Ontario

Ministry of Health

# Health Care Provider Fact Sheet: Influenza Immunization for Individuals ≥65 years of age

This document is intended for informational purposes only. It is not intended to provide medical or legal advice.

**Highlights of changes:**

- Switch from quadrivalent inactivated vaccines (QIV) to trivalent inactivated vaccines (TIV) for influenza vaccines.

## Universal Influenza Immunization Program (UIIP)

Ontario's Universal Influenza Immunization Program (UIIP) offers free influenza vaccine each year for individuals six months of age and older who live, work, or go to school in Ontario.

Individuals may be required to provide proof that they live, work, or attend school in Ontario to receive the publicly funded influenza vaccine. Having a health card is NOT a requirement, however, some health care providers may request one for their services. Eligible individuals without a health card can receive the influenza vaccine from a community health centre, participating pharmacy, local public health unit or other community clinic. During the influenza season, Ontarians can contact their local public health unit if they require assistance locating influenza vaccine.

## Importance of influenza vaccination

The influenza vaccine is the best defence against getting and spreading the influenza virus, helping to save lives and reduce the strain on our health care system. Protection against infection and illness from the influenza virus through influenza vaccination may provide added benefit in protecting against other diseases such as invasive Group A Streptococcal Disease (iGAS) or worsening of existing chronic illnesses such as cardiovascular disease.

During the respiratory illness season and with the expected COVID-19 and respiratory syncytial virus (RSV) circulation this fall, it will be essential to prevent morbidity and mortality related to influenza to reduce the pressure on the health care system to ensure there is capacity to respond to emergent health care activity.

Visit the ministry's website for more information for health care providers regarding the COVID-19 vaccine program and RSV prevention program.

## Publicly funded influenza vaccines for individuals ≥65 years of age

The publicly funded influenza vaccines available for individuals 65 years of age and older include:

1. Trivalent Inactivated Vaccine (TIV), also for individuals ≥6 months of age
2. High-Dose Trivalent Inactivated Vaccine (TIV-HD) for ≥65 years
3. Adjuvanted Trivalent Inactivated Vaccine (TIV-adj) for ≥65 years

| | **1. Trivalent Inactivated Vaccines** | | |
|---|---|---|---|
| UIIP Abbreviation | TIV | | |
| NACI Abbreviation | IIV3-SD | | IIV3-cc |
| Vaccine product | Fluviral | Fluzone® | Flucelvax® |
| Manufacturer | GSK | Sanofi Pasteur | Seqirus |
| Age indication | ≥6 months | ≥6 months | ≥6 months |
| Vaccine type | Egg-based | Egg-based | Cell culture-based |
| Micrograms of hemagglutinin | 15 µg | 15 µg | 15 µg |
| Dosage | 0.5 mL | 0.5 mL | 0.5 mL |
| Format | MDV | MDV and PFS | PFS |
| Route | IM | IM | IM |
| Most common allergens[1] | • Egg protein[2]<br>• Formaldehyde<br>• Thimerosal | • Egg protein[2]<br>• Formaldehyde<br>• Thimerosal[3] | Does NOT contain egg protein, formaldehyde or thimerosal |

MDV = Multi-dose vial PFS = Pre-filled syringe IM = Intramuscular injection

NACI = National Advisory Committee on Immunization

[1] Any component in a vaccine may be a potential allergen. This table identifies the most common allergens.

[2] See the contraindications and precautions section on page 8 regarding egg allergies

[3] Multi-dose vial format only

| | 2. High-Dose Trivalent Inactivated Vaccine | 3. Adjuvanted Trivalent Inactivated Vaccine |
|---|---|---|
| UIIP Abbreviation | TIV-HD | TIV-adj |
| NACI Abbreviation | IIV3-HD | IIV3-Adj |
| Vaccine product | Fluzone® High-Dose | Fluad® |
| Manufacturer | Sanofi Pasteur | Seqirus |
| Age indication | ≥65 years | ≥65 years |
| Vaccine type | Egg-based | Egg-based |
| Micrograms of hemagglutinin | 60 µg | 15 µg |
| Dosage | **0.5 mL (NEW)** | 0.5 mL |
| Adjuvant | No | Yes |
| Format | PFS | PFS |
| Route | IM | IM |
| Most common allergens[1] | • Egg protein[2]<br>• Formaldehyde | • Egg protein[2]<br>• Formaldehyde<br>• Kanamycin<br>• Neomycin |

PFS = Pre-filled syringe IM = Intramuscular injection

NACI = National Advisory Committee on Immunization

[1] Any component in a vaccine may be a potential allergen. This table identifies the most common allergens.

[2] See the contraindications and precautions section on page 7 regarding egg allergies

[3] Multi-dose vial format only

**Important notes:**

- Fluzone® and Fluzone® High-Dose are DIFFERENT products. Fluzone® High-Dose is authorized ONLY for individuals aged 65 years and older. Please use caution when administering Fluzone® products.

## Eligible populations and timing of immunizations

All individuals in the COVID-19 and UIIP high-risk and priority groups are eligible for both vaccines as soon as available. Everyone who is eligible for COVID-19 early vaccination (prior to general population) is also eligible for UIIP early vaccination.

### 1. High-risk populations

The following individuals are at increased risk of influenza-related complications or are more likely to require hospitalization and **should receive** the influenza vaccine **as soon as it becomes available in the fall**:

- Residents in congregate living settings (e.g. chronic care facilities, long-term care homes, retirement homes)
- Adults 65 years of age and older
- All pregnant individuals
- All children 6 months to 4 years of age
- Individuals in or from First Nations, Métis or Inuit communities
- Individuals 6 months of age and older with the following underlying health conditions:
    - Cardiac or pulmonary disorders
    - Diabetes mellitus or other metabolic disease
    - Cancer
    - Conditions or medication which compromise the immune system
    - Renal disease
    - Anemia or hemoglobinopathy
    - Neurologic or neurodevelopment conditions
    - Class 3 obesity (body mass index of 40 or more)
    - Children and adolescents (6 months to 18 years) undergoing treatment with acetylsalicylic acid for long periods

### 2. Priority Populations

To optimize co-administration with COVID-19 vaccine, the following individuals **may receive** influenza vaccine **as soon as it becomes available in the fall:**

- Staff and care providers in congregate living settings (e.g. chronic care facilities, long-term care homes, retirement homes)
- Health care workers
- First responders
- Members of underserved communities
- Individuals whose occupational or recreational activities increase their risk of exposure to avian influenza A viruses

- Individuals with significant exposure to birds or mammals are more likely to have significant exposure to influenza A(H5N1) through interactions with birds or mammals (such as poultry, livestock, slaughterhouse and processing plant workers, wildlife officers/researchers, and veterinarians). Seasonal influenza vaccines do not provide protection against infection with influenza A(H5N1) viruses. However, they may reduce the risk of seasonal human and influenza A(H5N1) virus co-infection and possible viral reassortment leading to a human-transmissible virus with pandemic potential.

**3. General population**

All individuals (6 months of age and older without contraindications) who do not belong to the high-risk or priority populations described above **may receive** the influenza vaccine **starting on October 27, 2025.**

Individuals in the following two groups are **particularly recommended** to receive the influenza vaccine, once eligible (starting October 27, 2025):

I. Individuals capable of transmitting influenza to those listed in the high-risk populations section above and/or to infants under 6 months of age:
   - Care providers in the community
   - Household contacts (adults and children) of individuals at high risk of influenza related complications
   - Persons who provide care to children ≤ 4 years of age
   - Members of a household expecting a newborn during the influenza season
   - Those who provide services within a closed or relatively closed setting to persons at high risk of influenza related complications (e.g. crew on a ship)

II. People who provide essential community services

## Dose recommendations

For adults 65 years of age and older, one dose of the influenza vaccine is recommended annually because influenza viruses change often and immunity wanes between influenza seasons.

## Protection against influenza vaccine strains

Each year, the composition of the seasonal influenza vaccine is intended to protect against the anticipated circulating strains.

For the northern hemisphere's 2025/2026 season, the World Health Organization (WHO) has recommended the following strains be included:

| Influenza Strains | Egg-based TIVs<br>FluLaval<br>Fluzone®<br>Fluad® | Cell culture-based TIVs<br>Flucelvax® |
|---|---|---|
| A/Victoria/4897/2022 (H1N1)pdm09-like virus; | ✓ | |
| A/Croatia/10136RV/2023 (H3N2)-like virus; | **NEW** | |
| A/Wisconsin/67/2022 (H1N1)pdm09-like virus; | | ✓ |
| A/District of Columbia/27/2023 (H3N2)-like virus; | | **NEW** |
| B/Austria/1359417/2021 (B/Victoria lineage)-like virus; | ✓ | ✓ |

## B/Yamagata strain

Of note, there have been no confirmed naturally occurring B/Yamagata lineage virus detections since March 2020. As a result, the World Health Organization (WHO) no longer recommends the B/Yamagata strain to be included in the influenza vaccine formulations as it is no longer warranted.

NACI supports the removal of the B/Yamagata strain from influenza vaccines and the transition to trivalent influenza vaccines.

For the 2025/2026 influenza season in Canada, and in alignment with public health and regulatory agencies globally, all available influenza vaccine products will be trivalent formulations. Strains in the influenza vaccines authorized in Canada are aligned with WHO recommendations.

## Fluad® (TIV-adj)

Fluad® (TIV-adj) is an adjuvanted inactivated influenza vaccine that is licensed for persons 65 years of age and over. An adjuvant is a substance added to a vaccine that helps the recipient develop an improved immune response compared to receiving an unadjuvanted vaccine. This is important for vaccines targeted at older individuals who may not have as strong an immune response to influenza vaccine as younger individuals. The adjuvant in Fluad® is an oil-in-water mixture called MF59.

## Fluzone® High-Dose (TIV-HD)

Fluzone® High-Dose (TIV-HD) is an inactivated influenza vaccine that is licensed for persons 65 years of age and over. TIV-HD contains a higher amount of antigen per strain than standard-dose influenza vaccine formulations. The TIV-HD vaccine contains 60 µg of hemagglutinin (HA) protein for each of the three vaccine strains, compared to 15 µg of HA per strain in a standard-dose TIV.

Studies have shown that the higher antigen content in the high-dose vaccine improves the immune response and prevention of influenza hospitalizations for adults 65 years of age and older compared to standard-dose vaccine, which is important since older individuals may not respond as well to influenza vaccines compared to younger individuals.

## Recommendations for individuals ≥65 years

The TIV-HD and TIV-adj vaccines should be offered, when available, over TIV influenza vaccines for adults 65 years of age and older. If a preferred product is not available, any of the available age-appropriate influenza vaccines should be used. The most important thing is for older adults to be vaccinated. Do not delay vaccination to wait for a particular product.

To date, there is limited evidence directly comparing TIV-HD and TIV-adj formulations or TIV-adj and TIV formulations. As a result, there is no preferential recommendation for the use of TIV-HD versus TIV-adj vaccine for this age group.

Per NACI recommendations for individuals 65 years of age and older, the following information should be considered when discussing vaccine options:

- There is limited evidence directly comparing TIV-HD and TIV-adj against each other.
- TIV-HD and TIV-adj both appear to provide better protection compared to TIV standard dose.
- TIV-HD and TIV-adj are both effective alternatives to TIV, with no identified difference in safety, based on direct evidence among adults 65 years of age and older.

For more information on the vaccines available for individuals 65 years of age and older, please refer to the following:

- An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Statement on Seasonal Influenza Vaccine for 2025-2026,
- An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Supplemental guidance on influenza vaccination in adults 65 years of age and older and;

## Co-administration

The influenza vaccines for individuals 65 years of age and older (i.e., TIV-HD, TIV-adj, and TIV) may be given at the same time, or at any time before or after other vaccines, including COVID-19 vaccine and/or respiratory syncytial virus (RSV) vaccine. There are, however, no direct studies on the co-administration of Shingrix® with Fluad® (TIV-adj) or Fluzone® High-Dose (TIV-HD). With Fluad®, it is unknown how the adjuvants may interact when Shingrix® is co-administered.

If multiple injections are to be given at the same visit, separate limbs should be used if possible. Alternatively, the injections may be administered into the same muscle separated by at least 2.5 cm (1”). Different immunization equipment (needle and syringe) must be used for each vaccine.

## Contraindications and Precautions

Do not administer influenza vaccine to:

- Persons with a history of serious allergic reaction (anaphylaxis) to a previous dose of influenza vaccine, and/or
- Persons with proven immediate or anaphylactic hypersensitivity to any ingredient in the vaccine, except for egg.

According to NACI, egg-allergic individuals may be vaccinated against influenza using the full dose of any age-appropriate product, including TIV, TIV-HD and TIV-adj. See section IV of the Canadian Immunization Guide chapter on Influenza and statement on seasonal influenza vaccine for 2018-2019 for studies supporting the NACI recommendation for egg-allergic individuals.

Anyone who has developed Guillain-Barré Syndrome (GBS) within six weeks of a previous influenza vaccination should generally NOT be vaccinated, HOWEVER, this should be weighed against the risks of not being protected against influenza.

Those with a severe acute illness at the time of immunization should wait until the symptoms subside before being immunized. Immunization should not be delayed because of minor acute illness, with or without fever.

## Vaccine effectiveness

Influenza viruses are constantly changing through antigenic drift (slow changes over time) and antigenic shift (sudden big changes). As a result, they can change from one season to the next and they can even change within the course of one influenza season. The influenza vaccine is made to protect against the influenza viruses that surveillance and research indicate will likely be most common during the upcoming influenza season as recommended by WHO.

Protection offered from the influenza vaccine varies from year-to-year depending on how well the strains included in the vaccine match the circulating strains. How well the influenza vaccine works also depends on other factors such as the age and health status of the person. Influenza immunization has been shown to reduce the number of physician visits, hospitalizations and deaths.

Although a less than ideal match between the vaccine strain(s) and circulating strain(s) may result in reduced vaccine effectiveness, even mismatched vaccines can generally provide some protection against circulating influenza viruses. Influenza vaccines also protect against multiple strains, therefore if one strain in the vaccine is not a good match to a circulating strain, there are other flu strains in the vaccine which may still be a good match to circulating virus strains.

It generally takes about two weeks following immunization to develop protection against influenza. As protection wanes over time and influenza strains change frequently, it is important to be immunized each year (each influenza season). The vaccine will not protect

against other respiratory illnesses, or COVID-19 that may have some of the same symptoms and be mistaken for influenza.

## Vaccine safety

Influenza vaccines authorized for use in Canada are safe and well tolerated. As with other vaccines, they must be authorized for use by the Canadian regulator, Health Canada, following review of a products safety and how well it works (e.g. clinical trial and other evidence).

Once a vaccine is authorized for use in Canada, provincial surveillance in Ontario and national surveillance coordinated by Health Canada and the Public Health Agency of Canada ensures ongoing monitoring of adverse effects following immunization.

Very small amounts of preservatives, such as thimerosal, may be added to a vaccine to prevent the growth of disease-causing microbes in the vaccine. The World Health Organization states that thimerosal in vaccines is safe as the amount in vaccines is far below harmful levels.

## Adverse events

Many people who receive influenza vaccine have no side effects or adverse events. For those that do, side effects are usually mild and last a few days. The most common side effects from the influenza vaccine are:

- Redness, swelling, and soreness at the injection site
- Headache
- Tiredness/weakness
- Fever

Life-threatening allergic (anaphylactic) reactions are very rare. If they do occur, it is typically within a few minutes to a few hours after receiving the vaccine.

Other rare events associated with the influenza vaccine include the following:

### Guillain-Barré Syndrome (or GBS)

GBS is a rare disease that causes muscle paralysis and has been associated with certain infectious diseases (e.g., Campylobacter, a bacteria that causes diarrhea). Some studies have found a possible small association between injectable flu vaccine and GBS. Overall, these studies estimated the risk for GBS after vaccination as fewer than 1 or 2 cases of GBS per one million people vaccinated. Other studies have not found any association. In comparison to the very small risk of GBS, the risk of illness and death associated with influenza infections is much greater. Even though GBS following flu illness is rare, GBS is more common following flu illness than following flu vaccination. Anyone who has developed Guillain-Barré Syndrome (GBS) within six weeks of a previous influenza vaccination should generally NOT be vaccinated, HOWEVER, this should be weighed against the risks of not being protected against influenza.

### Oculorespiratory Syndrome (ORS)

In Canada, during the 2000/2001 influenza season, ORS was reported after administration of the influenza vaccine in some individuals. Symptoms include redness in both eyes that are not itchy, plus one or more respiratory symptoms occurring within 24 hours of influenza immunization, with or without swelling of the face. Since the 2000/2001 influenza season, there have been far fewer cases of ORS reported per year.

Individuals who experienced ORS symptoms in the past may be safely re-immunized with influenza vaccine except for those who have experienced ORS with severe lower respiratory symptoms (wheeze, chest tightness, difficulty breathing) within 24 hours of influenza immunization. These individuals should seek expert medical advice before being immunized again with influenza vaccine.

## Guidance on reporting Adverse Events Following Immunization (AEFI)

To ensure the ongoing safety of vaccines in Ontario, reporting AEFIs by physicians, nurses, pharmacists or other persons authorized to administer an immunizing agent is mandatory under the *Health Protection and Promotion Act*. Vaccine providers are asked to report AEFIs through local public health units using the Ontario AEFI Reporting Form.

Those administering vaccines should advise vaccine recipients or their parents/guardians to contact their health care provider if they experience an adverse event after vaccination. Health care providers should report any event which may be related to receipt of a vaccine, as outlined in Public Health Ontario's AEFI Reporting fact sheet. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

Some common or mild events do not need to be reported. These include:

- Fever that is not accompanied by any other symptoms
- Injection site reactions that last less than 4 days and does not extend past the nearest joint
- Vasovagal syncope (without injury)
- Events that are clearly attributed to other causes

Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Signs and symptoms of severe allergic reaction, including:
    - Hives
    - Swelling of the mouth or throat
    - Trouble breathing, hoarseness or wheezing
- Convulsions (seizures)
- High fever (over 40°C or 104°F)
- Other serious reactions

## Observation period following immunization

NACI recommends a 15-minute post-vaccination observation period, as specified in the Canadian Immunization Guide (CIG). If there is a specific concern about possible vaccine allergy, 30 minutes is a preferred interval.

## Record of immunization

Each vaccine recipient should be provided with a permanent personal immunization record, the Yellow Immunization Card. Vaccine recipients, or their parents or guardians, should be instructed to keep the record in a safe place and to present it at every health care visit so that it can be updated.

## Post-puncture shelf life and product dimensions

| Vaccine | Post-puncture shelf life | Package dimension (cm) |
|---|---|---|
| Fluad® | Not applicable | 15.4 x 13.0 x 2.4 |
| Flucelvax® | Not applicable | 15.4 x 13.0 x 2.4 |
| Fluviral | 28 days* | 2.7 x 2.7 x 6.9 |
| Fluzone® High-Dose | Not Applicable | 10.4 x 9.9 x 2.3 |
| Fluzone® | Multi-dose vial<br>28 days* | Multi-dose vial<br>5.8 x 5.4 x 3.6 |
| | Pre-filled syringe<br>Not applicable | Pre-filled syringe<br>10.4 x 9.9 x 3.8 |

* Report all vaccine wastage. Return only unopened vials / syringes / ampoules to PHU or OGPMSS (for Toronto clients) as wastage. Discard opened vials / syringes / ampoules through biohazard waste. Influenza vaccine should be returned using your public health unit's vaccine return form. Visit your local public health unit's website or contact them directly regarding the process of returning vaccine.

## Health Care Provider information

Health care providers looking for more information about influenza, influenza vaccine, or the province's UIIP can refer to the Health Care Provider Fact Sheet: Information for the 2024/2025 Influenza Season sheet, Public Health Ontario or to their local public health unit.

## Public / patient information

Individuals looking for general information about influenza, the influenza vaccine or the province's UIIP can call ServiceOntario, INFOline at 1-866-532-3161 toll free in Ontario (TTY#1-800-387-5559) or visit: www.ontario.ca/flu. Questions about the vaccine that are specific to an individual's medical condition should be discussed with a health care provider or local public health unit.

## Additional information

Please visit the following websites or call your local public health unit:

a) Universal Influenza Immunization Program: www.ontario.ca/page/universal-influenza-immunization-program

b) Public Health Agency of Canada - National Advisory Committee on Immunization (NACI) Statement on Seasonal Influenza Vaccine: www.phac-aspc.gc.ca/naci-ccni/#rec

c) Public Health Ontario: www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/influenza

d) Immunize Canada: www.immunize.ca/

e) Centers for Disease Control and Prevention (CDC) - Seasonal Influenza: www.cdc.gov/flu/

f) List of public health unit locations: www.ontario.ca/page/public-health-unit-locations

Version française disponible en communiquant avec le 1-866-532-3161 ATS: 1-800 387-5559 (site web: www.ontario.ca/fr/page/programme-universel-de-vaccination-contre-la-grippe).