoms have subsided • No specific interval recommended between infection and vaccination

Abrysvo – Adverse Events Following Immunization (AEFI)

Observation Post-administration: Vaccine recipients should be observed for at least 15 minutes after immunization. A 30-minute observation period is preferred should concerns regarding possible allergies arise.

- **Common side effects** during clinical trials included:
  - Pain at the injection site
  - Headache
  - Myalgia (aching, tenderness, or soreness in the muscles)
  - Nausea
- A slightly higher rate of preterm births (not statistically significant) was observed in the RSV vaccine group compared to the placebo group.
  - Current data cannot definitively establish or dismiss a direct association between the vaccine and preterm birth
  - The National Advisory Committee on Immunization (NACI) recommends the vaccine's use on a case-by-case basis in pregnancy
- As Abrysvo is a new vaccine, its safety and tolerability will continue to be monitored in post-market safety surveillance.
- Healthcare providers (e.g., physicians, nurses, and midwives) are required by law (i.e., *Health Protection and Promotion Act,* s.38) to report AEFIs associated with the RSV vaccine to their local public health unit.

Eligibility Guidelines for Beyfortus after Abrysvo During Pregnancy

- **For the following infants whose parent received Abrysvo™, Beyfortus® should be administered to:**
  - Infants born less than 14 days after administration of Abrysvo™ or
  - Infants who meet the medical criteria for increased risk from severe RSV disease:
    - All premature infants (i.e., born < 37wGA)
    - Chronic lung disease (CLD), including bronchopulmonary dysplasia, requiring ongoing assisted ventilation, oxygen therapy or chronic medical therapy in the six months prior to the start of RSV season
    - Hemodynamically significant congenital heart disease (CHD) 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.

Administration Settings - Ontario

Beyfortus (NACI Preferred Product) – arrival at provincial depot mid-to-late October

i. **In-season births:** Hospitals soon after birth before discharge

ii. **Out of season Infants and Births Outside Hospital:** Primary Care, Public Health supportive role

iii. **Second RSV Season Infants (up to 2 y/o and at high risk):** Pediatric Specialists, Primary Care, Outpatient Hospital Clinics

Abrysvo – can be ordered now

i. Primary Care
ii. Obstetricians
iii. Midwives

Midwives and Infant RSV Prevention Products

- PHUs have been encouraged to work with local midwifery groups to ensure access to Beyfortus and Abrysvo for their pregnant patients and newborns.

- Hospitals have been directed to share medical directives among OH regions/hospitals and to include midwives so that infants born in the hospital under midwife care may receive immunization with Beyfortus before discharge

Access for community births and unattached clients:

- The ministry has requested PHUs to work with local midwifery practices to:
  - Encourage the referral of the infant to their primary care provider (if they have) to receive Beyfortus immunization as soon as possible;
  - Assist with linking the infant to clinics in local communities or local hospitals that are offering Beyfortus immunization, when the infant is unattached to a primary care provider (e.g., Peel, York);
  - Provide Beyfortus immunization when all other options above have been exhausted.

Storage & Stability

Beyfortus	Abrysvo

• To ensure optimal protection, Beyfortus must be stored in a refrigerator at +2˚C and +8˚C and kept in the outer carton until administration to protect it from the light.
• It cannot be frozen, shaken, or exposed to heat.
• Only under extenuating circumstances, it may be kept at room temperature (+20˚C and +25˚C) for a maximum of 8 hours, then discarded if not used.
• Once removed from the refrigerator, it cannot be returned to the refrigerator and must be administered within 8 hours or discarded.
	• To ensure optimal protection, Abrysvo (both the lyophilized antigen powder and diluent) must be stored in a refrigerator at +2˚C and +8˚C and kept in the original carton until administration to protect it from light.
	• It cannot be frozen.
	• After reconstitution:
	  • It should be administered immediately (within 4 hours).
	  • It must be stored between +15˚C and +30˚C.
	  • It cannot be returned to the refrigerator.
	  • It cannot be frozen.

Health Care Provider (HCP) RSV Vaccine Ordering and Wastage Reduction Strategies

- HCPs will order products from their distributor (PHU or OGPMSS) according to their typical order processes. Please contact your local PHU for more information.
- Fridge inspections and new site set-ups should be coordinated through local public health units.
    - The internal refrigerator temperature must be stabilized between +2˚C and +8 +8˚C for a recommended period of 7 consecutive days prior to stocking the vaccine. Some PHUs may have different requirements.
- Storage and transporting of product must comply with the Vaccine Storage and Handling Guidelines. This includes:
    - Having the appropriate packing materials, including an insulated cooler, gel pack(s), flexible ice blankets, and a temperature monitoring device (i.e., digital maximum-minimum thermometer).
    - Documenting twice daily refrigerator temperatures (current, maximum, minimum) using a temperature logbook.
        - Refer to pages 15 and 16 of the guidelines for important information about transporting vaccines outside a midwifery practice. This process applies to all immunization products transported to a patient's home or clinic where it is not normally stored)
    - Under no circumstances may immunization products be stored in personal refrigerators.
    - Having a contingency plan in the event of a refrigerator malfunction or electricity disruption

For More Information:

1. Please contact your local Public Health Units - Immunization Program
    - Public Health Nurses in the Healthy Babies Healthy Children will not have detailed implementation information.
    - List of health units sorted by municipality
    - List of municipalities sorted by health unit
    - List of public health unit offices and sub-offices
2. Check out our ministry website for health care professionals for guidance documents: Health Care Providers Website
3. The ministry has factsheets available for parents and caregivers: Public Website
4. Provincial Council for Maternal and Child Health website

Appendices and Resources

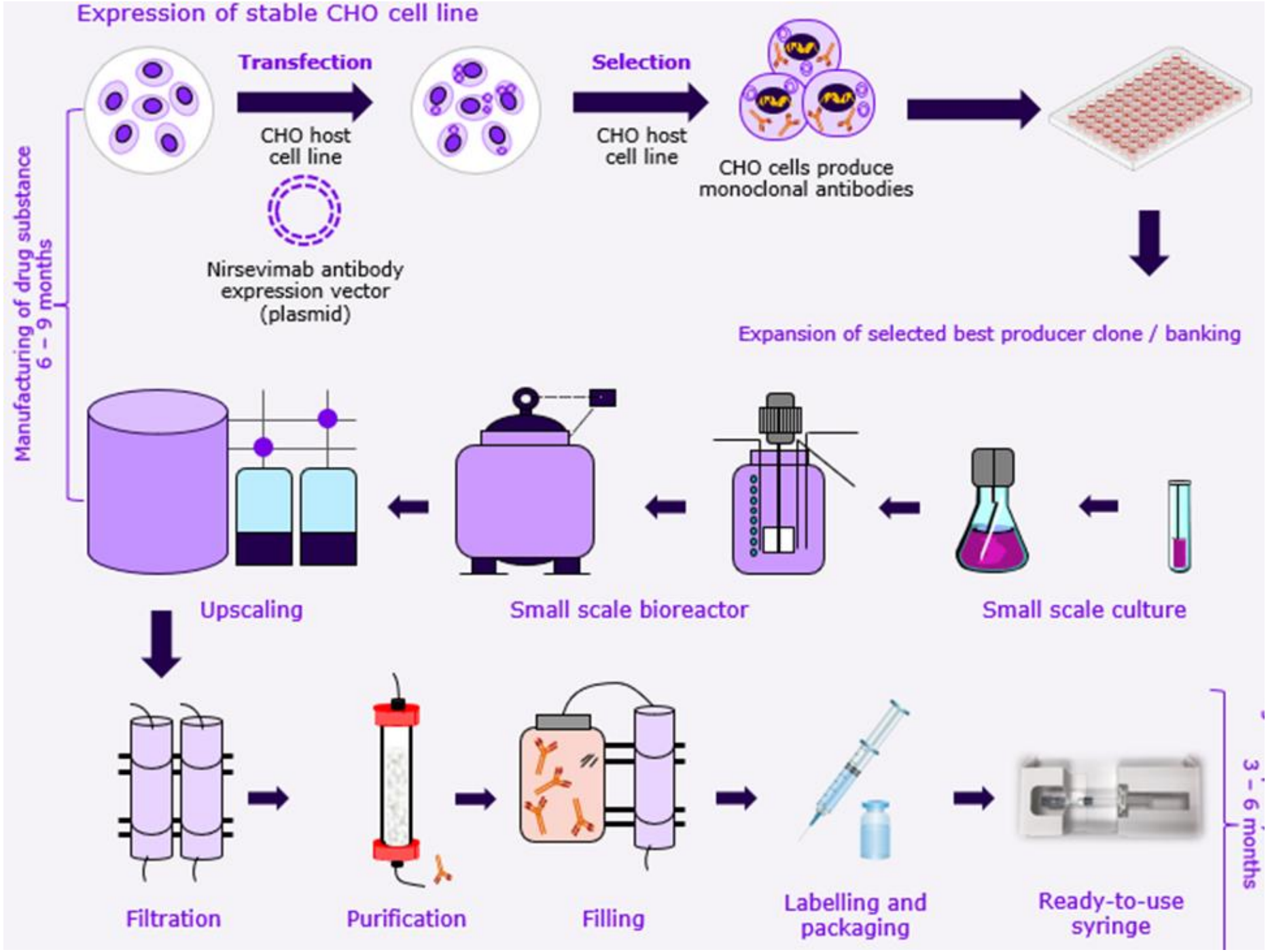
Ontario

Manufacturing Process for Nirsevimab

Duration of entire process: 12 – 18 months

No fetal cells are used in any step of the production

- Chinese Hamster Ovary (CHO) are used as the host cell line, which will be transfected with a nirsevimab antibody expression vector (plasmid).
- Selection of the CHO cells producing mAb followed by 2 rounds of single cell cloning and expansion of selected best producer clones
- Sequential amplification in culture of expressing cell line from 1mL to 12kL
- Culture undergoes a series of purification steps ending up in > 99% pure concentrated solution
- This concentrated solution is stored frozen
- The concentrated composition is further processed into the drug product which further undergoes purification and filling and release
- All these steps are framed with a comprehensive and coherent analytical / quality checks and validation of the processes further leading to the release of product
- The released product is processed further for filling into refilled syringes, then these syringes are labelled, packed, and shipped for distribution


Expression of stable CHO cell line
Transfection
CHO host cell line
Nirsevimab antibody expression vector (plasmid)
Selection
CHO host cell line
CHO cells produce monoclonal antibodies
Expansion of selected best producer clone / banking
Manufacturing of drug substance 6 – 9 months
Small scale culture
Small scale bioreactor
Upscaling
Filtration
Purification
Filling
Labelling and packaging
Ready-to-use syringe
3 – 6 months

Ontario

Available Resources Online

Association	Materials
Association of Ontario Midwives	Respiratory Syncytial Virus Resources
Provincial Council for Maternal and Child Health (PCMCH)	Fact Sheet for Providers English RSV Fact Sheet - For Providers (EN) Final (pcmch.on.ca) French RSV Fact Sheet - For Providers (FR) Final (pcmch.on.ca) Fact Sheet for Parents English RSV Fact Sheet - For Parents (EN) Final (pcmch.on.ca) French RSV Fact Sheet - For Parents (FR) Final (pcmch.on.ca)
Centre for Effective Practice	RSV prevention program resource for infants in Ontario 2024-2025:
OMA	Physician webpage: includes an overview of the program as well as information about how to bill for counselling and administration of the antibody/vaccine
CPHA Health Digest	Vaccine Hesitancy
CPS	Practice Point: Working with vaccine-hesitant parents – an update

Available Resources Online

Association	Materials
Canadian Premature Babies Foundation	Podcasts | CPBF (cpbf-fbpc.org) – Season 3 E1: RSV epi and burden of care in 2023 E2: RSV mitigation and treatment E3: Decreasing the risk of transmitting RSV to your preemie E4: Bringing a preemie home during RSV season YouTube: New approaches to deal with RSV (Oct/23) Special Preemie Chat- RSV (Nov/23) Common Respiratory Illnesses – Parent Handbook RSV factsheet National Survey Results (2023) – focus on parental knowledge and understanding of RSV and how to reduce the risk of infection
Canadian Immunization Guide	Communicating effectively about immunization
SOGC	SOGC Statement on RSV Immunization to Prevent Infant RSV Infection Video: Give it Your Best Shot - making vaccine recommendations during pregnancy

Available Resources Online

Association	Materials
19 to Zero	Vaccine Conversations: Training Program for Optimized Vaccine Communication Booster Hesitancy Refusal Special Populations Healthcare Workers Channel Tools to overcome vaccine hesitancy Vaccine and vaccine hesitancy in Ontario
Immunize Canada	Video: RSV in young children: A guide for parents and caregivers Fact sheet: RSV What you need to know Products Available in Canada to protect against RSV RSV resources including factsheets, program charts, videos, posters, social media images, NACI statements Counselling the Public – resources to help counsel people of all ages about the importance of immunization

Available Resources Online

Association	Materials
BORN	O'MAMA Website - information for families from pre-pregnancy to newborn care and includes immunization information. They are planning to add the infant rsv product information • Immunization section
Health Network for Uninsured Clients (HNUC)	Newborn OHIP eligibility for undocumented parents
Public Health Ontario	Ontario Respiratory Virus Tool | Public Health Ontario An anticipated update in fall of 2024 will include RSV data on the summary page The PIDAC – ICP document Best Practices for Infection Prevention and Control in Perinatology | February 2015 Based on publication date, information on immunization does not reflect the 2024-25 program The Key features of Influenza, SARS-CoV-2 and Other Common Respiratory Viruses (publichealthontario.ca) As above, information on immunization does not reflect the 2024-25 program

Association of Ontario Midwives

Delivering what matters.

RSV: AOM ADVOCACY AND SUPPORTS

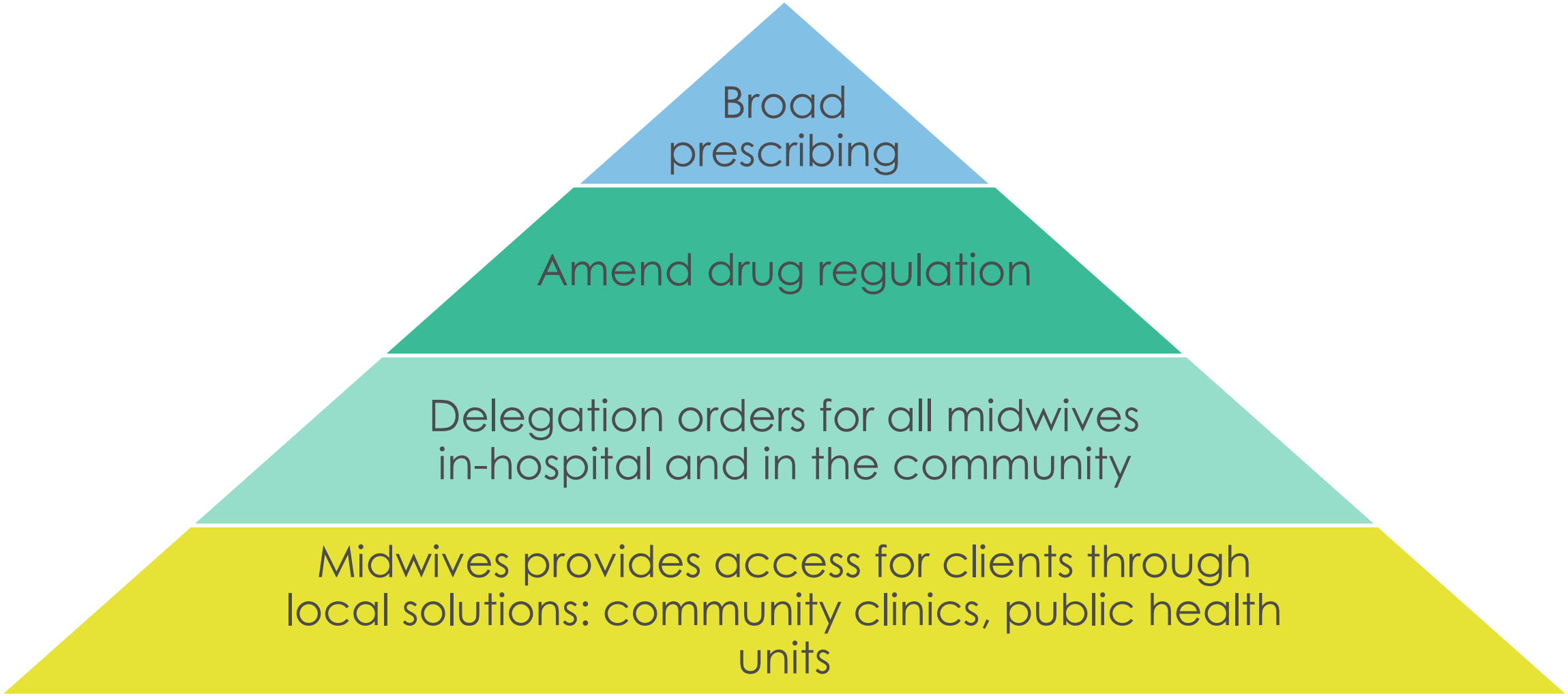
Designated drug advocacy

"Ontario's current approach of ***restricting midwives to a list of drugs stifles our ability to provide care.*** *It creates red tape for patients. It means patients must obtain additional appointments elsewhere simply to access a medication -* ***creating barriers to timely access to care and increasing cost and risk.***

One example of the ***imminent redundancy of the list in the proposed Regulation concerns the need to protect newborns from RSV.*** *How many babies will end up in hospital because of the unnecessary barriers set by this Regulation?*

- AOM, November 2023

Hierarchy of Solutions



AOM to MOH

- Advocate to change word "**vaccine**" to "**immunization**" in the regulation **BEFORE** the start of RSV season

- Provide a **province wide** medical directive for midwives

- Request that hospitals and public health units work with their midwifery partners to ensure access **both in and out** of hospital

AOM to HEALTH PARTNERS

- Mobilized BORN, PCMCH to send letters to Regulatory Branch

- Met with CEO, HIROC regarding issue of delegation especially as it pertains to community births

- Liaise with CMO to ensure consistency of messaging and to amplify their efforts

AOM TO MIDWIVES

- Seeking opportunities to share medical directives with Head Midwives
- Collating ways that midwives are creating access for clients
- Developed a resource on considerations for managing adverse reactions in the community setting
- Updated Rm Rx: pharmacopeia app with information for Beyfortus and Abrysvo
- Created a resource hub on our website

CONTINGENCY PLANNING FOR COMMUNITY BIRTHS

- Seek extension of hospital medical directive to community settings
- Visit general care provider (i.e., GP, NP, Family Health Team, CHC)
- Consider post-partum programs (i.e., out-patient bilirubin clinic, Family Health Team that offers tongue tie releases or lactation support)
- Obtain a medical directive from a local HCP (i.e., Pediatrician, GP, NP) to administer in clinic or other out-of-hospital setting
- Direct to a regional Public Health vaccine clinic. Clinics will serve uninsured and/or unattached.

Resource Hub

Respiratory Syncytial Virus

Respiratory Syncytial Virus (RSV) is a common lower respiratory tract infection affecting most children before they reach the age of 2.(1)

Health Canada has approved several new products for use in the protection of infants.

1. nirsevimab, a long-acting monoclonal antibody for newborns, most effective for the first 6 months after administration;
2. RSVpreF, an RSV stabilized vaccine for pregnant individuals, offering both active and passive immunity for newborns.

Beyfortus administration in community settings: FAQ

- **How can my client born in the community receive Beyfortus?**
- **Who do I contact at my local public health unit regarding Beyfortus administration?**
- **How do I prepare to manage adverse reactions to Beyfortus in the community setting?**
- **What considerations exist for the timing of BEYFORTUS administration in the community setting?**

https://www.ontariomidwives.ca/respiratory-syncytial-virus

Association of Ontario **Midwives**

Resources

Resources for midwives

Toolkits, Fact Sheets and Instructions

RSV Symptoms, Treatment, Prevention and Risks
Health Canada provides a summary of RSV symptoms and effective prevention measures as well as specific information on what healthcare providers need to know.

Protecting Infants and High-Risk Children during RSV Season: For Healthcare Providers
This PCMCH fact sheet available in English and French supports healthcare providers in understanding the changes associated with the recent expansion of Ontario's RSV prevention program for infants and high-risk children.

2024-2025 RSV Prevention Program for infants in Ontario
This toolkit, created by the Centre for Effective Practice includes patient resources, conversation guides, eligibility guides and more to support primary care through Ontario's new RSV Prevention Program for infants in the 2024-2025 RSV season.

Respiratory Syncytial Virus (RSV) prevention program: Eligibility criteria
Information from the Ministry of Health outlining eligibility criteria for the RSV prevention program.

BORN RSV Data Collection
The BIS is changing to capture the new data about infant RSV protection. As of November 2024, four new data elements will be included. More information can be found in the RSV Data Elements List and the BORN RSV Data Collection FAQ.

RSVpreF administration instructions
Safety and administration instructions for the RSV stabilized vaccine for pregnant individuals can be viewed here.

Guidance

NACI Statement on the prevention of RSV disease in infants
This statement from the National Advisory Committee on Immunization focuses on the protection of infants and children from RSV disease highlighting two immunization products. It provides independent advice and recommendations for immunization providers.

Client Handouts

Protecting your child from RSV: For Parents and Expectant Parents
This fact sheet for clients available in English and French from PCMCH includes essential tips and recommendations for safeguarding infants and high-risk children from RSV, with a focus on the monoclonal antibody medication.

Webinars

Updates in Pediatric RSV Prevention for Midwifery Practice with Dr. Jasleen Kaur Grewal
This webinar will provide midwives with information regarding the changing landscape of pediatric RSV prevention in the Canadian context. This presentation will provide a comprehensive overview of RSV, its impact on public health, and an understanding of new developments in RSV prevention including vaccines and monoclonal antibodies.

https://www.ontariomidwives.ca/respiratory-syncytial-virus

General Pharmacopeia Resources

https://www.ontariomidwives.ca/preventing-medication-errors

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QUESTIONS