

Ministry of Health

Health Care Provider Qs & As: Influenza Immunization Information for Individuals ≥ 65 years of age

This Qs & As sheet is intended for informational purposes only. It is not intended to provide medical or legal advice.

1. What publicly funded influenza vaccines are available for individuals ≥ 65 years of age for Ontario's 2023/2024 Universal Influenza Immunization Program (UIIP)?

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

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

| | 1. Quadrivalent Inactivated Vaccines | |
|--|---|---|
| UIIP Abbreviation | QIV | |
| NACI Abbreviation | IIV4-SD | |
| Vaccine product | FluLaval Tetra | Fluzone® Quadrivalent |
| Manufacturer | GSK | Sanofi Pasteur |
| Age indication | ≥ 6 months | ≥ 6 months |
| Vaccine type | Egg-based | Egg-based |
| Micrograms of hemagglutinin | 15 μ g | 15 μ g |
| Dosage | 0.5 mL | 0.5 mL |
| Format | MDV | MDV and PFS |
| Route | IM | IM |
| Most common allergens¹ | <ul style="list-style-type: none"> • Egg protein² • Thimerosal | <ul style="list-style-type: none"> • Egg protein² • Thimerosal³ |

| | 2. High-Dose Quadrivalent Inactivated Vaccine | 3. Adjuvanted Trivalent Inactivated Vaccine |
|--|---|--|
| UIIP Abbreviation | QIV-HD | TIV-adj |
| NACI Abbreviation | IIV4-HD | IIV3-Adj |
| Vaccine product | Fluzone® High-Dose Quadrivalent | 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 | 0.7 mL | 0.5 mL |
| Adjuvant | No | Yes |
| Format | PFS | PFS |
| Route | IM | IM |
| Most common allergens¹ | <ul style="list-style-type: none"> • Egg protein² | <ul style="list-style-type: none"> • Egg protein² • Kanamycin • Neomycin |

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

NACI = National Advisory Committee on Immunization

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

²The National Advisory Committee on Immunization (NACI) indicates that egg allergy is not a contraindication for influenza vaccination and that egg-allergic individuals may be vaccinated against influenza using the full dose of any age-appropriate product. 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 (www.phac-aspc.gc.ca/naci-ccni/#rec).

³ Multi-dose vial format only

Important notes:

- Fluzone® Quadrivalent and Fluzone® High-Dose Quadrivalent are **different products**. Please use caution when administering Fluzone® products to ensure that the right vaccine is being administered to the right person.

2. What is QIV-HD and how is it different than the QIV?

The QIV-HD and QIV both contain four influenza strains (A(H3N2), A(H1N1) and two B strains), however, QIV-HD contains a higher amount of antigen per strain than standard-dose influenza vaccine formulations. The QIV-HD contains 60 µg of hemagglutinin (HA) protein for each of the four vaccine strains, compared to 15 µg of HA per strain in a standard dose QIV.

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

More details on the specific strains included in this season's influenza vaccines are outlined in the Health Care Provider Qs & As: Information for the 2023/2024 Influenza Season document.

3. What is Fluad® (TIV-adj)?

Fluad® is an adjuvanted inactivated influenza vaccine that is licensed for persons 65 years of age and over. The adjuvant is designed to improve the immune response to the vaccine, which is important since older individuals may not have as strong an immune response to influenza vaccine as younger individuals. The adjuvanted vaccine is a trivalent vaccine, meaning it is designed to protect against three influenza viruses: two influenza A viruses and one influenza B virus.

4. What is an adjuvant?

An adjuvant is a substance added to a vaccine that helps the recipient develop an improved immune response compared to receiving an unadjuvanted vaccine. The adjuvant in Fluad® is an oil-in-water mixture called MF59.

5. Which influenza vaccine should individuals ≥65 years of age receive?

The QIV, QIV-HD and TIV-adj ALL protect against the flu, and the most important thing is for older adults to be vaccinated. DO NOT DELAY VACCINATION TO WAIT FOR A PARTICULAR PRODUCT.

For individual-level decision making, NACI states that when available, high-dose should be used over standard-dose inactivated influenza vaccine, given the burden of influenza A(H3N2) disease and the good evidence of better protection compared to standard-dose in adults 65 years of age and older.

However, NACI states that in the absence of a specific product, any of the available age appropriate influenza vaccines should be used. There is NO PREFERENTIAL RECOMMENDATION for the use of QIV-HD versus TIV-adj vaccine for this age group.

To date, no studies have directly compared QIV-HD and TIV-adj formulations or TIV-adj and QIV formulations.

The following information should be considered when discussing vaccine options:

- There is insufficient evidence to make a preferential recommendation between QIV-HD and TIV-adj. There is good evidence of QIV-HD providing better protection compared to QIV standard dose.
- In considering use of TIV-adj and QIV standard dose, given the increased burden of disease associated with influenza A(H3N2) in older adults, better protection against influenza A(H3N2) afforded by the TIV-adj may be more important, especially in those with multiple co-morbid conditions and compromised health status.

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

- *Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2023-2024* available at: www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html and;
- Public Health Ontario's *Influenza Vaccines for the 2023-2024 Influenza Season* available at: www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/influenza.

6. How many doses of the influenza vaccine are needed to provide protection?

One dose of the influenza vaccine is needed each year to provide protection each influenza season.

7. Who can administer the influenza vaccine?

Individuals who can administer the influenza vaccine include:

- Regulated health professionals who are authorized under the *Regulated Health Professions Act, 1991* to administer vaccines.
 - Note: trained pharmacists, pharmacy technicians, pharmacy students and interns may only administer publicly funded influenza vaccine to individuals 2 years of age and older.
- Trained individuals under a delegation made in accordance with the requirements set by the regulatory College of the regulated health professional.

8. Can these vaccine cause influenza?

No. The publicly funded standard dose QIV, QIV-HD and TIV-adj are all inactivated vaccines so individuals cannot get influenza from the vaccine.

9. Do any of the publicly funded influenza vaccines offer protection against COVID-19 or other diseases?

The influenza vaccine will not protect against respiratory viruses other than influenza, including the coronavirus that causes COVID-19, but will help prevent infection and illness from the influenza virus.

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.

10. Will the influenza vaccine increase risk of infection or severe outcomes related to COVID-19?

No. Expert groups and evidence indicate that getting the influenza vaccine will not increase your risk of COVID-19 infection or severe outcomes related to COVID-19.

11. Can the influenza vaccine be given at the same time as other vaccines?

| Vaccine | Intervals (if applicable) |
|-----------------------------|---|
| COVID-19 and other vaccines | <p>The influenza vaccines for 65+ (i.e., QIV-HD, TIV-adj, and QIV) may be given at the same time with other vaccines, or at any time before or after other vaccines, including COVID-19 vaccine. There are no direct studies on the co-administration of Shingrix® with Fluvad® (TIV-adj) or Fluzone® High-Dose Quadrivalent (QIV-HD) - see Shingrix® section below.</p> <p>If given by injection at the same time, 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.</p> |
| Shingrix® | <p>No studies have been conducted that have assessed the co-administration of Shingrix® with adjuvanted or high-dose influenza vaccines. With Fluvad®, it is unknown how the adjuvants may interact when Shingrix® is co-administered.</p> |

12. Can the vaccine be given to individuals when they are ill?

It is dependent on the severity of the symptoms. Those with a severe acute illness with or without fever should wait until the symptoms subside before being immunized. Individuals with symptoms of acute illness, including minor symptoms such as sore throat, should be recommended to complete the COVID-19 Self-Assessment Tool (available at: covid-19.ontario.ca/self-assessment). If the individual screens negative using the Self-Assessment Tool, influenza immunization may be provided.

13. What are the common side effects from the influenza vaccine?

The most common side effects from the influenza vaccine are:

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

These side effects are generally mild and last only a few days.

14. Who should NOT get the influenza vaccine?

Anyone who has had a serious allergic reaction (anaphylaxis) to a previous dose of influenza vaccine or to any ingredient in the vaccine, except for egg, should NOT be vaccinated. According to NACI, egg-allergic individuals may be vaccinated against influenza using the full dose of any age-appropriate product, including QIV, QIV-HD and TIV-adj.

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.

15. How long should the observation period be following influenza 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 safer interval.

The link to the CIG is available at: www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-8-vaccine-administration-practices.html#p1c7a4

NACI previously allowed consideration for a reduced post-vaccination observation period, between 5 to 15 minutes for the administration of influenza vaccine during the pandemic, at times when appropriate physical distancing in post-vaccination waiting areas could not otherwise be maintained due to the volume of individuals seeking immunization and only when specific conditions were met:

- Past history of receipt of influenza vaccine and no known history of severe allergic reactions (including anaphylaxis) to any component of the influenza vaccine being considered for administration.
- No history of other immediate post-vaccination reactions (e.g., syncope with or without seizure) after receipt of any vaccines.
- The vaccine recipient is accompanied by a responsible adult who will act as a chaperone to monitor the vaccine recipient for a minimum of 15 minutes post-vaccination. In the case of two responsible adults, both can be vaccine recipients for the purposes of this criterion, if both agree to monitor the other post-vaccination.
- The vaccine recipient will not be operating a motorized vehicle or self-propelled or motorized wheeled transportation or machinery for a minimum of 15 minutes after vaccination.
- The vaccine recipient and the responsible adult chaperone are aware of when and how to seek post-vaccination advice and given instruction on what to do if assistance and medical services are required.
- The vaccine recipient and the responsible adult agree to remain in the post-vaccination waiting area for the post-vaccination observation period and to notify staff if the recipient feels or looks at all unwell before leaving. They should be informed that an individual exhibiting any symptom suggestive of an evolving adverse event following immunization (AEFI) at the end of the shortened post-observation period necessitates a longer period of observation in the clinic.

The link to the NACI guidance on reduced observation period is available at: www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-duration-observation-period-post-influenza-vaccination-during-covid-19-pandemic.html

16. What information should be provided to individuals related to potential adverse events following immunization (AEFI) with the influenza vaccine?

The influenza vaccine, like any medicine, may cause adverse events, which in most cases are mild, lasting only a few days. 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. Some studies have found a possible small association between injectable influenza vaccine and Guillain-Barré Syndrome (GBS) and others have not found any association. Oculorespiratory Syndrome (ORS) may occur in extremely rare instances. Please refer to question 21 of the Health Care

Provider Q & A: Information for the 2023/2024 Influenza Season sheet for further details.

As per the s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are aware of the need to immediately report adverse events following immunization to their health care provider. Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions

Health care providers (e.g., physicians, nurses and pharmacists) are required by law (i.e., Health Protection and Promotion Act, s. 38) to report AEFIs to their local public health unit. Reports should be made using the Ontario AEFI Reporting Form (available at: www.publichealthontario.ca/vaccinesafety) and sent to the local public health unit.

A list of public health units is available at:

www.health.gov.on.ca/en/common/system/services/phu/locations.aspx.

17. Where can health care providers find more information about the UIIP?

Health care providers looking for more information about influenza, influenza vaccine, or the province's UIIP can refer to the Health Care Provider Qs & As: Information for the 2023/2024 Influenza Season sheet, Public Health Ontario (www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/influenza) or to their local public health unit.

A list of public health units is available at:

www.health.gov.on.ca/en/common/system/services/phu/locations.aspx.

18. Where can members of the public / patients get more information about influenza or any other vaccines?

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.

A list of public health units is available at:

www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

For additional information on influenza or the vaccine, please visit the following websites or call your local public health unit:

- a) Universal Influenza Immunization Program: www.ontario.ca/influenza
- 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.health.gov.on.ca/en/common/system/services/phu/locations.aspx

Version française disponible en communiquant avec le 1-866-532-3161 ATS: 1-800 387-5559 (site web: www.health.gov.on.ca/fr/pro/programs/publichealth/flu/)