The Manitoba Seasonal Influenza Immunization Program Plan 2017-18

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

Table of Contents

I. Purpose ……..……..…… 3

II. Important Program Dates ……..…….. 3

III. Eligibility Criteria ...……..... 4

IV. National and Provincial Recommendations .....……..…….…...…... 5

V. Vaccine Products …….……..……..... 6

VI. Vaccine Distribution …….. 9

VII. Documentation ……..……..…….…. 10

a. Adverse Events Following Immunization (AEFI)

b. Data Entry – Panorama

c. Consent

d. Storage and Handling Requirements

VIII. Communications ..…….....…….. 13

IX. Evaluation ..……...……...……..... 13

I. Purpose

The purpose of this document is to provide **all** immunization providers and regional health authorities (RHAs), including the First Nations and Inuit Health Branch (FNIHB), with the provincial program plan for the 2017-18 influenza (flu) season.

II. Important Program Dates

- **Spring 2017:** the National Advisory Committee on Immunization's (NACI's) *"Statement on Seasonal Influenza Vaccine for 2017-18"* has been posted on the Public Health Agency of Canada (PHAC) website: www.phac-aspc.gc.ca/naci-ccni/index-eng.php.
- **August 14th - September 15th:** health care providers can begin placing orders for flu vaccine; orders will be collected and shipped once product arrives in Manitoba (mid/late September). Shipment will follow a schedule based on priority locations and then based on client ID.
- **September 1st:** deadline for health care providers and regions to submit their clinic dates, times and locations for inclusion on MHSAL website and/or through Health Links–Info Santé. Please email information to: Kellie.Navitka@gov.mb.ca
- **August / September:** the updated seasonal flu website, (www.gov.mb.ca/health/flu/index.html) will go live; updated print materials including promotional/educational resources (e.g. factsheet, poster, brochure, etc.), and order forms will be posted on the seasonal flu website or you can visit the Health Information Resources for Health Care Professionals at: http://www.gov.mb.ca/health/jmc/hirorderform.pdf
- **Late-September:** MHSAL mails the annual pneumococcal polysaccharide 23 (Pneu-P-23) reminder letters 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.
- **1st week of October (exact date TBD):** the 2017-18 Seasonal Influenza Immunization Campaign will formally begin.

III. Eligibility Criteria

The National Advisory Committee on Immunization (NACI) recommends flu vaccination for all individuals aged 6 months and older, with particular focus on people at high risk of influenza-related complications or hospitalization as well as people capable of transmitting flu to those at high-risk.

For 2017-18, the seasonal flu vaccine is available free-of-charge to all Manitobans over 6 months of age, and is especially important for Manitobans at increased risk of serious illness from the flu, their caregivers and close contacts. This includes:

- People 65 years of age and older
- Residents of personal care homes or long-term care facilities
- Children six to 59 months of age
- Individuals with the following chronic health conditions:
    - An immune system weakened by disease or medical treatment
    - Cardiac or pulmonary disorders (ex: cystic fibrosis, asthma)
    - Individuals aged six months to 18 years on long-term acetylsalicylic acid (Aspirin®) therapy
    - Neurologic or neurodevelopmental conditions
    - Diabetes and other metabolic diseases
    - Renal disease
    - Anemia or hemoglobinopathy
    - Obesity (body mass index ≥40)
- Pregnant women
- Health care workers and first responders
- Regular caregivers of children up to five years of age
- Indigenous peoples

International students and out-of-province visitors are 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 data entry forms/fields, “no PHIN”.

National and Provincial Recommendations

Every year, NACI releases an updated statement on seasonal flu vaccine. MHSAL and Manitoba's Provincial Vaccine Advisory Committee (PVAC) thoroughly review and examine NACI's annual statement in order to inform provincial recommendations and program details. NACI's updated annual influenza statement for 2017-18 is available online (https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2017-2018.html) and MHSAL's *Seasonal Influenza Management Protocol* is also available online at www.gov.mb.ca/health/flu/pro.html.

For the 2017-18 flu season, MHSAL supports the following key NACI recommendations:

- All people over 6 months of age are recommended to receive the seasonal flu vaccine. However, immunization programs should continue to focus on those at high-risk of influenza-related complications, those capable of spreading flu to individuals at high-risk of complications and those who provide essential community services.
- All influenza vaccines may be given at the same time as, or at any time before or after administration of, other live attenuated or inactivated vaccines.
- 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 (needle) or live attenuated influenza vaccine (nasal spray).
- NACI has reviewed the data on administering flu vaccine to egg allergic persons and has concluded that egg allergic individuals may be vaccinated against the flu using inactivated influenza vaccine (needle) or live attenuated influenza vaccine (nasal spray) 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.
- Influenza vaccination provides benefits to health care workers and to their patients for whom they care. NACI considers the provision of influenza vaccination to be an essential component of the standard of care for all health care workers for the protection of their patients. 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.
- In adults 65 years of age and older, given the burden of influenza A(H3N2) disease and evidence of better efficacy in this population, NACI has concluded that Fluzone® High-Dose should provide superior protection compared with the standard dose vaccine.

For more information about provincial vaccine recommendations and program standards, please access Manitoba's *Immunization Program Manual*, available online at: www.gov.mb.ca/health/publichealth/cdc/div/manual/index.html.

IV. Vaccine Products

As per the World Health Organization (WHO), all seasonal quadrivalent influenza vaccines for 2017-18 in the northern hemisphere contain:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus;
- an A/Hong Kong/4801/2014 (H3N2)-like virus; and
- a B/Brisbane/60/2008-like virus.
- B/Phuket/3073/2013-like virus

The decision to include specific influenza 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 2017-18 flu season, MHSAL will offer the following three flu vaccines to the general population:

1. **Fluzone® Quadrivalent (Sanofi Pasteur):** an inactivated influenza vaccine in multi-dose vials (MDV) and pre-filled syringes (PFS) for intramuscular injection (needle), supplied in 5.0mL, 10-dose MDV as well as single-dose (0.5mL) PFS in packages of ten. As per the product monograph, the vaccine is to be kept at 2° to 8° Celsius. Once punctured, the multi dose vial can be used to the expiry date indicated on the vial label.

2. **Flulaval® Tetra (GlaxoSmithKline):** an inactivated influenza vaccine in MDV for intramuscular injection (needle), supplied in 5.0mL, 10-dose MDV. As per the product monograph, the vaccine is to be kept stored at 2° to 8° Celsius. The vaccine is stable for 12 months. **Once punctured, the multi dose vial should be discarded within 28 days**.

3. **FluMist® Quadrivalent (AstraZeneca):** a live attenuated influenza vaccine, for intranasal administration (nasal spray), will be supplied in pre-filled single use glass sprayers in packages of ten (0.2mL dose given as 0.1mL in each nostril). As per the product monograph, the vaccine is to be kept stored at 2°to 8° Celsius. Use the product before the expiration date on the sprayer label.

*Fluzone® Quadrivalent, Flulaval® Tetra Quadrivalent and FluMist® Quadrivalent **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.*

For the 2017-18 flu season, MHSAL will offer a high-dose seasonal influenza vaccine (Fluzone® High-Dose) for residents of long-term care facilities (LTCFs) aged 65 years and older.

Residents of LTCFs 65 years of age and older are at higher risk of complications from influenza, and the immune response to influenza 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 (60ug vs. 15ug) compared to the standard inactivated influenza vaccine. Fluzone® High-Dose is a trivalent inactivated vaccine (TIV) and protects against three (2A + 1B) of the influenza strains predicted to be circulating in North America during the 2017-18 influenza season. Given the burden of Influenza A(H3N2) disease and evidence of better efficacy in this age group, it is expected that high dose TIV will provide superior protection compared with the standard dose influenza vaccine.

The higher antigen concentrations contained within Fluzone® High-Dose may result in higher rates of post-injection local adverse events compared to standard dose influenza vaccine, but they are expected to last only two to three days and rarely interfere with normal activities. 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 vaccines. Fluzone® High-Dose has been authorized for use in Canada since 2015.

Staff of LTCFs and residents < 65 years of age should be immunized with standard-dose influenza vaccine (Fluzone® Quadrivalent or FluLaval® Tetra).

For product information as well as other manufacturer-developed tools and resources, please visit the respective manufacturer's website:

- Sanofi Pasteur (Fluzone® Quadrivalent):
  http://www.vaccineshoppecanada.com/document.cfm?file=fluzone_qiv_e.pdf
  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://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/flumist-qlaiv-product-monograph-en.pdf

http://www.astrazeneca.ca/en/Home/

- Sanofi Pasteur (Fluzone® High-Dose):

  https://www.vaccineshoppecanada.com/document.cfm?file=fluzone_hd_e.pdf

  http://www.sanofipasteur.ca/

Characteristics of influenza vaccines available for use in Manitoba, 2017-2018*				
	Fluzone® Quadrivalent	**Flulaval® Tetra**	**FluMist® Quadrivalent**	**Fluzone® High-Dose**
Vaccine Preparations	QIV	QIV	QLAIV	TIV
Formats available	MDV and PFS	MDV	Prefilled single use glass sprayer	Single dose prefilled syringe
Authorized ages for use	≥ 6 months	≥ 6 months	2 - 59 years	≥ 65 years ¥
Adjuvant	No	No	No	No
Antigen content (each of strains)	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	$10^{6.5\text{-}7.5}$ FFU of live attenuated reassortants /0.2 mL dose given as 0.1 mL in each nostril	60 µg HA /0.5 mL dose
Thimerosal	Yes - MDV No - PFS	Yes	No	No
Antibiotics	None	None	Gentamicin	No
Other clinically relevant non-medicinal ingredients	Egg protein Formaldehyde Triton X-100 Sucrose	Egg protein α-tocopheryl hydrogen succinate polysorbate 80 formaldehyde ethanol sodium deoxycholate sucrose	Egg protein gelatin hydrosylate sucrose arginine monosodium glutamate	Formaldehyde, egg protein Triton X-100

**For more information, see Appendix A, Table 4 of the Statement on Seasonal Influenza Vaccine for 2017-2018: www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2017-2018.html*

¥ Fluzone® High-Dose is available free-of-charge for Manitobans 65 years of age and older who live in a long-term care facility.

V. Vaccine Distribution

Manitoba uses a mixed provider delivery model for Manitoba's Publicly-Funded Immunization Program, with public health nurses, nurses, nurse practitioners, physicians, physician assistants, and pharmacists administering vaccines in private and public health settings. It is important for immunization providers to take this into consideration when they are ordering influenza vaccine because unused vaccines in an immunization provider's fridge cannot be returned to the Provincial Vaccine Warehouse and redistributed. MHSAL requests that immunization providers consider ordering based on the amount administered last year to reduce potential wastage. If additional doses are required, subsequent orders can be placed with the Provincial Vaccine Warehouse (at no penalty to the immunization provider). Where possible, immunization 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. Immunization providers may order influenza vaccine starting on August 14th, 2017 and up to 4:00pm on September 15th, 2017 in order to be placed in their respective distribution groups, which have been outlined below. Any orders placed after 4:00pm on the 15th will be placed in the last distribution group.

To place an order for influenza vaccine, please submit an order online or via fax with the *Vaccines and Biologics Order Form*: www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf, or as directed through Panorama, the provincial electronic public health immunization and vaccine inventory management system.

Provided flu vaccine manufacturers meet delivery timelines as per the contractual obligations for the 2017-18 season, all flu vaccine orders will be shipped according to the following schedule:

1. Hospitals, personal care homes (PCHs) and First Nations communities;
2. Providers/facilities with Client ID (Holding Point #) ending in 4, 5 or 6;
3. Providers/facilities with Client ID (Holding Point #) ending in 7, 8 or 9;
4. Providers/facilities with Client ID (Holding Point #) ending in 0,1, 2 or 3;
5. Providers/facilities that order after 4:00pm on September 15th 2017.

Within each of these groups, orders will be processed in the sequence in which the order is received by the Provincial Vaccine 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.gov.mb.ca/health/flu/distribution.html.

VI. Documentation

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 (7) 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 (1) 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; and,
3. Is either serious, of special importance 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 ≥24 hours based on known date/time of admission and discharge or
    - 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); or,
- Is a congenital anomaly/birth defect; or
- 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 "of special interest" if it is any one of the following:

- Anaphylaxis
- Encephalitis (including SSPE)
- Acute disseminated encephalomyelitis
- Myelitis
- Aseptic meningitis / other meningitis (physician diagnosis)
- Guillain Barre Syndrome
- Acute cerebellar Ataxia

- Intussusception
- Thrombocytopenia (Brighton Collaboration diagnostic certainty level 1: platelet count <150 AND clinical signs/symptoms of spontaneous bleeding)
- Emerging signal event based on group consensus

The foregoing list of adverse events of special interest may be amended periodically based on emerging issues or generation of evidence that enables rejection of the hypothesis that vaccine and event are causally related.

An AEFI is considered "unexpected" if any of the following criteria is met:

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

The AEFI module of Panorama, the provincial electronic public health immunization and vaccine inventory management system, 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: http://www.gov.mb.ca/health/publichealth/cdc/docs/aefi_form.pdf. and submit to the regional MOH listed on Appendix A of the form. 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.gov.mb.ca/health/publichealth/cdc/div/aefi.html.

b. Data Entry:

Every health care provider and facility including the First Nations and Inuit Health Branch (FNIHB) must account for **every** dose of flu vaccine administered. MHSAL's provincial immunization registry has transitioned from the Manitoba Immunization Monitoring System (MIMS) to Panorama. Currently Panorama is available throughout all provincial Public Health Offices, with the exception of some First Nations communities (until FNIHB public health nurses are able to direct-enter into Panorama, all doses administered by FNIHB staff will continue to be direct-entered into MIMS).

With the exception of FNIHB, immunizations are entered into the provincial immunization registry (Panorama) in one of three (3) ways:

1. Data entry by Panorama users.
    - Health care providers that 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) or when an individual does not have a PHIN, or it is unknown, immunization 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.
        - This form can be accessed online at: http://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf
        - The listing of public health offices in Manitoba is located at: http://www.gov.mb.ca/health/publichealth/offices.html
2. Uploaded from the Drug Program Information Network 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 (ex: regional nurse practitioners).

Weekly and end of season influenza surveillance reports for 2017-18 as well as the previous eight seasons, can be accessed online at: www.gov.mb.ca/health/publichealth/surveillance/reports.html.

c. Consent:

As per MHSAL' *Informed Consent Guidelines for Immunization* (www.gov.mb.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.gov.mb.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 Agents and Biologics* and corresponding resources for all storage and handling requirements (www.gov.mb.ca/health/publichealth/cdc/coldchain.html). Vaccines must be stored in a temperature monitored refrigerator between 2º to 8º Celsius. In the event that vaccines have been exposed to temperatures outside of 2º to 8ºCelsius, you must report the adverse storage condition incident to

MHSAL. Please complete/submit the online form (www.gov.mb.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 should 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.

VII. Communications

All promotional/educational resources (ex: factsheets, posters, brochures) will be available to order, free-of-charge, from the Materials Distribution Agency (MDA), and will also be posted on MHSAL seasonal flu website (www.gov.mb.ca/health/flu/index.html). Some resources from last year require 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 (ex: eligibility criteria) and then again in September, 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 around the first week of October (exact date TBD).

VIII. Evaluation

Health care providers including public health officials within the RHAs (Immunization Coordinators, Public Health Managers and Medical Officers of Health) may be contacted by MHSAL for feedback on this Program Plan and/or other influenza program planning activities coordinated by MHSAL.