Q&A: Publicly Funded Seasonal Inactivated Influenza Vaccine Information for 2018-2019

NOVA SCOTIA

Highlights for 2018-19

The inactivated high-dose trivalent influenza vaccine (HD-TIV) will be offered to Long Term Care Facility (LTCF) residents 65 years and older. LTCFs include nursing homes and residential care facilities.

The inactivated quadrivalent influenza vaccine (QIV) will be offered for all other individuals 6 months of age and older. This also includes all staff and those residents of LTCFs under 65 years of age.

Vaccine Products

Inactivated High-dose Trivalent Vaccine

- The product used will be:
  - Fluzone® High-Dose (Sanofi) – this product contains four times the virus antigen per strain in comparison to the standard-dose influenza vaccine. Evidence indicates better protection for those 65 years and older compared to the standard-dose influenza vaccine.
- The components of the vaccine include:
  - A/Michigan/45/2015 (H1N1) pdm09-like virus;
  - A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus; and
  - B/Colorado/06/2017-like virus (B/Maryland/15/2016 BX-69A)

Inactivated Quadrivalent Vaccine

- The products used will include:
  - Fluzone® Quadrivalent (Sanofi)
  - Flulaval® Tetra (Glaxo Smith Kline [GSK]): Use of imprecise equipment may lead to inability to withdraw the full 10 doses. For the Flulaval® Tetra product, the 1 mL syringe is recommended as per the instruction sheet. The 3 mL syringe should be avoided since the injection volume is 0.5 mL.
- The components of the vaccine include:
  - A/Michigan/45/2015 (H1N1) pdm09-like virus;
  - A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;
  - B/Colorado/06/2017-like virus (B/Maryland/15/2016 BX-69A); and
  - B/Phuket/3073/2013-like virus

Table: Characteristics of influenza vaccine products available in Nova Scotia for 2018 -19 season*

Product Name	Fluzone® High-Dose (LTCFs residents ≥ 65 years only)	Flulaval® Tetra	Fluzone® Quadrivalent
Manufacturer	**Sanofi Pasteur**	**GlaxoSmithKline**	**Sanofi Pasteur**
Vaccine Preparation	TIV	QIV	QIV
Vaccine Type	Inactivated (Split virus)	Inactivated (Split virus)	Inactivated (Split virus)
Route of Administration	IM	IM	IM
Authorized Ages for Use	65 years and older**	6 months and older	6 months and older
Antigen Content (Each of Strains)	60 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose
Adjuvant	No	No	No
Formats Available	Single dose pre-filled syringes	5 mL multi-dose vial	5 mL multi-dose vial
Post-Puncture Shelf Life for Multi-Dose Vials	Not applicable	28 days	Up to expiry date indicated on vial label
Product Stability	Store between +2°C to +8°C. Must not be frozen and must be protected from light.	Store between +2°C to +8°C. Must not be frozen and must be protected from light.	Store between +2°C to +8°C. Must not be frozen and must be protected from light.
Thimerosal	No	Yes	Yes
Antibiotics (Traces)	None	None	None
Other Clinically Relevant Non-Medicinal Ingredients	Formaldehyde Egg protein Triton X-100	Egg protein α-tocopheryl hydrogen succinate Polysorbate 80 Formaldehyde Ethanol Sodium deoxycholate Sucrose	Egg protein Formaldehyde Triton X-100 Sucrose

*Adapted from: Appendix A, Table 4 of the *Statement on Seasonal Influenza Vaccine for 2018-19*. For further information refer to product monographs

** Fluzone High-Dose is available free for residents of Long Term Care Facilities 65 years and older only

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1. How do I order my supply of vaccine and when will it arrive?

Immunization providers should initially order a two to four-week supply of influenza vaccine and continue to order monthly. Order only the amount you estimate you will use within the month. To minimize wastage, it is important to record current doses on hand in your practice on the order form when requesting new orders. **We encourage you to start immunizing as soon as you receive your vaccine supply**. Please try to first immunize people at greatest risk of influenza-related complications and those people who live with or care for them.

Seasonal influenza vaccine is sent from the manufacturer to the Nova Scotia Provincial Bio-Depot over a period of 6-8 weeks in varying quantities. Vaccine will be distributed from Public Health offices the week of **October 15th**. It is critical for Public Health to manage the supply of vaccine to ensure equitable distribution to all immunization providers.

Every year, there are potential delays in vaccine development and distribution from vaccine manufacturers. In addition, distribution from the Provincial Bio-Depot takes a week to 10 days, so it is impossible for every provider to receive their supply at the exact same time. We ask for your patience and your help explaining the situation when clients ask why some providers have vaccine earlier than others.

Supply of HD-TIV is only available for LTCF residents 65 years of age and older. Order forms for this vaccine will be sent by local public health to LTCFs and only those Pharmacies and Family Physicians responsible for the vaccine administration to residents of LTCFs 65 years of age and older, as identified by the LTCFs. Completed order forms should be faxed to local public health. Order forms will be reviewed and approved by the Immunization Coordinator Provincial Biological Depot and vaccine will be distributed accordingly.

Orders for the QIV product can be placed through the local public health office.

2. What are my accountabilities as an immunization provider?

Reporting

- Adverse Events Following Immunization are to be reported to local Public Health as per the It's the Law: Reporting Adverse Events Following Immunization poster (see Q 16).
- Physicians are to use MSI billing codes (see Q 14).
- Pharmacists are to use pharmacy billing codes (see Q 15).
- Other immunization providers are to complete aggregate data collection forms that are provided by and returned to Public Health.

Reporting Cold Chain Breaks

Report all cold chain breaks to the local Public Health office. Vaccine that is exposed to a cold chain break must be bagged, dated, labelled "Do not use" and refrigerated while waiting to receive direction from Public Health on the use of affected vaccines.

Competency

Immunizers will follow their respective professional guidelines (e.g. CRNNS, CPSNS, CLPNNS, and NSCP) with respect to immunization competency and professional responsibility. Immunizers may need to be deemed competent by their employing agency or college to provide immunization.

Safety

Epinephrine must be present during vaccine administration.

- Clients must be monitored for at least 15 minutes post-immunization.
- Documentation of vaccine administration must include the lot number of the vaccine in case of recall or adverse event.

Duty of Care/Role Model

Annual influenza immunization of health care workers is very important for reducing influenza-related morbidity and mortality among high risk groups and individuals to whom you provide care. All immunization providers should receive an annual influenza vaccine.

3. What is the dosage and frequency of the influenza vaccines?

As per the National Advisory Committee on Immunization (NACI) Influenza 2018-19 statement, the dose for inactivated unadjuvanted influenza vaccine is 0.5 ml. **The dosing for ages 6 months – 23 months may differ from the product monograph.**

Age Group	QIV (Fluzone® or Flulaval Tetra)	HD-TIV (Fluzone® HD)	No. of Doses
6 months-8 years*	0.5 ml	-	1 or 2*
9 years and older	0.5ml	-	1
65 years and older **(LTCF residents only)**	-	0.5ml	1

*Children ages 6 months to less than 9 years who are receiving seasonal influenza vaccine for the first time should be given two doses, with a minimum interval of four weeks between doses. Children less than 9 years old who have been previously immunized with one or more doses of seasonal influenza vaccine are to receive one dose of influenza vaccine each year thereafter.

4. Who is eligible to receive influenza vaccine?

Immunization against influenza is publicly funded and advised for all Nova Scotians 6 months and older. The vaccine is free of charge.

Residents of LTCFs, 65 years of age and older should be offered the HD-TIV product. All other individuals should be offered the QIV product.

As in previous years, those without a valid Nova Scotia health card are eligible to receive publicly funded influenza vaccine.

5. Which groups are highly recommended to receive influenza vaccine?

- People at high risk of influenza-related complications or hospitalization.
- People capable of transmitting influenza to those at high risk.

Please refer to the NACI Influenza 2018-19 statement for further details.

6. Who should NOT routinely be given influenza vaccine?

- Infants less than 6 months of age.
- People who have had an anaphylactic reaction to a previous dose.
- People who have had an anaphylactic reaction to any of the vaccine components (with the exception of egg).
- People who have a serious acute febrile illness.
- People known to have had Guillain-Barré Syndrome within 6 weeks of a previous influenza vaccine.

7. Should people who have experienced Ocular Respiratory Syndrome (ORS) following receipt of a previous influenza vaccine be immunized?

Individuals who have experienced ORS without lower respiratory tract symptoms may be safely re-immunized with influenza vaccines. People who have experienced ORS with lower respiratory tract symptoms should have an expert review.

8. Should people who are allergic to eggs receive the influenza vaccine?

Individuals with egg allergies may be vaccinated against influenza using inactivated influenza vaccines without a prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg and without any extra precautions. As with any vaccine administration, providers must be prepared with the necessary equipment, knowledge and skills to respond to a vaccine emergency.

9. Should pregnant women receive the influenza vaccine?

Yes. NACI strongly recommends the QIV product for pregnant women at any stage of pregnancy.

10. Is influenza vaccine safe for breastfeeding mothers?

Yes, the QIV product is safe for breastfeeding mothers.

11. Can I draw up the influenza vaccine into syringes to be used at a later time?

No. The manufacturer has no data to confirm that immunogenicity of the product will be preserved after prolonged exposure to the plastic of the syringe. There are also concerns regarding bacterial contamination, increased potential for vaccine administration errors and vaccine wastage. Therefore, influenza vaccine should be injected as soon as possible after being drawn up.

12. How soon following immunization does protection develop and how long does it last?

Protection from the influenza vaccine generally begins 10 to 14 days after immunization and may last 6 months or longer.

13. What are the side effects of the inactivated influenza vaccine?

The most common reaction is pain at the injection site. Tenderness, erythema and swelling may also be noted at the injection site. Myalgia, headache, fatigue and arthralgia may also be common post influenza vaccination.

The high-dose influenza vaccine has been associated with higher rates of malaise, myalgia and fever in comparison to the standard dose vaccine. Most of these reactions are mild and resolve within a few days.

14. How do physicians bill for influenza immunization?

MSI billing information for influenza (Flu) and polysaccharide pneumococcal (PC) vaccines:

Billing requires a health service code, a modifier, and a diagnostic code				
Immunization	**Health Service Code**	**Modifier**	**MSUs**	**Diagnostic Code**
Influenza	13.59L	RO=INFL	6.0	Select diagnostic code from the table below
	13.59L	RO=HDIN	6.0	
Pneumococcal	13.59L	RO=PNEU	6.0	
Patient Status			**Diagnostic Codes**	
			FLU	**PC and FLU**
Pregnant			V221	N/A
Males & non-pregnant females			V048	V066

Provincial immunization tray fee:

Health Services Code	**Description**	**MSUs**
13.59M	Provincial immunization tray fee	1.5 per multiple (max 4/visit)

Notes for billing:

- If one vaccine is administered but no associated office visit is billed (i.e. the sole purpose for the visit is the immunization), claim the immunization at a full fee of 6.0 MSUs.
- If two vaccines are administered at the same visit but no associated office visit is billed (i.e. the sole purpose for the visit is the immunization), claim for each immunization at a full fee of 6.0 MSUs each. Any subsequent injections after two will be paid at 50%.
- If one vaccine is administered in conjunction with a billed office visit, claim both the office visit and the immunization at full fee.
- For children less than 12 months of age, if a vaccine is administered in conjunction with a well-baby care visit, claim the well-baby care visit and the immunization.
- If two vaccines are administered in conjunction with a billed office visit, claim the office visit and the first injection can be claimed at full fee. All subsequent injections will be paid at 50%.

15. How do pharmacists bill for influenza immunization?

Pharmacy billing information provides data on pharmacist-administered vaccines as part of assessing overall vaccine coverage rates.

Fees for the administration of publicly-funded influenza vaccine by pharmacists to Nova Scotia residents 5 years of age and over with a valid Nova Scotia Health Card are billed to the Department of Health and Wellness via the Pharmacare online adjudication system. The claim must contain the following in the patient's insurance field:

- Patient ID – the patient's Nova Scotia Health Card Number
- Carrier ID – NS

If a patient is already set up in the pharmacy system with Pharmacare coverage (e.g., Seniors' Pharmacare, Family Pharmacare), a separate patient file does not need to be created.

Claims must be submitted using the DIN of the vaccine administered to the patient, unless the patient is pregnant or is a child receiving a second vaccine dose. The following table provides direction related to submitting claims using a PIN for pregnant women or children receiving a second dose.

Claims are submitted with the administration fee in the professional fee field. Providers are not reimbursed for ingredient costs or markups for these claims as they are able to access publicly-funded vaccine at no charge.

More details can be found within the Nova Scotia Pharmacare Programs Pharmacists' Guide.

Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines

Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines		
CPhA Claim Standard Field #	**CPhA Claim Standard Field Name**	**Content**
D.56.03	DIN/GP#/PIN	**DINs** • Fluzone Quadrivalent MDV 02432730 • Fluzone Quadrivalent PFS 02420643 • FluLaval Tetra 02420783 • **Fluzone High-Dose 02445646 (Only for residents of LTCFs ≥ 65 years of age)** **PIN for pregnant women** • Fluzone Quadrivalent 93899895 • FluLaval Tetra 93899893 **PIN for second dose for children** • Fluzone Quadrivalent 93899896 • FluLaval Tetra 93899894
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Pharmacists prescriber ID
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D 67.03	Cost Upcharge	DDDDD (dollar value - not adjudicated)
D.68.03	Professional Fee	$12.00

16. What adverse events need to be reported to Public Health?

All adverse events not normally expected (i.e. listed in the product monograph) that are temporally related to the administration of the vaccine need to be reported to local public health in accordance with the *It's the Law: Reporting of Adverse Events Following Immunization* poster.

17. Can the inactivated influenza vaccine cause influenza illness?

No. The inactivated influenza vaccine does not contain live virus and cannot cause influenza.

18. Can you receive the inactivated influenza vaccine before or after having donated/received blood or Immune Globulin?

Yes.

19. Can the influenza vaccine be administered with other vaccines or if other vaccines have been received recently?

Yes, you can administer influenza vaccine at the same time as other vaccines (e.g. adult pertussis vaccine, pneumococcal vaccine) but with separate needles and syringes in different sites. There is no interval of time needed between receiving inactivated influenza vaccine and any other vaccines.

20. Where can I get more information on influenza vaccines?

For more information on influenza vaccine, contact your local Public Health office. You may also check the following websites:

- Public Health Agency of Canada (NACI): Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2018-19
- Nova Scotia Department of Health and Wellness
- Canadian Public Health Association
- Immunize Canada

21. How is "long-term care facility (LTCF)" defined for the purposes of HD-TIV eligibility?

For the purposes of HD-TIV eligibility, LTCFs are nursing homes and residential care facilities. This also includes the Veterans Memorial Unit.

Only individuals 65 years of age and older living in LTCFs are eligible to receive HD-TIV.

Respite care clients 65 years of age and older admitted to LTCFs are only eligible to receive the HD-TIV while in the LTCF. Individuals in transitional beds are not eligible to receive the HD-TIV.

22. Why is HD-TIV being offered to only residents of LTCFs and not all individuals 65 years and older?

Influenza is a significant cause of death and hospitalization in Nova Scotia, especially for residents of closed facilities like LTCFs. Residents are at increased risk of influenza and influenza related complications due to age, compromised health status and institutional living environment. Given these risk factors for residents of LTCFs and the ability of the vaccine to provide superior protection in comparison to the standard dose inactivated trivalent influenza vaccine, this vaccine is offered for free to residents of such facilities. All staff and residents of LTCFs less than 65 years of age should be offered the QIV.

23. Why is HD-TIV being offered only to those aged 65 years and older residing in a LTCF and not those who are younger than 65 years?

This is based on the NACI recommendation. In addition, the product is licensed only for those aged 65 years of age and older.

24. What if an individual eligible for HD-TIV refuses the vaccine?

The individual must be made aware that the HD-TIV provides better protection in individuals 65 years of age and older in comparison to the QIV. If an individual refuses Fluzone® High-Dose, Fluzone® or Flulaval® Tetra should be offered.

25. Can a LTCF resident 65 years and older who received QIV in the 2018-19 season receive HD-TIV?

LTCF residents 65 years and older who have received the QIV should not be re-immunized with the HD-TIV. NACI recommends either the QIV or HD-TIV for those 65 years and older.

26. How can someone who is 65 years of age or older and not living in a LTCF access HD-TIV?

Individuals 65 years or older who wish to receive the HD-TIV may purchase the vaccine through a health care provider. Some health plans may cover the cost of the vaccine.

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