

~ **FINAL PROGRAM PLAN** ~

**Manitoba's 2018/19 Seasonal Influenza  
Immunization Program**

**September 2018\***

Manitoba Health, Seniors and Active Living  
Active Living, Indigenous Relations, Population and Public Health Division  
Active Living, Population and Public Health Branch

\* Subject to change; please go to [www.manitoba.ca/health/flu/pro.html](http://www.manitoba.ca/health/flu/pro.html) to access the most current version of this Interim Program Plan.

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The content of this Interim Program Plan are that of the opinion of Manitoba Health, Seniors and Active Living in consultation with the National Advisory Committee on Immunization's (NACI's) **Statement on Seasonal Influenza Vaccine for 2018/19.**

## Acronyms

<b>ACIP</b>	Advisory Committee on Immunization Practices
<b>AEFI</b>	Adverse event following immunization
<b>CI</b>	Confidence interval
<b>DPIN</b>	Drug Programs Information Network
<b>FNIHB</b>	First Nations and Inuit Health Branch
<b>GBS</b>	Guillain-Barré syndrome
<b>IIV</b>	Inactivated influenza vaccine
<b>ILI</b>	Influenza-like illness
<b>LAIV</b>	Live attenuated influenza vaccine
<b>LTCF</b>	Long-term care facility
<b>MDV</b>	Multi-dose vial
<b>MHSAL</b>	Manitoba Health, Seniors and Active Living
<b>MOH</b>	Medical Officer of Health
<b>NACI</b>	National Advisory Committee on Immunization
<b>ORS</b>	Oculo-respiratory syndrome
<b>PFS</b>	Pre-filled syringe
<b>PHIN</b>	Personal health identification number
<b>PVAC</b>	Provincial Vaccine Advisory Committee
<b>RCT</b>	Randomized controlled trial
<b>RHA</b>	Regional health authority
<b>VE</b>	Vaccine effectiveness
<b>WHO</b>	World Health Organization

## Purpose

The purpose of this Program Plan is to provide **all** health care providers and regional health authorities (RHAs), including the First Nations and Inuit Health Branch (FNIHB), that participate in the annual Manitoba Seasonal Influenza Immunization Program, with the provincial program details for the upcoming 2018/19 influenza (flu) season.

## 2018/19 Program Dates

- **May 1:** The National Advisory Committee on Immunization's (NACI's) "*Statement on Seasonal Influenza Vaccine for 2018/19*" is posted on the Government of Canada, National Advisory Committee on Immunization website at: [www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html).
- **August 15 - September 14:** Health care providers can place their first order for this year's flu vaccine. Orders will be collected and shipped once product arrives in Manitoba (late September). Shipment will follow a schedule based on priority locations and then based on client ID (more detail provided below under "Vaccine Distribution"). For more information on the provincial delivery of the flu vaccine, go to: [www.manitoba.ca/health/flu/distribution.html](http://www.manitoba.ca/health/flu/distribution.html).
- **August 31:** The updated provincial "seasonal flu" website, ([www.manitoba.ca/health/flu/index.html](http://www.manitoba.ca/health/flu/index.html)) will go live (**updated and live, August 1**). Updated print materials including promotional/educational resources (e.g. factsheet, poster, brochure, etc.) and order forms will be posted on the seasonal flu website.
- **September 3:** Deadline for health care providers and regions to submit their clinic dates, times and locations for inclusion on the Manitoba Health, Seniors and Active Living (MHSAL) website and/or through Health Links–Info Santé. Please email information to: [Angela.Peck@gov.mb.ca](mailto:Angela.Peck@gov.mb.ca).
- **September 28:** MHSAL will mail the annual pneumococcal polysaccharide 23 (Pneu-P-23) reminder letter to people who have turned 65 years of age in the past year and who have never received a dose of Pneu-P-23 vaccine.
- **1<sup>st</sup> week of October (exact date TBD):** Launch of the provincial 2018/19 Seasonal Influenza Immunization Program advertising campaign.

## Provincial Eligibility Criteria and Recommendations for Use

For the 2018/19 season, the seasonal flu vaccine is available free-of-charge to all Manitobans aged six months and older, and is especially important for individuals at increased risk of serious illness from the flu, their caregivers and close contacts, including:

- people 65 years of age and older
- residents of personal care homes or long-term care facilities (LTCFs)
- children six to 59 months of age
- individuals with the following chronic health conditions:
  - an immune system weakened by disease or medical treatment (e.g. cancer)
  - cardiac or pulmonary disorders (e.g. cystic fibrosis, asthma)
  - long-term acetylsalicylic acid (Aspirin®) therapy (for those between six months and 18 years of age *only*)
  - neurologic or neurodevelopmental conditions including neuromuscular, neurovascular, neurodegenerative and seizure disorders (and, for children, including febrile seizures and isolated developmental delay), but excluding migraines and psychiatric conditions without neurological conditions
  - diabetes and other metabolic diseases
  - renal disease
  - anemia or hemoglobinopathy
  - obesity (body mass index  $\geq 40$ )
- pregnant women
- health care workers and first responders
- regular caregivers of children up to five years of age
- household contacts of anyone at increased risk of serious illness from the flu including those with infants under six months of age and/or expecting a newborn
- Indigenous peoples

**International students and out-of-province visitors continue to be eligible to receive the flu vaccine free-of-charge regardless of third party insurance and/or MHSAL coverage.** Please report all doses administered to non-Manitoba residents by indicating on the data entry forms/fields, “no personal health identification number (PHIN)”.

Children younger than nine years of age who have NEVER received a flu vaccine need two doses, at least four weeks apart, of either inactivated influenza vaccine (IIV; needle) or live attenuated influenza vaccine (LAIV; nasal spray). *NOTE: LAIV is approved for use in individuals two to 59 years of age.*

NACI recommends that all influenza vaccines be given at the same time as, or at any time before or after administration of, other live attenuated or inactivated vaccines. NACI recognizes that some health care providers may choose to give LAIV and other live vaccines simultaneously or separated by at least four weeks to avoid any possibility of immune interference. Alternatively, an IIV may be given.

The risk of influenza-related hospitalization increases with length of gestation. Pregnant women are considered at high risk of influenza-related complications including hospitalization and are therefore recommended to receive the flu vaccine at any stage of pregnancy.

Influenza vaccination provides benefits to health care workers and to their patients for whom they care. The provision of influenza vaccination is an essential component of the standard of care for all health care workers for the protection of their patients. Immunization of care providers decreases their own risk of illness, as well as the risk of death and other serious outcomes among the patients for whom they provide care. For the purposes of influenza vaccination, health care workers include any person, paid or unpaid, who provides services, works, volunteers or trains in a health care setting. A health care setting is any location where health care is provided, including emergency care, prehospital care, hospital, LTCF, home care, ambulatory care and facilities/locations in the community where care is provided (e.g. infirmaries in schools, immunization clinics, etc.) (page 8, [www.manitoba.ca/health/publichealth/cdc/docs/ipc/rpap.pdf](http://www.manitoba.ca/health/publichealth/cdc/docs/ipc/rpap.pdf)). (**Note:** NACI and MHSAL recommend IIV, instead of LAIV, for health care workers).

## Overview of National/Provincial Recommendations

Every year, NACI updates its recommendations regarding the use of the seasonal flu vaccine. MHSAL and Manitoba's Provincial Vaccine Advisory Committee (PVAC) thoroughly review and examine NACI's annual recommendations to inform provincial recommendations and program details. NACI's **Statement on Seasonal Influenza Vaccine for 2018/19** is available online ([www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html)) and MHSAL's **Seasonal Influenza Management Protocol** is also available online at [www.manitoba.ca/health/flu/pro.html](http://www.manitoba.ca/health/flu/pro.html).

For more information about provincial program standards, please access Manitoba's *Immunization Program Manual*, available online at: [www.manitoba.ca/health/publichealth/cdc/div/manual/index.html](http://www.manitoba.ca/health/publichealth/cdc/div/manual/index.html).

## Vaccine Efficacy and Effectiveness

Influenza vaccine has been shown to be efficacious, with higher efficacy demonstrated against laboratory-confirmed influenza than clinically defined outcomes. Immunization has been shown to reduce the number of physician visits, hospitalizations and deaths in high-risk adults.

An updated literature review by NACI ([www.canada.ca/en/public-health/services/publications/healthy-living/executive-summary-literature-review-update-efficacy-effectiveness-fluzone-high-dose-fluad-trivalent-inactivated-influenza-vaccines-adults-65-older.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/executive-summary-literature-review-update-efficacy-effectiveness-fluzone-high-dose-fluad-trivalent-inactivated-influenza-vaccines-adults-65-older.html)) found evidence that Fluzone® High-Dose provides superior relative protection compared with standard-dose IIV for adults 65 years of age and older. To date, only one study has measured *quadrivalent* influenza vaccine efficacy. In that study, vaccine efficacy was estimated at 59% in children three to eight years of age, in comparison to children who received hepatitis A vaccine. No literature was found on head to head efficacy or effectiveness studies directly comparing *trivalent* and *quadrivalent* formulations, for either inactivated or live attenuated formulations. (For detailed efficacy data pertaining to FluMist® Quadrivalent or Fluzone® High-Dose, see **Vaccine Products**.)

## Vaccine Safety

**Influenza vaccines are safe and well tolerated.** Data from post marketing surveillance of influenza vaccines in Canada (Canadian Adverse Events Following Immunization Surveillance System) have shown seasonal influenza vaccines to have a safe and stable adverse event following immunization (AEFI) profile with no unexpected events.

All influenza vaccines currently authorized for use in Canada are considered safe for use in persons with latex allergies. The multi-dose vial (MDV) formulations of IIV contain minute quantities of thimerosal, which is used as a preservative to keep the product sterile. Large cohort studies of health databases have demonstrated that there is no association between childhood vaccination with thimerosal-containing vaccines and neurodevelopmental outcomes, including autistic-spectrum disorders. All single dose formulations [i.e. pre-filled syringes (PFS)] of IIV (Fluzone® Quadrivalent, FluMist® Quadrivalent and Fluzone® High-Dose) are thimerosal-free.

With intramuscularly injected (needle) vaccines (Fluzone® Quadrivalent, Flulaval® Tetra and Fluzone® High-Dose), injection site reactions are common but are generally classified as mild and transient. Fluzone® High-Dose tends to induce higher rates of systemic reactions post-injection compared to standard-dose IIV, but most of these reactions are mild and short-lived. The most adverse events following administration of FluMist® Quadrivalent are nasal congestion and runny nose. Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online at: [www.manitoba.ca/health/flu/factsheets.html](http://www.manitoba.ca/health/flu/factsheets.html) for more information on vaccine safety for

each of the flu vaccines that are offered as part of Manitoba's Seasonal Influenza Immunization Program.

**Guillain-Barré syndrome (GBS):** studies suggest that the absolute risk of GBS in the period following seasonal and influenza A (H1N1)pdm09 influenza vaccination is about one excess case per one million vaccinations and that the risk of GBS associated with influenza illness is larger (about 17 cases per million influenza-coded health care encounters, which are a proxy for influenza illness) than that associated with influenza vaccination. Avoiding subsequent influenza vaccination of persons known to have had GBS within six weeks of a previous influenza vaccination appears prudent at this time. However, the potential risk of GBS recurrence associated with influenza vaccination must be balanced against the risk of GBS associated with influenza infection itself.

**Oculo-respiratory syndrome (ORS):** found during the 2000/01 flu season; few cases have been reported since then. ORS is not considered to be an allergic response. Persons who have a recurrence of ORS upon revaccination do not necessarily experience further episodes with future vaccinations. Individuals who have experienced ORS without lower respiratory tract symptoms may be safely re-immunized with influenza vaccine. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review.

## **Vaccine Contraindications and Precautions**

NACI has reviewed the data on administering flu vaccine to egg allergic persons and has concluded that egg allergic individuals may be vaccinated using any of the seasonal influenza vaccines available as part of Manitoba's Seasonal Influenza Immunization Program without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, and without any extraordinary precautions, but ensuring that immunizers be prepared with the necessary equipment, knowledge and skills to respond to a vaccine emergency.

As a precautionary measure, FluMist® Quadrivalent recipients should avoid close association with persons with severe immune compromising conditions for at least two weeks following immunization. Additionally, it is recommended that FluMist® Quadrivalent not be administered until 48 hours after antiviral agents active against influenza are stopped, and that those antiviral agents, unless medically indicated, not be administered until two weeks after receipt of FluMist® Quadrivalent so that the antiviral agents do not kill the replicating vaccine virus.

Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online ([www.manitoba.ca/health/flu/factsheets.html](http://www.manitoba.ca/health/flu/factsheets.html)) for a complete list of contraindications and precautions for each of the flu vaccines that are offered as part of Manitoba's Seasonal Influenza Immunization Program.



## Vaccine Products

As per the World Health Organization (WHO), all seasonal quadrivalent influenza vaccines, inactivated and attenuated, for the 2018/19 season in the northern hemisphere contain:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus
- **an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus**
- **a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage)**
- a B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)<sup>1</sup>

The decision to include specific flu vaccines as part of Manitoba's Seasonal Influenza Immunization Program depends on a multitude of factors such as cost-benefit and other programmatic and operational considerations. For the 2018/19 season, MHSAL may offer the following four flu vaccines as part of its annual Seasonal Influenza Immunization Program (product composition to be confirmed following national allotment finalization):

1. **Fluzone® Quadrivalent (Sanofi Pasteur):** a quadrivalent IIV in MDV and PFS for intramuscular (IM) injection (needle), supplied in 5.0mL, 10-dose MDV as well as single-dose (0.5mL) PFS in packages of ten. The vaccine is to be kept at 2° to 8° Celsius. Once punctured, the MDV can be used to the expiry date indicated.
2. **Flulaval® Tetra (GlaxoSmithKline):** a quadrivalent IIV in MDV for IM injection (needle), supplied in 5.0mL, 10-dose MDV. The vaccine is to be kept stored at 2° to 8° Celsius. **Once punctured, the MDV should be discarded within 28 days.**
3. **FluMist® Quadrivalent (AstraZeneca):** a quadrivalent LAIV for intranasal administration (nasal spray), will be supplied in pre-filled single use glass sprayers in packages of 10 (0.2mL dose given as 0.1mL in each nostril). The vaccine is to be kept stored at 2° to 8° Celsius. Use the product before the expiration date on the sprayer label. *More detailed information provided below.*
4. **Fluzone® High-Dose (Sanofi Pasteur):** a trivalent IIV in PFS for intramuscular injection (needle) supplied in a single 0.5mL/dose. The vaccine is to be kept at 2° to 8° Celsius. Use the product before the expiration date. *More detailed information provided below.*

Please note: **ALL** flu vaccines **MUST** be administered by a health care professional who is registered or licensed to provide health care under an Act of the Legislature and who is authorized under that act to administer vaccines.

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<sup>1</sup> The **two bolded strains** are different from last year's seasonal quadrivalent influenza vaccine and the last strain listed is not included in the trivalent IIV, Fluzone® High-Dose.

The ever-present possibility of antigenic drift, which may occur in one or more influenza virus strains, requires seasonal flu vaccines to be reformulated and administered annually.

<b>Characteristics of influenza vaccines available for use in Manitoba, 2018/19*</b>				
	<b>Fluzone® Quadrivalent</b>	<b>Flulaval® Tetra</b>	<b>FluMist® Quadrivalent</b>	<b>Fluzone® High-Dose</b>
<b>Vaccine Preparations</b>	QIV	QIV	QLAIV	TIV
<b>Formats available</b>	MDV and PFS	MDV	Prefilled single use glass sprayer	Single dose prefilled syringe
<b>Authorized ages for use</b>	≥ 6 months	≥ 6 months	2 - 59 years	≥ 65 years †
<b>Adjuvant</b>	No	No	No	No
<b>Antigen content (each of strains)</b>	15 µg haemagglutinin (HA) /0.5 mL dose	15 µg HA /0.5 mL dose	10 <sup>6.5-7.5</sup> fluorescent focus units (FFU) of live attenuated reassortants /0.2 mL dose given as 0.1 mL in each nostril	60 µg HA /0.5 mL dose
<b>Thimerosal</b>	Yes - MDV No - PFS	Yes	No	No
<b>Antibiotics</b>	None	None	Gentamicin	No
<b>Other clinically relevant non-medicinal ingredients</b>	Egg protein Formaldehyde Triton X-100 Sucrose	Egg protein α-tocopheryl hydrogen succinate polysorbate 80 formaldehyde ethanol sodium deoxycholate sucrose	Egg protein gelatin hydroxylate sucrose arginine monosodium glutamate	Formaldehyde, egg protein Triton X-100
<p>*For more information, see Appendix A, Characteristics of influenza vaccines available for use in Canada, 2018-19 of the Statement on Seasonal Influenza Vaccine for 2018-19: <a href="http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html">www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html</a></p> <p>† Fluzone® High-Dose is available free-of-charge to Manitobans 65 years of age and older who live in a long-term care facility.</p>				

For product information as well as other manufacturer-developed tools and resources, please visit:

- Sanofi Pasteur (Fluzone® Quadrivalent):
  - [https://pdf.hres.ca/dpd\\_pm/00045506.PDF](https://pdf.hres.ca/dpd_pm/00045506.PDF)
  - [www.sanofipasteur.ca/](http://www.sanofipasteur.ca/)
- GSK (Flulaval® Tetra Quadrivalent)
  - <http://ca.gsk.com/media/590283/flulaval-tetra.pdf>
  - <https://health.gsk.ca/>
- AstraZeneca (FluMist® Quadrivalent):
  - [https://pdf.hres.ca/dpd\\_pm/00045021.PDF](https://pdf.hres.ca/dpd_pm/00045021.PDF)
  - [www.astrazeneca.ca/en/Home/](http://www.astrazeneca.ca/en/Home/)
- Sanofi Pasteur (Fluzone® High-Dose):
  - [https://pdf.hres.ca/dpd\\_pm/00045494.PDF](https://pdf.hres.ca/dpd_pm/00045494.PDF)
  - [www.sanofipasteur.ca/](http://www.sanofipasteur.ca/)

### a. FluMist® Quadrivalent

FluMist® Quadrivalent is a LAIV that is administered as a nasal spray. The virus strains are cold-adapted and temperature sensitive, so they replicate in the nasal mucous rather than the lower respiratory tract, and they are attenuated so they do not produce influenza-like illness (ILI).

#### Vaccine effectiveness among children and adolescents (two to 17 years of age):

As a result of the data showing relatively lower VE of FluMist® Quadrivalent, specifically with respect to children aged two to 17 years of age, ACIP recommended that for the 2016/17 and 2017/18 seasons, **FluMist® Quadrivalent NOT be used**. NACI reviewed the data from the United States as cited by ACIP as well as VE data from the United Kingdom, Finland, Canada and the manufacturer (AstraZeneca) and concluded that FluMist® Quadrivalent would continue to be a recommended vaccine option for the 2016/17 and 2017/18 seasons but would no longer be preferentially recommended for children. For the 2018/19 season, ACIP has reversed its decision; FluMist® Quadrivalent will be used but is no longer preferentially recommended for children in the United States. **Similarly, NACI also notes that the current evidence for the 2018/19 season does not support a recommendation for the preferential use of FluMist® Quadrivalent in children and adolescents 2 to 17 years of age. NACI concludes that the current evidence is consistent with FluMist® Quadrivalent providing comparable protection against influenza to that afforded by Fluzone® Quadrivalent and Flulaval® Tetra.** The observational study data reviewed highlight the challenge in interpreting LAIV and IIV, VE when point estimates by influenza subtype are derived based on small sample sizes associated with wide confidence intervals (CIs).

#### Vaccine effectiveness among adults (18 to 59 years of age):

A literature search conducted in early 2016 identified three studies examining the effectiveness of LAIV in adult populations published since NACI conducted its literature review in 2011. Most of these studies found that LAIV and IIV had similar efficacy and effectiveness or, that IIV was more efficacious. Given the small number of studies with adult participants, it is uncertain what factors influence the relative efficacy and effectiveness of LAIV compared to IIV. Additionally, in efficacy studies, IIV has typically been shown to be more immunogenic in adults than was LAIV. Greater rates of seroconversion to LAIV occurred in baseline seronegative individuals compared to baseline seropositive individuals in both child and adult populations, because pre-existing immunity may interfere with response to a live vaccine. For healthy adults up to 59 years of age, NACI considers IIV and LAIV to be acceptable choices, unless contraindicated.

**In conclusion, MHSAL recommends that *healthy* children two to 17 years of age can be immunized with LAIV and that a small number of *healthy* adults up to 59 years of age who are needle averse may also be immunized with LAIV if they would otherwise refuse vaccination if**

**only a needle-option (IIV) were available.** The following table is a historical timeline of the use of FluMist® Quadrivalent (as well as the previous trivalent formulation) in Canada and the USA including a historical synopsis of NACI and ACIP recommendations.<sup>2</sup>

<b>Canadian Landscape:</b>	<b>American Landscape:</b>
<p><b>June 2010:</b> Health Canada approved FluMist® (trivalent IIV) for use in individuals 2 to 59 years of age.</p>	<p><b>June 2003:</b> FluMist® approved for use in individuals 5 to 49 years of age.</p>
<p><b>2011/12 season:</b> NACI recommended FluMist® for use in healthy individuals 2-17 years of age.</p>	<p><b>September 2007:</b> FDA extended approval to include individuals 2 to 49 years of age.</p>
<p><b>2013-14 season:</b> NACI preferentially recommended FluMist® in young children (younger than 6 years of age) based on superior efficacy and continued to recommend its use in healthy children 2-17 years of age.</p>	<p><b>October 2007:</b> ACIP recommended use of FluMist® in children 2-5 years of age. ACIP recommended that either FluMist® or inactivated influenza vaccine could be used for healthy, non-pregnant persons aged 2-49 years (no preference).</p>
<p><b>January 2014:</b> in response to a national vaccine shortage, MB publicly funds FluMist® mid-season for individuals 2-59 years of age.</p>	<p><b>February 2012:</b> FDA licensed FluMist® Quadrivalent, replacing the trivalent formulation beginning with the 2013/14 season.</p>
<p><b>October 2014:</b> Health Canada approved FluMist® Quadrivalent for use in individuals two to 59 years of age, replacing the trivalent formulation.</p>	<p><b>2014/15 season:</b> for the first time, ACIP preferentially recommended that when available, FluMist® Quadrivalent should be used for healthy children aged 2-8 years.</p>
<p><b>2014/15 season:</b> MB offers FluMist® Quadrivalent to individuals 2-17 years of age, with preferential use in children younger than 6 years of age. Needle averse adults up to 59 years of age could also get FluMist® Quadrivalent.</p>	<p><b>2015/16 season:</b> in the absence of data demonstrating consistent greater relative effectiveness (particularly with respect to the H1N1 strain), ACIP no longer makes a preferential recommendation for FluMist® Quadrivalent; any vaccine type or formulation could be used.</p>
<p><b>2016/17 season to present:</b> Based on the most recent evidence, NACI continues to recommend FluMist® Quadrivalent but no longer preferentially recommends. MB updated its provincial recommendations to be consistent with NACI.</p>	<p><b>2016/17 season:</b> ACIP recommended that FluMist® Quadrivalent NOT be used.</p>
	<p><b>2018/19 season:</b> ACIP is recommending the use of FluMist® Quadrivalent for healthy, non-pregnant individuals 2-49 years of age.</p>

<sup>2</sup> NACI is a committee of experts in the fields of pediatrics, infectious disease, immunology, medical microbiology, internal medicine and public health that advises the Public Health Agency of Canada. Likewise, ACIP is a panel of medical and public health experts that advises the Centers for Disease Control and Prevention of the U.S Department of Health and Human Services.

## **b. Fluzone® High-Dose**

**MHSAL is continuing to offer the high-dose inactivated influenza vaccine (Fluzone® High-Dose) to residents of long-term care facilities (LTCFs) aged 65 years and older, including chronic care residents. Clients in interim/transitional care beds, respite care clients as well as new, unimmunized residents admitted to a LTCF during the flu season are also eligible. Staff of LTCFs and residents of LTCFs less than 65 years of age should be immunized with standard-dose IIV.**

Residents of LTCFs 65 years of age and older are at higher risk of complications from the flu, and the immune response to flu vaccines in this population is thought to be less effective than that seen in younger populations. In order to elicit a stronger and more effective immune response among elderly individuals, Fluzone® High-Dose is being offered because it contains four times the amount of influenza virus antigen per strain (60 µg vs. 15 µg) compared to the standard-dose IIV. Fluzone® High-Dose is a *trivalent* IIV and protects against three (2A + 1B) of the influenza strains predicted to be circulating in North America during the 2018/19 season. Given the burden of influenza A(H3N2) disease and evidence of better efficacy in this age group, it is expected that Fluzone® High-Dose will provide superior protection compared with standard-dose IIV.

The higher antigen concentrations contained within Fluzone® High-Dose may result in higher rates of post-injection local adverse events compared to standard-dose IIV, but they are expected to last only two to three days and rarely interfere with normal activities. Studies reported higher rates of malaise, myalgia, and moderate to severe fever. Various studies noted a higher rate of systemic reactions with Fluzone® High-Dose, but serious adverse events were similar in frequency between the high- and standard-dose IIV. Fluzone® High-Dose has been authorized for use in Canada since 2015.

Two randomized controlled trials (RCTs) and one retrospective cohort study measured the relative efficacy of Fluzone® High-Dose compared to a standard-dose IIV in adults 65 years of age and older. Relative efficacy of high-dose versus standard-dose IIV against lab-confirmed symptomatic influenza was 12.5% (95% CI: -141 to 66%) in one RCT during the 2009-10 season, in which the pandemic A(H1N1) flu virus predominated and represented a vaccine strain mismatch. Canadian authorization of the high-dose vaccine was based on a second, larger RCT conducted over two seasons (2011/12, 2012/13) in which the relative efficacy was 24% (95% CI: 10 to 36%) compared to standard-dose IIV. In the retrospective cohort study of Medicare beneficiaries in the USA, Fluzone® High-Dose was estimated to be 22% (95% CI: 15 to 29%) more effective than standard-

dose IIV in preventing probable influenza-related illness, and 22% (95% CI: 16 to 27%) more effective than standard-dose IIV in preventing hospital admission due to an influenza diagnosis.

## Vaccine Distribution

Manitoba uses a mixed provider delivery model for the Manitoba Immunization Program, with public health nurses, nurses, nurse practitioners, midwives, physicians, physician assistants and pharmacists administering vaccines in private and public health settings. It is important for all health care providers to take this into consideration when they are ordering influenza vaccine because unused vaccines in a health care provider's fridge cannot be returned to the Provincial Distribution Warehouse and redistributed. All health care providers must order based on the amount administered last year to reduce wastage. **Failure to reconcile vaccine doses ordered with administered (and reported) may result in health care providers receiving fewer vaccine doses than ordered.** It is therefore paramount that all influenza vaccine doses administered be reported to MHSAL (see **Documentation - Data Entry** for more information on how to report vaccine doses administered). **Influenza vaccine wastage should be less than 10% at the end of the influenza season.** Subsequent orders can be placed with the Provincial Distribution Warehouse (at no penalty to the health care provider), while supplies last.

**Health care providers may order influenza vaccine starting August 15, 2018, and up to 4 p.m. on September 14, 2018, in order to be placed in their respective distribution groups, which have been outlined below. Any orders placed after 4 p.m. on the 14<sup>th</sup> will be placed in the last distribution group.** Where possible, health care providers at the same facility should submit one order for flu vaccine (that covers all providers in the facility) to expedite orders and reduce the number of individual orders that are being shipped to one location.

To place an order for influenza vaccine, please submit an order online or via fax/email using the *Vaccines and Biologics Order Form*:

[www.manitoba.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf](http://www.manitoba.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf), or as directed through Panorama, the provincial electronic public health immunization and vaccine inventory management system.

If you are a LTCF or are ordering on behalf of a LTCF, please complete and submit the *2018/19 Influenza and Pneumococcal Vaccine Order Form for Long-Term Care Facilities*:

[http://www.gov.mb.ca/health/publichealth/cdc/protocol/influpnevcorderform\\_ltcf.pdf](http://www.gov.mb.ca/health/publichealth/cdc/protocol/influpnevcorderform_ltcf.pdf).

Provided flu vaccine manufacturers meet delivery timelines as per the contractual obligations for the 2018/19 season, all flu vaccine orders will be shipped according to the following schedule:

1. hospitals, LTCFs and First Nations communities
2. providers/facilities with Client ID (Holding Point #) ending in 0, 1, 2 or 3
3. providers/facilities with Client ID (Holding Point #) ending in 4, 5 or 6
4. providers/facilities with Client ID (Holding Point #) ending in 7, 8 or 9
5. providers/facilities that order after 4:00pm on September 14, 2017

Within each of these groups, orders will be processed in the sequence in which the order is received by the Provincial Distribution Warehouse (on or after the vaccine ordering start date).

If one or more flu vaccine manufacturers fail to deliver flu vaccine on time, distribution could be substantially delayed or product substitutions may take place. In the event that this occurs, MHSAL will communicate important flu vaccine distribution and delivery information to immunization providers in a timely manner and post it on the “Vaccine Distribution and Supply” website:

[www.manitoba.ca/health/flu/distribution.html](http://www.manitoba.ca/health/flu/distribution.html).

## Documentation

Adverse events following immunization (AEFI), doses administered, consent obtained and incidents of adverse storage conditions must be recorded and reported to MHSAL.

### **a. Adverse Events Following Immunization (AEFI)**

In accordance with The Public Health Act, health care providers are to report to the regional Medical Officer of Health (MOH) a reportable AEFI within seven days of becoming aware of the AEFI (as per section 59 of The Act). Health care providers should report a serious AEFI (see below) within one business day, which can be by telephone, followed by the complete report thereafter.

A reportable AEFI is an event that:

1. is temporally associated with a vaccine
2. has no other clear cause at the time of reporting
3. is either serious or unexpected

An AEFI is considered “serious” if any of the following criteria are met:

- results in death
- is life-threatening, that is, where the patient was at real, rather than hypothetical, risk of death at the time of the event/reaction
- requires in-patient hospitalization, defined as any of the following:
  - hospital stay lasting  $\geq$  24 hours based on known date/time of admission and dischargeor,

- hospital stay involving all or part of two consecutive days (i.e. admission and discharge date are at least one day apart but specific time of admission is not specified)
- results in prolongation of existing hospitalization
- results in persistent or significant disability/incapacity (if known at the time of reporting)
- is a congenital anomaly/birth defect
- is medically important, defined as:
  - an event or reaction that might not be immediately life-threatening, or result in death or hospitalisation, but might jeopardise the patient or might require intervention to prevent one of the other seriousness criteria

An AEFI is considered “unexpected” if either of the following criteria is met:

- is not listed in the most current Health Canada-approved product monograph for vaccines marketed in Canada
- listed in the product monograph but is different in nature, severity, frequency, specificity or outcome

The AEFI module of Panorama allows public health providers with access to Panorama to report AEFIs using Panorama. Health care providers without Panorama access should complete a **Reporting Form for Adverse Events Following Immunization** online at: [www.manitoba.ca/health/publichealth/cdc/docs/aeфи\\_form.pdf](http://www.manitoba.ca/health/publichealth/cdc/docs/aeфи_form.pdf) and submit to your regional MOH (see bottom of form for link to list of MOH contact information). All forms received will also be entered into Panorama for vaccine safety surveillance in Manitoba, and will be included as part of the client immunization record in the provincial immunization registry within Panorama. All MOH recommendations of an individual’s AEFI should be recorded in the client’s personal health record.

**MHSAL reviews all submitted AEFI reports. If a link is found between a possible adverse event and a vaccine, public health officials take appropriate actions to ensure the safety of patients.**

For more information on AEFI, visit: [www.manitoba.ca/health/publichealth/cdc/div/aeфи.html](http://www.manitoba.ca/health/publichealth/cdc/div/aeфи.html).

## **b. Data Entry**

Every health care provider and facility including FNIHB **MUST ACCOUNT FOR EVERY DOSE OF FLU VACCINE ORDERED AND ADMINISTERED** by ensuring that doses are recorded in the client’s electronic public health record. Immunizations are entered into a client’s electronic public health record via the Manitoba Immunization Registry (Panorama) in one of three ways:

1. Data entry by Panorama users.



- Health care providers who have access to Panorama can enter the immunization data directly into Panorama if their permissions allow for data entry. For those who do not have access to Panorama and in instances where a health care provider is unable to enter information directly into Panorama (i.e. Private Flu Clinic), as well as for instances where the individual does not have a PHIN (or the PHIN is unknown), health care providers are to complete the *Immunization Inputting Form for Health Care Providers* and submit it to the local Public Health office where it will be entered manually into Panorama by regional staff.
  - This form can be accessed online at: [www.manitoba.ca/health/publichealth/cdc/div/docs/iifhcp.pdf](http://www.manitoba.ca/health/publichealth/cdc/div/docs/iifhcp.pdf)
  - The listing of public health offices in Manitoba is located at: [www.manitoba.ca/health/publichealth/offices.html](http://www.manitoba.ca/health/publichealth/offices.html)
- 2. Uploaded from the Drug Programs Information Network (DPIN) system when administered by pharmacists.
- 3. Uploaded from the Claims Processing System (Physician Billing) when administered by fee-for-service physicians and other health care providers that shadow bill (e.g. regional nurse practitioners).

Surveillance of influenza immunization uptake is included in the weekly and end of season influenza surveillance reports. Reports for 2018/19 as well as the previous nine seasons can be accessed online at: [www.manitoba.ca/health/publichealth/surveillance/reports.html](http://www.manitoba.ca/health/publichealth/surveillance/reports.html).

### **c. Consent**

As per MHSAL's *Informed Consent Guidelines for Immunization* ([www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf](http://www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf)), verbal and/or written consent must be obtained prior to immunization and must be documented via a consent form, medical chart or electronic health record. To assist with obtaining consent for influenza and Pneu-P-23 immunizations, a *Seasonal Influenza and Pneumococcal Vaccine Consent Form* is available online at: [www.manitoba.ca/health/flu/docs/flupneumo\\_consentform.pdf](http://www.manitoba.ca/health/flu/docs/flupneumo_consentform.pdf)

### **d. Storage and Handling Requirements**

As with all vaccines and biologics, please refer to the online *Cold Chain Protocol – Immunizing Vaccines and Biologics* and corresponding resources for all storage and handling requirements ([www.manitoba.ca/health/publichealth/cdc/coldchain.html](http://www.manitoba.ca/health/publichealth/cdc/coldchain.html)). Vaccines must be stored in a temperature monitored refrigerator between 2° to 8° Celsius. In the event that vaccines have been exposed to temperatures outside of 2° to 8°Celsius, health care providers MUST report the adverse storage condition incident to MHSAL. Please complete/submit the online form

([www.manitoba.ca/health/publichealth/cdc/docs/ccf.pdf](http://www.manitoba.ca/health/publichealth/cdc/docs/ccf.pdf)) or submit the required information directly through Panorama. **MHSAL does not allow the use of bar fridges to store vaccines and regular mercury thermometers are not be used to monitor the fridge temperature.** Fridges should only contain vaccines. No food or other biologics should be kept in the vaccine fridge.

## Communications

All promotional/educational resources (e.g. factsheets, posters, brochures) will be available to order, free-of-charge, from the Materials Distribution Agency, and will also be posted on MHSAL's Seasonal Flu website ([www.manitoba.ca/health/flu/index.html](http://www.manitoba.ca/health/flu/index.html)). The following three informational factsheets are being updated for the 2018/19 season and will be posted online: "Seasonal Influenza Vaccine Public Health Factsheet;" "Questions & Answers: Seasonal Influenza Public Health Factsheet;" and "Seasonal Influenza Vaccine for Residents of Long-Term Care Facilities Public Health Factsheet." Please note that the "Because it's about him too. Get vaccinated. Don't spread the flu" **brochure** is being discontinued and will no longer be available online or for order from the Materials Distribution Agency. Lastly, the following two educational resources for health care providers are being updated and will be available online only: "Live Attenuated Influenza Vaccine (LAIV) (FluMist® Quadrivalent): Questions and Answers for Health Care Providers" and "Seasonal Influenza Vaccine for Residents of Long-Term Care Facilities: Questions & Answers for Health Care Providers." The remainder of flu promotional/educational resources will be the same as last year (i.e. do not require any updates). A communiqué will be sent advising of when the updated resources are available.

As with previous years, MHSAL will communicate with health care providers including RHAs and FNIHB frequently throughout the summer to support planning of mass clinics. Generally, mass letters are faxed to all health care providers in June, or as soon as possible, advising of the general parameters of the Program (e.g. eligibility criteria) and then again in September (or as needed), with any updated details of the program (resources, vaccine products and ordering, high-risk groups, etc).

All provincial advertising and official program launch will commence October (exact date TBD).