( )

Insert Health Care Agency

MEDICAL DIRECTIVE: Influenza Vaccine

(FluLaval® Tetra, Fluzone® Quadrivalent, Afluria® Tetra, Fluzone® High-Dose Quadrivalent, Fluad® Adjuvanted Trivalent)

Original Date: 2022/10

Next Review Date: 2023/10

Contact Officer: ( )

Insert Agency Contact Officer

Order/Delegated Procedure

Administer injectable influenza immunizations.

Recipient Clients

All individuals six months of age and older without contraindications to the influenza vaccine who live, work, or go to school in Ontario.

Authorized Implementers

Health care providers of ( ) including nurses, nursing students

above named agency

under the supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, education, training at clinics and observation by the ( ).

agency designate

Indications

The influenza vaccine is indicated for all individuals aged 6 months or older who do not have contraindications to the vaccine, and who live, work and attend school in Ontario with particular focus on: people at high risk of influenza-related complications or hospitalization, people capable of transmitting influenza to those at high risk, people who provide essential community services, and people in direct contact with poultry infected with avian influenza during culling operations as listed in **Table 1.**

Table 1: Groups for whom influenza vaccination is particularly recommended

Individuals at high risk of influenza-related complications or hospitalization

• All pregnant women
• Adults and children 6 months of age and over with the following chronic health conditions:
  o Cardiac or pulmonary disorders (includes bronchopulmonary dysplasia, cystic fibrosis, and asthma)
  o Diabetes mellitus and other metabolic diseases
  o Cancer, immune compromising conditions (due to underlying disease, therapy or both, such as solid organ transplant or hematopoietic stem cell transplant recipients)
  o Renal disease
  o Anemia or hemoglobinopathy
  o Neurologic or neurodevelopment conditions (includes neuromuscular, neurovascular, neurodegenerative, neurodevelopmental conditions, and seizure disorders [and, for children includes febrile seizures and isolated developmental delay], but excludes migraines and psychiatric conditions without neurological conditions)
  o Morbid obesity (body mass index [BMI] of 40 and over)
  o Children 6 months to 18 years of age undergoing treatment for long periods with acetylsalicylic acid, because of the potential increase of Reye's syndrome associated with influenza
• People of any age who are residents of nursing homes and other chronic care facilities
• Adults 65 years of age and older
• All children 6-59 months of age
• Indigenous peoples

People capable of transmitting influenza to those at high risk and/or infants under 6 months of age

• Health care and other care providers in facilities and community settings who, through their activities, are capable of transmitting influenza to those at high risk;
• Household contacts, both adults and children, of individuals at high risk, whether or not the individual at high risk has been vaccinated:
  o Household contacts of individuals at high risk
  o Household contacts of infants less than 6 months of age, as these infants are at high risk but cannot receive influenza vaccine
  o Members of a household expecting a newborn during the influenza season
• Those providing regular childcare to children 0-59 months of age, whether in or out of the home
• Those who provide services within closed or relatively closed settings to people at high risk (e.g., crew on a ship)

Others
• People who provide essential community services • People who are in direct contact with poultry infected with avian influenza during culling operations

Contraindications

Clients are **NOT ELIGIBLE** for influenza immunization under this medical directive if there is a risk of serious adverse reaction identified during their health assessment (see **Table 2**).

Table 2: Contraindications for the influenza vaccine

TIV-adj Fluad®	**QIV-HD** Fluzone® High-Dose Quadrivalent	**QIV** FluLaval Tetra Fluzone® Quadrivalent	**QIV** Afluria® Tetra
Individuals under 65 years of age	**Individuals under 65 years**	**Infants under 6 months of age**	**Children under age 5**
People for whom the vaccine is not authorized for use in their age group **People who have had an anaphylactic reaction to a previous dose of influenza vaccine** **People who have had an anaphylactic reaction to any of the vaccine components of that specific influenza vaccine (i.e egg allergy).** • Although the National Advisory Committee on Immunization (NACI) indicates that egg-allergic individuals may be vaccinated against influenza, an egg allergy is a contraindication at (above named agency) clinics. • FluLaval Tetra, Fluzone® Quadrivalent, Afluria® Tetra, Fluzone® High-Dose and Fluad® contain traces of egg protein. People with an allergy to eggs **SHOULD NOT** receive the influenza vaccine at (above named agency) and should be referred to their health care provider. **People who have developed Guillain-Barré Syndrome (GBS) within 6 weeks of a previous influenza immunization** • People with a history of Guillain-Barré Syndrome (GBS) should be referred to their health care provider for assessment. **People who have had Oculorespiratory Syndrome (ORS) should NOT receive the influenza immunization at an (above named agency) clinic and should be referred to their health care provider** • Defined as the presence of bilateral red eyes and one or more associated respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, or sore throat) that starts within 24 hours of influenza immunization, with or without facial oedema. • Individuals who have experienced ORS without lower respiratory tract symptoms may be safely revaccinated with influenza vaccine. Individuals who experienced ORS with lower respiratory tract symptoms should be referred for expert review.			

Clients who have had an allergic reaction to **ANY vaccine** should be assessed carefully prior to administering the influenza vaccine to ensure that there are no common components between the influenza vaccine and the vaccine to which they were allergic. Consultation with the (agency manager) or designate should be sought if

there is any question about whether the influenza vaccine should be administered.

NOTE: Those with a severe acute illness, with or without fever, should wait until the symptoms subside before being immunized.

Consent

Nurses must obtain informed consent from the client or legal guardian, as applicable in accordance with the *College of Nurses Practice Guideline (2017): Consent*

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks and benefits arereviewed,
- The client has read and/or understands the information provided on the appropriate Influenza vaccine. Thenurse must ensure the client has no contraindications to the vaccine as specified in the "Contraindications" section of this Medical Directive and on the (above named agency) consent form, and query regarding current health (i.e., acute illness, immunosuppression),
- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction, and
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client can give consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision. In obtaining consent from a parent, the nurse must ask the parent if they are the "custodial parent". If a parent is not the custodial parent or legal guardian, please contact the (agency designate) to assist in determining who can provide consent.

Administering the Influenza Vaccine

The influenza vaccine may be given at the same time as other vaccines or at any time before or after other vaccines 5 years of age and older ONLY.

Co-administration with COVID-19 vaccine is NOT currently recommended for individuals 6 months to under 5 years of age. It is advised to wait 14 days between vaccine products when administering COVID-19 vaccine and other vaccines to prevent mistakenly connecting an adverse event to one particular vaccine or the other. [14]

NACI recommends that COVID-19 vaccines may be given concomitantly with, or at any time before or after, other vaccines. * Including live, non-live, adjuvanted, or unadjuvanted vaccines.[11]

Specifically, when administered concomitantly with COVID-19 vaccines, they should be administered at different injection sites using separate injection equipment. [11]

If given at the same time as other vaccines given by injection, separate limbs should be used, if possible. Alternately, the injections may be administered into the same muscle separated by at least 2.5 cm (1"). Different administration sets (needle and syringe) must be used for each vaccine given by injection.[1]

NACI recommends:

- Children 9 years of age and older and adults should receive 1 dose of influenza vaccine each year, and
- Children 6 months to less than 9 years of age receiving seasonal influenza vaccine for the first time in their life should be given 2 doses of influenza vaccine, with a minimum interval of 4 weeks between doses. Children 6 months to less than 9 years of age who have been vaccinated with one or more doses of seasonal influenza vaccine in the past should receive 1 dose of influenza vaccine per season thereafter. The same vaccine product does not need to be used for both doses.[3]

Table 3: Publicly funded influenza vaccines available for Ontario's Universal Influenza Immunization Program (UIIP) during the 2022-2023 influenza season

	Quadrivalent Inactivated Vaccine			**High-Dose Quadrivalent Inactivated**	**Adjuvanted Trivalent Inactivated Vaccine**
UIIP Abbreviation	QIV			QIV-HD	TIV-adj
NACI Abbreviation	IIV4-SD			IIV4-HD	IIV3-Adj
Vaccine Product	**FluLaval® Tetra**	**Fluzone® Quadrivalent**	**Afluria® Tetra**	**Fluzone® High-Dose Quadrivalent**	**Fluad®**
Age Indication	**≥6 months**	**≥6 months**	**≥5 years**	**≥65 years**	**≥65 years**
Vaccine Type	Egg-based			Egg-based	Egg-based
Amount of active ingredient (each strain)	15 µg of HA*			60 ug of HA*	15 µg of HA*
Dosage	0.5 mL			**0.7 ml**	0.5 mL
Format	Multidose vial (MDV)	Multidose vial (MDV) Prefilled syringe (PFS)	Multidose vial (MDV) Prefilled syringe (PFS)	Prefilled syringe (PFS)	Prefilled syringe (PFS)

Table 3: Publicly funded influenza vaccines available for Ontario's Universal Influenza Immunization Program (UIIP) during the 2022-2023 influenza season

	Quadrivalent Inactivated Vaccine	High-Dose Quadrivalent Inactivated	Adjuvanted Trivalent Inactivated Vaccine
Strains	**A**/Victoria/2570/2019 (H1N1)pdm09-like virus; **A**/Darwin/9/2021 (H3N2)-like virus; **B**/Austria/1359417/2021 (B/Victoria lineage)-like virus; **B**/Phuket/3073/2013 (B/Yamagata lineage)-like virus.	**A**/Victoria/2570/2019 (H1N1)pdm09-like virus; **A**/Darwin/9/2021 (H3N2)-like virus; **B**/Austria/1359417/2021 (B/Victoria lineage)-like virus; **B**/Phuket/3073/2013 (B/Yamagata lineage)-like virus.	**A**/Victoria/2570/2019 (H1N1)pdm09-like virus; **A**//Darwin/9/2021 (H3N2)-like virus; **B**//Austria/1359417/2021 (B/Victoria lineage)-like virus
Route	Intramuscular injection		

*****HA refers to hemagglutinin
**FFU refers to fluorescent focus units

Important Notes:

- Use caution when administering Fluzone® products. Fluzone® and Fluzone® High-Dose Quadrivalent are different products. Fluzone® High-Dose Quadrivalent is an influenza vaccine only authorized for those 65 years of age and older.
- Afluria® Tetra is authorized for children 5 years of age and over.

Administration

Follow (above named agency) procedures and corresponding influenza vaccine product monographs for administration and drug product information.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the (agency designate).

Storage and Stability

As per the Ministry of Health's Vaccine Storage and Handling Guidelines:

- Store FluLaval Tetra®, Afluria Tetra®, Fluzone® Quadrivalent, Fluzone® High-Dose Quadrivalent, and Fluad® Adjuvanted Trivalent Inactivated vaccine between +2°C and +8°C.
- Do not freeze the vaccine. If frozen, discard the vaccine.

- Protect the vaccine from light.
- Do not use vaccine after expiration date.
- A multi-dose vial should be marked with the date of first puncture and returned to the recommended storage conditions.
- Do not mix medicinal products.

Managing Adverse Reactions

Advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic.*[11]

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine, particularly the following:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions[10]

If a reaction as described above occurs while at (above named agency) clinic, refer to the (above named agency) Medical Directive (Management of Anaphylaxis).

Guidelines for Implementing the Order/Procedure

When initiating immunization with an influenza vaccine under this directive, (above named agency) nurses shall understand and follow, as applicable:

- (above named agency) MEDICAL DIRECTIVE: Management of Anaphlaxis
- (above named agency) Injection Technique Procedure
- (above named agency) Documentation Policy and Procedure
- CNO Practice Guideline: Consent (2017)
- CNO Practice Standard: Medication (2022)
- Canadian Immunization Guide, Evergreen Edition (2021 or as current)
- Product monograph: FLULAVAL TETRA (2022-2023)
- Product monograph: FLUAD® adjuvanted trivalent vaccine (2022-2023)
- Product monograph: AFLURIA TETRA®
- Product monograph: FLUZONE® quadrivalent vaccine quadrivalent types A and B (split virion) (2022-2023)
- Product monograph: FLUZONE® High-Dose Quadrivalent influenza virus vaccine types

A and B (split virion) (2022-2023)

- Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2022–2023

Nurses and nursing students are expected to consult with the (agency manager or designate)

if unable to perform their nursing duties in a safe and effective manner.

At all clinics where immunizing agents are administered, the (agency designate) will be

available for consultation by (method of communication).

Documentation and Communication

Documentation will be completed following the (above named agency)

and the College of Nurses of Ontario Documentation Practice Standard.

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:**

References

1. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019. Available from:https://www.cno.org/globalassets/docs/prac/41001_documentation.pdf
2. College of Nurses of Ontario. Medication. Toronto, ON: 2019. Available from: https://www.cno.org/globalassets/docs/prac/41007_medication.pdf
3. Government of Canada. Public Health Agency of Canada (PHAC). Canadian immunization guide chapter on influenza and statement on seasonal influenza vaccine for 2022-2023. Available from:https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html
4. GlaxoSmithKline Inc. Product monograph: FLULAVAL TETRA (2022-2023) quadrivalent influenza vaccine (split virion, inactivated). Available from: https://ca.gsk.com/media/6650/2022-2023-flulaval-tetra-pm-english-20apr2022.pdf

5. Government of Canada, Public Health Agency of Canada (PHAC). Canadian immunization guide. 2018. Available from https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html

6. Sanofi Pasteur Limited. Product monograph: FLUZONE® quadrivalentinfluenza virus vaccine quadrivalent types A and B (split virion). Toronto, ON; 2022-2023. Available from: https://products.sanofi.ca/en/fluzone-qiv.pdf

7. Sanofi Pasteur Limited. Product monograph: FLUZONE® High-Dose Quadrivalent influenza virus vaccine types A and B (split virion). Toronto, ON: 2022-2023. Available from: https://products.sanofi.ca/en/fluzone-qiv-hd-en.pdf

8. Ministry of Health. Vaccine storage and handling guidelines. Toronto, ON: 2012. Available from : https://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf

9. Ministry of Health. 2022/2023 Universal Influenza Immunization Program (UIIP). Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/

10. Government of Canada. Public Health Agency of Canada (PHAC). Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic.

11. Government of Canada. National Advisory Committee on Immunization (NACI): Statements and Publications. Recommendations on the use of COVID-19 vaccines. 2022. Available from https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-use-influenza-vaccine-covid-19.html

12. Seqirus UK Limited. Product monograph: FLUAD® Adjuvanted Trivalent InactivatedVaccine. 2022-2023. Mississauga, ON. Available from: https://www.seqirus.ca/-/media/seqirus-canada/docs-en/2022-2023-fluad-product-monograph.pdf

13. Seqirus UK Limited. Product Monograph AFLURIA Quadrivalent Inactivated Vaccine.2022-2023. Mississauga, ON. Available from:https://www.gov.mb.ca/health/flu/docs/pm/afluria-tetra.pdf

14. Ministry of Health (2022-2023) Health Care Provider Q & As: Influenza Immunization Information for Individuals 6 months to 64 years of age. *Government of Ontario* https://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/docs/flu_uiip_6mo-64yrs_2022-23.pdf