

# Manitoba's Influenza and COVID-19 Immunization Program Plan Fall/Winter 2023-24

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Manitoba Health  
Population and Public Health Division  
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.

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## Acronyms

<b>ACIP</b>	Advisory Committee on Immunization Practices
<b>AEFI</b>	Adverse event following immunization
<b>AESI</b>	Adverse events of special interest
<b>CI</b>	Confidence interval
<b>COVID-19</b>	Coronavirus Disease of 2019
<b>DPIN</b>	Drug Programs Information Network
<b>GBS</b>	Guillain-Barré syndrome
<b>IIV</b>	Inactivated influenza vaccine
<b>ILI</b>	Influenza-like illness
<b>ISC</b>	Indigenous Services Canada
<b>LAIV</b>	Live attenuated influenza vaccine
<b>LTCF</b>	Long-term care facility
<b>MDV</b>	Multi-dose vial
<b>MH</b>	Manitoba Health
<b>MOH</b>	Medical Officer of Health
<b>NACI</b>	National Advisory Committee on Immunization
<b>ORS</b>	Oculo-respiratory syndrome
<b>PDW</b>	Provincial Distribution Warehouse
<b>PFS</b>	Pre-filled syringe
<b>PHIMS</b>	Public Health Information Management System
<b>PHIN</b>	Personal health identification number
<b>PVAC</b>	Provincial Vaccine Advisory Committee
<b>RCT</b>	Randomized controlled trial
<b>SDO</b>	Service Delivery Organization
<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 Service Delivery Organizations (SDOs), including Indigenous Services Canada, that participate in Manitoba's Seasonal Influenza Immunization Program, with the provincial program details for the upcoming 2023-24 influenza (flu) and COVID season.

## 2023-24 Program Dates

- **February 2023:** World Health Organization released the recommended strains for the 2023-24 northern hemisphere influenza vaccines in February. Manitoba is expecting egg-based flu vaccines with four recommended flu strains.
- **June 2023:** Manitoba followed recommendations from the National Advisory Committee on Immunizations (NACI) to lower the age of co-administration for Flu and COVID-19 vaccines to individuals aged 6 months and older. NACI's "Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2023-24" can be accessed at: [www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html#a4.5](http://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html#a4.5)
- **July 2023:** Manitoba Health announced that the ordering and distribution of the COVID-19 and influenza vaccines will be combined. All providers who want to participate in the influenza and COVID-19 immunization program must register. Providers are asked to complete the registration form online by August 15, 2023, to ensure receipt of all communications, allow for the creation of distribution groups, and allocation planning.
- **August 25:** The provincial "seasonal flu" website [www.manitoba.ca/health/flu/index.html](http://www.manitoba.ca/health/flu/index.html) is updated along with print materials including promotional/educational resources (i.e. factsheet, poster, brochure, etc.) and order forms. Documents may be updated online sooner as they are finalized
- **September 2023:** Starting in 2023/24 Influenza season, all pharmacists will be required to enter the publicly funded flu and COVID-19 immunizations they administer into PHIMS. Doses entered into DPIN will not be captured into PHIMS. All other vaccines administered by pharmacists are still to be recorded in DPIN.

Any pharmacy that does not have access to PHIMS yet and will be participating in the influenza and COVID-19 immunization programs will be required to be set up with PHIMS. For those who have access to PHIMS, an updated ISA will be required. Once registered, pharmacies will be contacted for any next steps.

- **Mid September:** Deadline for health care providers, such as pharmacies, physicians, and SDOs, to submit their clinic dates, times and locations for inclusion on the Manitoba Health (MH) Vaccine Finder website. Information can be emailed to [vaccines@gov.mb.ca](mailto:vaccines@gov.mb.ca).
- **September 30:** The annual pneumococcal polysaccharide 23 (Pneu-P-23) and High-Dose Influenza vaccine reminder letter will go out to people who have turned 65 years of age in the past year.
- **Early to Mid October:** Launch of the provincial 2023-24 Seasonal Influenza and COVID-19 Immunization Program advertising campaign.
- **October 23:** Regional public health immunization clinics can begin.
- **October 31:** Personal care homes should be completed their influenza immunization programs for their residents.

## SEASONAL INFLUENZA

### Eligibility Criteria

For the 2023-24 influenza season, all Manitobans 6 months of age and older will be eligible to receive the seasonal influenza (flu) vaccine free of charge.

The flu vaccine 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 individuals

- breastfeeding women if not given during that pregnancy
- health care workers and first responders
- those who provide services within closed or relatively closed settings to people at high risk (e.g., crew on a ship)
- people who provide essential community services
- 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
- People who are in direct contact with poultry infected with avian influenza during culling operations.

**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 Manitoba Health coverage. Administration fees may still apply.**

## Recommendations

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*Starting in 2023/24 Influenza season, all pharmacists will be required to enter the publicly funded flu immunizations they administer into PHIMS.*

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### Infants and Children

Children younger than nine years of age who have NEVER received a flu vaccine need two doses, at least four weeks apart. As per NACI, children 6 months to less than 9 years of age who have been properly vaccinated with one or more doses of seasonal influenza vaccine in any previous season should receive one (1) dose of influenza vaccine per season thereafter.

- Several studies have looked at whether these two initial doses need to be given in the same season. It appears that for children 6-23 months, similar immunogenicity was found whether the 2 doses were given in the same or separate season when there was no change or only minor vaccine strain change in the vaccine formulation between seasons. When there is a major B lineage change between seasons the seroprotection rates were considerably reduced. Because children 6-23 months of age are less likely to have had prior priming exposure to an influenza virus, special effort is warranted to ensure that a two-dose schedule is followed for previously unvaccinated children in this age group.

## Pregnant and Breastfeeding Women

NACI recommends the inclusion of all pregnant individuals in the Flu Immunization program at any stage of pregnancy. Pregnant individuals and newborn infants are considered at high risk of influenza-related complications including hospitalization. The risk of influenza-related hospitalization increases with length of gestation and therefore pregnant individuals are recommended to receive the flu vaccine as soon as it is available at any stage of pregnancy. If not provided during pregnancy, the mother and other household contacts should be immunized as soon as possible after birth of the child to protect the infant. Infants cannot be immunized against influenza until 6 months of age. Annual influenza vaccination is recommended during breastfeeding if not given during pregnancy [www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-4-immunization-pregnancy-breastfeeding.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-4-immunization-pregnancy-breastfeeding.html).

## Health Care Workers

Influenza vaccination provides benefits to health care workers (HCWs) and to the patients to whom they provide care. Health care providers being immunized decreases their own risk of illness, as well as the risk of death and other serious outcomes among the patients to whom they provide care.

- NACI considers the receipt of influenza vaccination to be an essential component of the standard of care for all HCWs and other care providers for their own protection and that of their patients, regardless of whether the high-risk individual has been vaccinated.
- 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 (i.e. physician offices, immunization clinics, etc.).

All doses administered including to those without a Personal Health Identification Number (PHIN) from MH are to be reported to MH. See Documentation section below on the ways to report the administered doses.

## Overview of National/Provincial Recommendations

As per NACI, the national goal of the annual influenza immunization programs in Canada is to prevent serious illness caused by influenza and its complications, including death.

As part of the National Immunization Strategy (NIS), the national influenza vaccination coverage goals by 2025 includes achieving 80% coverage among:

- Adults 65 years of age and older
- Adults 18-64 years with chronic medical conditions



- Health care professionals

Every year, NACI updates its recommendations regarding the use of the seasonal flu vaccine. MH and Manitoba's Provincial Vaccine Advisory Committee (PVAC) thoroughly reviews and examines NACI's annual recommendations to inform provincial recommendations and program details.

**NACI's Canadian Immunization Guide and Statement on Seasonal Influenza Vaccine for 2023-24** is available online at [www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html#a4.5](http://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html#a4.5).

**MH Seasonal Influenza Management Protocol** is also available online at [www.manitoba.ca/health/flu/pro.html](http://www.manitoba.ca/health/flu/pro.html).

Annual vaccination is recommended since the strains contained within the vaccine are changed every year to provide a better match against the viruses expected to circulate, and because the body's immune response to influenza vaccination is unlikely to persist beyond a year.

## Vaccine Efficacy and Effectiveness

Influenza vaccine has been shown to be efficacious in clinical trials although real-world effectiveness can vary depending on a number of factors including how well the vaccine strain match with circulating strains. Even when there is a less-than-ideal match or lower effectiveness against one strain, the possibility of lower VE should not preclude vaccination, particularly for people at high risk of influenza-related complications and hospitalization. Vaccinated individuals are still more likely to be protected compared to those who are unvaccinated. Immunization has been shown to reduce the number of physician visits, hospitalizations and deaths in high-risk adults.

## Contraindications and Precautions

Influenza vaccines are contraindicated in persons with a history of anaphylaxis after previous administration of the vaccine and in persons with proven immediate or anaphylactic hypersensitivity to any component, except egg, of the specific vaccine or its container.

NACI has reviewed the data on administering flu vaccine to egg allergic persons and has concluded that egg allergic individuals may be vaccinated using a full dose of any of the seasonal influenza vaccines available. This is irrespective of a past severe reaction to egg and does not require a prior influenza vaccine skin test. However, immunizers must be prepared with the necessary equipment, knowledge and skills to respond to a vaccine emergency. The observation period post-vaccination of at least 15 minutes is recommended.

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.

## Adverse Events of Special Interest

With intramuscularly injected (needle) vaccines (Fluzone® Quadrivalent, Flulaval® Tetra, Afluria® Tetra, and Fluzone® High-Dose Quadrivalent), injection site reactions are common but are generally classified as mild and transient.

- Fluzone® High-Dose Quadrivalent tends to induce higher rates of reactions post-injection compared to standard-dose IIV due to the higher antigen dose, but most of these reactions are mild and short-lived.

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.

There are a few Adverse Events of Special Interest (AESI)<sup>1</sup> that need to be watched out for when giving the flu vaccine, including but not limited to the following:

**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. In comparison, the risk of GBS associated with influenza illness is larger with about 17 cases per million influenza-coded health care encounters, which are a proxy for influenza illness. 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):** ORS was identified during the 2000/01 flu season. Since then, there have been far fewer cases reported per year according to the CAEFISS. ORS is not considered to be an allergic response. Persons who have an occurrence or 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-vaccinated with influenza vaccine. Persons who experienced ORS with lower respiratory tract

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<sup>1</sup> An AESI is defined as an adverse event (serious or non-serious) that is “of scientific and medical concern specific to the sponsor’s product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted.” (Council for International Organizations of Medical Sciences (CIOMS) VII

symptoms should have an expert review. Health care providers who are unsure whether an individual previously experienced ORS versus an immunoglobulin E (IgE) mediated hypersensitivity immune response should seek advice. Data on clinically significant adverse events do not support the preference of one vaccine product over another when revaccinating those who have previously experienced ORS.

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 a mercury-based preservative to keep the product sterile. Large cohort studies of health databases have found that there is no association between thimerosal-containing vaccines and neurodevelopmental outcomes, including autistic-spectrum disorders. All single dose formulations [i.e., pre-filled syringes (PFS) of IIV (Fluzone® Quadrivalent, Afluria® Tetra, and Fluzone® High-Dose) are thimerosal-free.

For more information on the contents of influenza vaccine and others, please visit Contents of immunizing agents available for use in Canada: Canadian Immunization Guide - Canada.ca

For more information on how to report an adverse events following immunization (AEFI), see the Documentation section below.

## Vaccine Products

As per the World Health Organization (WHO), all quadrivalent influenza vaccines that have egg-based or recombinant manufacturing processes for the 2023-24 season in the northern hemisphere contains:

- an **A/Victoria/4897/2022 (H1N1)pdm09-like virus;**
- an **A/Darwin/9/2021 (H3N2)-like virus;**
- a **B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and**
- **A B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.**

For the 2023-24 season, please refer to the table available at

[www.gov.mb.ca/health/flu/docs/influenza\\_product\\_quick\\_reference\\_guide.pdf](http://www.gov.mb.ca/health/flu/docs/influenza_product_quick_reference_guide.pdf) to find details on the different flu vaccines that are part of this year's Seasonal Influenza Immunization Program. Which products and in what volumes Manitoba will receive will vary based on national allotment and availability.

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 authorized under that Act to administer vaccines. Please, refer to the Publicly Funded Provincial Immunization Program Standards available at [www.manitoba.ca/health/publichealth/cdc/div/manual/docs/standards.pdf](http://www.manitoba.ca/health/publichealth/cdc/div/manual/docs/standards.pdf)

## Fluzone® High-Dose Quadrivalent

Fluzone® High-Dose Quadrivalent contains four influenza strains (2A + 2B) and four times the amount of influenza virus antigen per strain (60 µg vs. 15 µg) compared to the standard-dose IIV. These are the same strains that are part of the standard-dose IIV. It is the recommended flu vaccine product for all individuals aged 65 years of age and older.

- NACI conducted an updated literature review in 2018, which showed that Fluzone® High-Dose has higher relative efficacy against severe outcomes, including hospitalizations and deaths, compared to a standard-dose IIV in adults 65 years of age and older. Given the evidence of better efficacy in this age group, it is expected that Fluzone® High-Dose Quadrivalent can provide superior protection compared with standard-dose IIV.

Staff and residents of LTCFs, assisted living, and supportive housing who are less than 65 years of age should be immunized with standard-dose IIV.

In the event that someone has been immunized with the standard dose when they were eligible for the high dose Influenza product, it is recommended to not administer the Fluzone® High-Dose Quadrivalent.

The higher antigen concentrations contained within Fluzone® High-Dose Quadrivalent 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 Quadrivalent, but serious adverse events were similar in frequency between the high- and standard-dose IIV.

Any reported adverse events following administration of Fluzone® High-Dose Quadrivalent are reviewed based on provincial procedures.

## COVID-19 (SARS-CoV-2)

### Eligibility Criteria

All people in Manitoba aged 6 months and older are eligible for COVID-19 vaccination. Please, refer to [www.manitoba.ca/covid19/vaccine.html](http://www.manitoba.ca/covid19/vaccine.html) for more information.

### Manitoba Health Recommended mRNA Immunization Schedule

For the 2023-24 season, please refer to the tables for the appropriate age group available at [www.manitoba.ca/covid19/vaccine.html](http://www.manitoba.ca/covid19/vaccine.html) to find details on the different COVID-19 vaccines that are part of this year's Seasonal Influenza and COVID-19 Immunization Program. Which products and in

what volumes Manitoba will receive will vary based on national allotment and availability. **Note: the Vaccine and Eligibility section will be updated as the products are approved by Health Canada and become available in Manitoba. The schedule currently posted online is based on the previous product availability and recommendations.**

Please note, **ALL** COVID-19 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 authorized under that Act to administer vaccines. Please, refer to the Publicly Funded Provincial Immunization Program Standards available at [www.manitoba.ca/health/publichealth/cdc/div/manual/docs/standards.pdf](http://www.manitoba.ca/health/publichealth/cdc/div/manual/docs/standards.pdf)

**International students and out-of-province visitors continue to be eligible to receive the COVID-19 vaccine free-of-charge regardless of third-party insurance and/or Manitoba Health coverage. Administration fees may still apply.**

## Recommendations

It is important to review a client's immunization history to determine the last dose of COVID-19 vaccine. For those with a complete primary series, the recommended interval is six months since the most recent previous COVID-19 vaccine received or COVID-19 infection (whichever is longer), however three months since the most recent COVID-19 vaccine dose is the minimum interval. Vaccine effectiveness increases with longer duration between doses.

**SEPTEMBER 13, 2023:** Updated formulations of the COVID-19 mRNA vaccines have been developed to protect against the XBB 1.5 strain of the COVID-19 virus. They have been approved for use in:

- Individuals age 6 months and older who have never received a COVID-19 vaccine.
- Individuals age 6 months and older who have already received a COVID-19 vaccine and need one or more additional doses to complete their primary series.
- Individuals age 6 months and older who have completed a primary series with COVID-19 vaccines and are recommended to receive an additional dose for fall 2023.

**Note: NACI may release additional recommendations for the use of the updated XBB 1.5 formulations as a primary series in fall 2023. The Program Plan will be updated as needed to reflect the new recommendations. Please refer to the most current release of the influenza and COVID-19 Immunization Program Plan.**

### Children aged 6 months to 4 years

Children 6 months to 4 years of age who have never been vaccinated against COVID-19 are eligible to receive two or three doses depending on the vaccine product.

Children must be at least six months of age at the time of their immunization appointment.

There are two products authorized for children aged 6 months to 4 years:

- **Moderna:** The primary series consists of 2 doses. The minimum interval between the first and second dose is four weeks.
- **Pfizer:** The primary series consists of 3 doses. The minimum interval between the first and second dose is 3 weeks. The minimum interval between the second and third dose is 8 weeks. Infants or children who received a dose of Pfizer/Comirnaty™ XBB.1.5 should receive Pfizer/Comirnaty™ XBB.1.5 to complete the three-dose course if possible.

Individuals who started their primary series with the original monovalent or bivalent vaccines can complete their primary series with the updated XBB.1.5 formulation. Regardless of which product was used to start a primary series, the previous dose(s) should be counted and the series need not be restarted.

Beginning in the fall 2023, individuals 6 months and older who have completed a primary series are eligible to receive one dose of the XBB.1.5 COVID-19 vaccine with a recommended interval of 6 months from the previous COVID-19 vaccine dose or known COVID infection (whichever is later). However, one dose of the XBB.1.5 formulation may be provided if it has been at least 3 months from any previous COVID-19 vaccine formulation (i.e.BA4/5).

For more information on the National Advisory Committee on Immunization (NACI) recommendations, please refer to the Canadian Immunization Guide at [www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html).

#### Individuals aged 5 and above

Individuals aged 5 and up who have never been vaccinated against COVID-19 vaccine are eligible to receive one dose of the new XBB.1.5 formulation.

Individuals 12 years and older who choose not to get an mRNA vaccine or have contraindications to an mRNA vaccine can get Novavax instead.

For more information on NACI's recommendations, please refer to the Canadian Immunization Guide at [www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html](http://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html).

#### Vaccine Eligibility for Infants, Children, Youth and Adults who are Moderately to Severely Immunocompromised

For the purposes of COVID-19 vaccine recommendations, the following individuals are considered moderately to severely immunocompromised due to a medical condition and/or treatment:

- are receiving active chemotherapy (or immunotherapy) for cancer;

- have received a solid organ transplant and are currently receiving chemotherapy or other immunosuppressive therapy;
- were born with moderate or severe dysfunction of their immune system;
- are living with untreated or advanced HIV-AIDS; or
- are taking certain medications that severely affect the immune system.

The following people should talk to their doctor to see whether they are considered to be immunocompromised:

- receiving hemodialysis or peritoneal dialysis;
- are on the list to receive a solid organ transplant; or
- have a ventricular assist device (VAD).

For the 2023/24 Fall immunization program, a dose of the new XBB.1.5 formulation of COVID-19 vaccine is recommended particularly for those at increased risk of COVID-19 infection or severe disease, including those who are immunocompromised. For those with a complete primary series, the dose should be given if it has been at least 3 months since the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later), however an interval of 6 months is recommended.

The below recommendations are based on the current CDC recommendations which can be found at: [www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html). MH will review and updated this section (as required).

If not previously immunized or if partially immunized against COVID-19:

- Individuals six months to four years of age who are moderately to severely immunocompromised are eligible to receive: three doses of the Moderna/Spikevax™ vaccine or four doses of the Pfizer/Comirnaty™ vaccine. The Moderna vaccine is preferred due to quicker protection from a three dose series.
- Individuals five years of age and older who are moderately to severely immunocompromised are recommended to receive three doses of COVID-19 vaccine. The interval between doses is four to eight weeks.
- Individuals who started their primary series with the original monovalent or bivalent vaccines can complete their primary series with the updated XBB.1.5 formulation. Regardless of which product was used to start a primary series, the previous dose(s) should be counted and the series need not be restarted.

If having previously completed a COVID-19 vaccine primary series:

- Individuals six months of age and older who are moderately to severely immunocompromised are recommended to receive one dose of the updated XBB.1.5 formulation in the fall of 2023 if it has been at least 3 months from the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later), however an interval of 6 months is recommended.

### Immunization after a COVID-19 infection

It is recommended to wait six months before getting your next dose of COVID-19 vaccine after a known SARS-CoV-2 infection.

Recommendations may be different if you are moderately to severely immunocompromised. Please speak to your health care provider to get the best advice on when to get your next vaccine dose after a COVID-19 infection.

For more information on NACI's recommendation on interval between infection and getting your next COVID-19 vaccine dose, please visit: [COVID-19 vaccine: Canadian Immunization Guide - Canada.ca](https://www.canada.ca/en/health-canada/services/covid-19/vaccine/canadian-immunization-guide.html).

## Overview of National/Provincial Recommendations

On September 12, 2023, NACI released further guidance for fall 2023. NACI recommends all previously vaccinated individuals receive a dose of the updated XBB.1.5 formulation of COVID-19 vaccine at least 6 months from the previous COVID-19 vaccine doses or infection, whichever is later. On October 27, 2023, NACI's updated guidance indicated that shorter intervals (i.e., 3 months to less than 6 months) following previous vaccination or infection have also not been shown to pose a safety risk.

It remains important that the following individuals who are at higher risk of severe disease or infection to be immunized against COVID-19, specifically:

- people aged 65+,
- residents of long-term care homes and other congregate living settings,
- Individuals with underlying medical conditions that place them at higher risk of severe COVID-19, including those who are immunocompromised,
- pregnant individuals,
- individuals in or from First Nations, Metis, and Inuit communities,
- members of racialized and other equity-deserving communities, and
- people who provide essential community service.



## Vaccine Efficacy and Effectiveness

COVID-19 vaccines play an important role in minimizing the impact of COVID-19 in the population, including significantly lowering the risk of severe illness such as hospitalization and deaths.

Vaccine effectiveness may be affected by the vaccine product received, the interval between doses, the time since the most recent dose, the age and health status of the recipient and their prior COVID-19 infection history. The emergence of immune evasive variants of concern has impacted vaccine effectiveness against COVID-19 infection and necessitated the development of the updated XBB.1.5 formulations of the COVID-19 vaccines.

Studies also continue to support vaccination during pregnancy. Vaccination with an original mRNA vaccine in pregnancy has been shown to confer protection to infants against COVID-19 infection and reduce hospitalization for infants under 6 months of age. Protection was highest for infants who were less than 2 months of age and began waning between 4-6 months.

## Adverse Events of Special Interest

Adverse events most commonly associated with COVID-19 vaccination are mild and go away on their own with minimal to no intervention. These include local reactions like redness, soreness and swelling as well as systemic reactions like chills, fatigue, joint pain, headache, low-grade fever and muscle aches.

Less commonly, more concerning adverse events have been reported. Below is a listing of AESI<sup>2</sup> that have been reported following COVID-19 vaccination in Manitoba in the two-year period from 2021 to 2022:

AESI	Count*	Rate (per 100k doses)
<b>mRNA</b>		
Anaphylaxis	54	1.65
Myocarditis/Pericarditis	45	1.38
Bell's Palsy	31	0.95
Seizure	24	0.74
Venous Thromboembolism	19	0.58

<sup>2</sup> An AESI is defined as an adverse event (serious or non-serious) that is “of scientific and medical concern specific to the sponsor’s product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted.” (Council for International Organizations of Medical Sciences (CIOMS) VII

Arrythmia	14	0.43
Stroke	11	0.34
Coronary Artery Disease	6	0.18
Guillain-Barré syndrome	3	0.09
Thrombocytopenia	3	0.09
<b>Viral vector†</b>		
Venous Thromboembolism‡	15	15.69
Bell's Palsy	5	5.23
Thrombocytopenia‡	5	5.23
Anaphylaxis	4	4.18
Stroke	4	4.18
Seizure	3	3.14

\*Only lists AESIs with count of 3 or more

†All associated specifically with the AstraZeneca product, which the province no longer carries

‡Including but not limited to the Thrombosis with Thrombocytopenia Syndrome/Vaccine-Induced Thrombosis with Thrombocytopenia

For more information on how to report an adverse events following immunization (AEFI), see the Documentation section below.

Learn more about:

- [Reported side effects following COVID-19 vaccination](#)
- [Vaccine safety and possible side effects: Allergic reactions](#)

## Contraindications and Precautions

People who had a severe and immediate (4 hours or less following vaccination) allergic reaction after receiving an mRNA COVID-19 vaccine or have a suspected or known allergy to a component of the vaccine (e.g., tromethamine, PEG in COVID-19 mRNA vaccines) should be referred to an allergist for further assessment. Where consultation with an allergist or other appropriate physician precludes further vaccination with an mRNA vaccine, vaccination with Novavax should be offered if the individual is in the authorized age group and does not have contraindications to the vaccine.

Individuals with a history of an allergic reaction to contrast dye can still receive an mRNA COVID-19 vaccine and should be observed for 30 minutes after vaccine administration.

As a precautionary measure, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis and/or pericarditis within 6 weeks following a previous dose of an mRNA COVID-19 vaccines.

Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom-free and at least 90 days have elapsed since vaccination.

Current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a dose of an updated formulation of mRNA COVID-19 vaccine

## Vaccine Products and monographs

To see the details of the various COVID-19 products available please see the COVID-19 Vaccine Comparison Chart located at [www.manitoba.ca/covid19/health-care-providers.html#comparison](http://www.manitoba.ca/covid19/health-care-providers.html#comparison).

Please refer to the product monographs for more specific details around each product [www.manitoba.ca/covid19/health-care-providers.html#product-monographs](http://www.manitoba.ca/covid19/health-care-providers.html#product-monographs).

**Note: Once approved by Health Canada, the product monographs for the updated COVID-19 vaccines are posted online.**

## PNEUMOCOCCAL IMMUNIZATION PROGRAM

Manitoba offers one dose of pneumococcal polysaccharide (Pneu-P-23) vaccine to all those 65 years of age and older. The Pneu-P-23 vaccine can be offered year round although it is usually co-administered with the flu vaccine. Some people under the age of 65 years of age could also be eligible for a Penu-P-23 vaccine. Please, see the full eligibility criteria at [www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html](http://www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html).

Some individuals may also be eligible for the Pneumococcal conjugate (Pneu-C-13) vaccine. Please, see eligibility criteria at [www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html](http://www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html).

## Vaccine Ordering and Distribution Process

Manitoba uses a mixed provider delivery model for Manitoba's Immunization Program, with nurses, nurse practitioners, midwives, physicians, physician assistants, and pharmacists administering vaccines in private and public health settings.

For the 2023-24 influenza season, Manitoba Health is combining the ordering of flu and COVID-19 vaccines into one model. The new distribution model is anticipated to be less labor intensive for providers, while increasing vaccine access to Manitobans.

Providers are required to register for the flu and COVID-19 immunization program. The registration form is available at: [forms.office.com/r/dTEvd2ZMYy](https://forms.office.com/r/dTEvd2ZMYy)

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*Starting in 2023/24 Influenza season, all pharmacists will be required to enter the publicly funded flu immunizations they administer into PHIMS, in addition to COVID-19 vaccines.*

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Providers who register will be sent order surveys. Responses to those surveys will be required by the indicated deadlines in order to receive product for that time period. Order surveys will be sent out every other week alternating between two (2) distribution groups.

Orders will be reviewed and may be adjusted based on vaccine availability, historical doses administered, as well as any shortages or delays that may occur. A confirmation email will include a list of all the products to be shipped, the approved quantities, as well as an approximate timeline for when deliveries should be expected.

Providers will also be expected to communicate any special hours of operation (e.g. Closed for lunch between 12-1, closed on Fridays, etc.) and whether or not they are open for weekend deliveries. This information is extremely important and will ensure an efficient and timely delivery schedule.

To expedite the order process and reduce the number of individual orders that are being shipped to one single location, health care providers at the same facility should submit one order for influenza, COVID-19, and pneumococcal vaccines (that covers all providers in the facility).

Health care providers are encouraged to start offering influenza, COVID-19 and pneumococcal vaccines to their patients as soon as they receive the product.

For information on the new distribution model as well as how to register for the program, please go to [www.manitoba.ca/fludistribution](http://www.manitoba.ca/fludistribution). All future updates pertaining to influenza and COVID-19 vaccine distribution/supply including shortages, and/or delays will be posted online at [www.manitoba.ca/fludistribution](http://www.manitoba.ca/fludistribution) and will also be emailed to providers at the email address provided at the time of registration.

Please note that vaccine wastage should be less than 5% at the end of the influenza season. Any unused vaccine from the previous influenza season is to be returned to the Provincial Distribution

Warehouse. Please, follow *Manitoba Health's Return Policy and Procedure* available at: [www.manitoba.ca/health/publichealth/cdc/div/docs/vbrp](http://www.manitoba.ca/health/publichealth/cdc/div/docs/vbrp).

## Monitoring the Safety of Vaccines

Vaccines are safe and well tolerated. Notwithstanding data from pre-marketing trials showing vaccines to have a safe and stable profile, steps are undertaken by national and provincial vaccine programs to monitor their use in post-marketing for any new safety issue that might emerge. In addition to routine passive surveillance, every year during the seasonal influenza vaccination campaigns, PHAC and the Federal/Provincial/Territorial Vaccine Vigilance Working Group (VWVG) of the Canadian Immunization Committee conduct expedited reporting of AEFIs with current influenza vaccines (usually weekly) in order to identify vaccine safety signals in a more timely manner. Refer to the [Canadian Adverse Events Following Immunization Surveillance System](#) (CAEFISS) web page for more information on post-marketing surveillance and AEFIs in Canada.

In addition, there is a pediatric hospital-based surveillance system known as the Immunization Monitoring Program ACTive (IMPACT) that utilizes an active surveillance approach whereby hospital records are actively searched for AEFI cases.

Specifically in Manitoba, an enhanced vaccine safety signal detection methodology first implemented during the COVID-19 vaccination campaign and has since been employed as well for other vaccine products will continue to be implemented during both the flu and COVID-19 campaigns. This involves a systematic, near-real time assessment of an identified risk associated with the use of the vaccine that uses dynamic data files and sequential analysis for early detection of adverse events. Urgent measures to protect the public are then immediately undertaken, where appropriate.

## Documentation

An immunizer is a health care provider who is registered or licensed to provide health care under current legislation and who is authorized under that legislation to administer vaccines to a client/patient.

Immunizers MUST record and maintain doses administered, informed consent, adverse events following immunization (AEFI), and incidents of adverse storage conditions as outlined in the provincial immunization program standards. Audits will be conducted periodically and documentation may be required to be submitted to MH, as requested.

Pharmacies that contract nurses to conduct flu and COVID-19 immunizations must ensure that they meet those standards and keep records of doses administered, informed consent, AEFI, and any other incidents.

For more information about provincial immunization 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) and the Provincial Immunization Competency Guideline at

<https://www.manitoba.ca/health/publichealth/cdc/div/manual/docs/immcomp.pdf>.

### a. Reporting an AEFI

In accordance with section 59 of The Public Health Act, health care providers and pharmacies are to report to the regional Medical Officer of Health (MOH) a reportable AEFI within seven days of becoming aware of the AEFI. Health care providers should report a serious AEFI (see below) within one business day, which can be by telephone, followed by the complete written 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 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)
- 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 PHIMS allows public health providers with access to report AEFIs directly into PHIMS. Health care providers without access to PHIMS should complete a **Reporting Form for Adverse Events Following Immunization** available online at:

[www.manitoba.ca/health/publichealth/cdc/docs/aeFI\\_form.pdf](http://www.manitoba.ca/health/publichealth/cdc/docs/aeFI_form.pdf) and submit it to their regional MOH (see last page of form for list of MOH contact information). All forms received will also be entered into PHIMS for vaccine safety surveillance in Manitoba, and will be included as part of the client immunization record in the provincial immunization registry within PHIMS. All MOH recommendations of an individual's AEFI should be recorded in the client's personal health record.

**Manitoba Health reviews all submitted AEFI reports. If a link is found between an 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/aeFI.html](http://www.manitoba.ca/health/publichealth/cdc/div/aeFI.html).

## b. Data Entry

Every health care provider and facility in Manitoba **MUST ACCOUNT FOR EVERY DOSE OF VACCINE ORDERED AND ADMINISTERED, INCLUDING FLU AND COVID VACCINES.**

Immunizations must be reported within two (2) business days of administration in the client's electronic public health record via the Manitoba Immunization Registry (PHIMS) to ensure accurate and up to date information is available. This can be completed in one of three ways:

- Electronically uploaded from the Claims Processing System (Physician Billing) when publicly funded immunizations are administered by fee-for-service physicians and other health care providers, that shadow bill (e.g. regional nurse practitioners).
- Direct entry into the Public Health Information Management System (PHIMS): health care providers that have access to PHIMS can enter flu and COVID-19 vaccine doses administered directly into Manitoba's Immunization Registry (assuming their permissions allow for data entry).
- If you do not have access to PHIMS, are unable to enter information directly into PHIMS (i.e. Private Flu Clinic), complete and submit for the doses administered using [www.manitoba.ca/health/publichealth/cdc/div/docs/iifhccp.pdf](http://www.manitoba.ca/health/publichealth/cdc/div/docs/iifhccp.pdf)
  - For doses administered to persons without a PHIN complete and submit [www.manitoba.ca/health/publichealth/cdc/div/manual/docs/vaccine-admin-](http://www.manitoba.ca/health/publichealth/cdc/div/manual/docs/vaccine-admin-)

[reporting-no-phin.pdf](#) and fax to Manitoba PHIMS Quality Assurance at 204-945-6482.

- All doses administered and reported will be recorded into Manitoba's Public Health Information Management System (PHIMS).

Documentation and record storage should also comply with the respective health care providers' regulatory body.

Surveillance of influenza and COVID-19 immunization uptake is included in the weekly and end of season respiratory surveillance reports. Reports for 2023-24 as well as for previous seasons can be accessed online at: [www.manitoba.ca/health/publichealth/surveillance/influenza/index.html](http://www.manitoba.ca/health/publichealth/surveillance/influenza/index.html)

### c. Consent

As per Manitoba Health *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, a combined influenza, COVID-19, and Pneu-P-23 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 and pharmacists MUST report the adverse storage condition incident to MH by completing/submitting 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 PHIMS.

For information on the storage and handling of COVID-19 vaccines, please refer to the Storage and Handling Quick Reference for Manitoba's COVID-19 Vaccines

[www.manitoba.ca/asset\\_library/en/covidvaccine/storage-handling-chart.pdf](http://www.manitoba.ca/asset_library/en/covidvaccine/storage-handling-chart.pdf).

**Manitoba Health does not allow the use of bar fridges to store vaccines and regular mercury thermometers are not to be used to monitor the fridge temperature.**

Fridges should only contain vaccines. No food or other biologics should be kept in the vaccine fridge. Health care providers and pharmacists who are holding clinics outside of their main facility, where a fridge may not be present, should review the **Packing, Storage and Handling for Off-Site Immunization Clinics** section of the *Cold Chain Protocol*. This will ensure that vaccines are



stored and transported properly and temperature of the vaccines are maintained and recorded throughout the time they are out of the fridge.

## Communications

Promotional/educational resources (i.e. factsheets, posters, brochures) will be available to order, free of charge, from the Materials Distribution Agency, and will also be posted on MH's Seasonal Flu website at [www.manitoba.ca/health/flu/pro.html](http://www.manitoba.ca/health/flu/pro.html) and COVID-19 website at [www.manitoba.ca/covid19/vaccine.html](http://www.manitoba.ca/covid19/vaccine.html) where they can be downloaded electronically.

The flu and COVID-19 promotional/educational resources may be updated for the 2023-24 season. Confirmation of such a change will be made once any final decisions are made and will be broadly communicated once the updated resources are available. The link to the Order Form to order promotional and educational resources will be provided once all products are available to order. As with previous years, Manitoba Health will communicate with health care providers including SDOs, pharmacists, and Indigenous Services Canada (ISC) 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 (i.e. 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 (estimated start date: October 24).

In order to provide more information to the public, MH will continue to post on the Vaccine Finder map any clinics that are being held where the public is able to attend. MH has also expanded the visibility of the influenza and COVID-19 vaccines for the public through geographical mapping to show any locations that have indicated that they have influenza or COVID-19 vaccine supply available and are accepting walk-ins/appointments from the public. This information is posted on the *Where Can I Get My Flu Vaccine* website [www.gov.mb.ca/health/flu/where.html](http://www.gov.mb.ca/health/flu/where.html) and [www.manitoba.ca/covid19/vaccine.html#finder](http://www.manitoba.ca/covid19/vaccine.html#finder).

Health care providers and pharmacies that are planning on hosting public clinics are to ensure that information about the clinic (i.e. date, times, location, accessibility, appointment or walk-in) is provided via email to [vaccines@gov.mb.ca](mailto:vaccines@gov.mb.ca) at least three week in advance. MH will make every effort to include these in the Vaccine Finder.