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National Advisory Committee Statement

Summary of the National Advisory Committee on Immunization (NACI) Statement on Seasonal Influenza Vaccine for 2015–2016

Gemmill I[1, 2], on behalf of the National Advisory Committee on Immunization (NACI)

[1] Chair, NACI
[2] Kingston, Frontenac and Lennox & Addington Public Health, Kingston, ON

Correspondence: NACI-CCNI@phac-aspc.gc.ca

Abstract

Background: The National Advisory Committee on Immunization (NACI) provides the Public Health Agency of Canada with ongoing and timely medical, scientific, and public health advice relating to immunization.

Objective: To summarize the update of the 2015−2016 recommendations by NACI regarding the use of seasonal influenza vaccines.

Methods: Annual influenza vaccine recommendations are developed by the Influenza Working Group for consideration by NACI, based on NACI's evidence-based process for developing recommendations, and includes: a consideration of the burden of influenza illness and the target populations for vaccination; efficacy and effectiveness, immunogenicity, and safety of influenza vaccines; vaccine schedules; and other aspects of influenza immunization.

Results: NACI continues to recommend influenza vaccination for all individuals aged 6 months and older, with particular focus on people at high risk of influenza-related complications or hospitalization, people capable of transmitting influenza to those at high risk, and others as indicated. For the 2015−2016 influenza season, the Statement has been updated to identify children and adolescents with neurologic or neurodevelopment conditions as a group at high risk for influenza-related complications or hospitalization. Several changes to product availability in Canada have also been noted. A new adjuvanted, trivalent influenza vaccine (Fluad Pediatric™ [Novartis]) will be available for use in children aged 6 to <24 months. The recommended choice of product for this age group, however, is quadrivalent inactivated influenza vaccine (QIV), because children are more likely to be affected by influenza B, and the QIV provides broader protection against both lineages of influenza B. If QIV is not available, either unadjuvanted or adjuvanted trivalent inactivated influenza vaccine (TIV) should be used. Only the quadrivalent formulation of the live attenuated influenza vaccine (LAIV) (FluMist® Quadrivalent [AstraZeneca]) will be available, and the recommendation for preferential use of LAIV in children 2 to 17 years of age who do not have contraindications to this vaccine remains unchanged following a review of information pertaining to reports of decreased effectiveness of LAIV in the United States during the 2013−2014 season. Finally, the intradermal trivalent influenza vaccine (Intanza® [Sanofi Pasteur]) will no longer be available for use in Canada. Other updates to the Statement include additional information reaffirming the safety of LAIV use in children with cystic fibrosis who are not considered immunosuppressed or receiving immunosuppressive treatment, as well as a revised definition for oculo-respiratory syndrome which, when it occurs, should be reported as an adverse event following immunization (AEFI) to local public health officials.

Conclusion: Vaccination is the safest, longest lasting and most effective way to prevent influenza.

Introduction

Every year, the National Advisory Committee on Immunization (NACI) provides the Public Health Agency of Canada with recommendations on seasonal influenza vaccines for the upcoming season as part of its mandate to develop evidence-based medical, scientific, and public health advice relating to immunization. NACI develops Advisory Committee statements on new vaccines and vaccine-related issues and maintains its evergreen edition of the *Canadian Immunization Guide* (1). The objective of this Statement is to summarize both the update of the *Canadian Immunization Guide* Chapter on Influenza and the *Statement of Seasonal Influenza Vaccine* for 2015−2016 (2).

Methods

Annual influenza vaccine recommendations are developed by the Influenza Working Group (IWG) for consideration by NACI, based on NACI's evidence-based process for developing recommendations (3). This process includes: a consideration of the burden of influenza illness and the target populations for vaccination; data on efficacy and effectiveness, immunogenicity, and safety, of influenza vaccines; vaccine schedules; and other aspects of influenza immunization.

Recommendations

NACI continues to recommend influenza vaccination for all individuals aged 6 months and older, with particular focus on people at high risk of influenza-related complications or hospitalization, people capable of transmitting influenza to those at high risk, and others as indicated (**Table 1**). In particular, following a recent publication by the Canadian Immunization Monitoring Program ACTive (IMPACT) (4), NACI now includes children and adolescents with neurologic or neurodevelopment conditions (including seizure disorders, febrile seizures and isolated developmental delay) as a chronic health condition, and therefore among the groups for whom influenza vaccination is particularly recommended. Healthy individuals 5 to 64 years of age also benefit from influenza vaccination, as do travellers aged 6 months and older, since in the tropics influenza occurs year round; in temperate zones, influenza occurs from November to March in the northern hemisphere and April to October in the southern hemisphere.

Table 1: NACI 2015−2016 recommendations for influenza vaccination[1]

People at high risk of influenza-related complications or hospitalization

- Adults, including pregnant women, and children with the following chronic health conditions:
  - cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma)
  - diabetes mellitus and other metabolic diseases
  - cancer, immune compromising conditions (due to underlying disease, therapy or both)
  - renal disease
  - anemia or hemoglobinopathy
  - conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration
  - morbid obesity (BMI ≥40)
  - children and adolescents (aged 6 months to 18 years) with the following conditions:
    - *neurologic or neurodevelopment conditions (including seizure disorders, febrile seizures and isolated developmental delay)*
    - 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.
- People ≥65 years of age.

- All children 6 to 59 months of age.
- Healthy pregnant women (the risk of influenza-related hospitalization increases with length of gestation, i.e., it is higher in the third than in the second trimester).
- Aboriginal Peoples.

People capable of transmitting influenza to those at high risk

- 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 of influenza complications.
- Household contacts (adults and children) of individuals at high risk of influenza-related complications (whether or not the individual at high risk has been immunized):
  - household contacts of individuals at high risk, as listed in the section above
  - household contacts of infants <6 months of age as these infants are at high risk of complications from influenza but cannot receive influenza vaccine
  - members of a household expecting a newborn during the influenza season
- Those providing regular child care to children ≤59 months of age, whether in or out of the home.
- Those who provide services within closed or relatively closed settings to persons at high risk (e.g., crew on a ship).

Others

- People who provide essential community services.
- People in direct contact during culling operations with poultry infected with avian influenza.

[1] New recommendations are noted in italic.

Children 6 to less than 24 months

For children 6 to 23 months of age NACI recommends that, given the burden of influenza B disease, quadrivalent inactivated influenza vaccine (QIV) should be used. If QIV is not available, either unadjuvanted or adjuvanted trivalent inactivated influenza vaccine (TIV) should be used. A new adjuvanted, trivalent influenza vaccine, Fluad Pediatric™ (Novartis), will be available on the Canadian market, starting in the 2015−2016 influenza season, for use in children aged 6 to <24 months and is administered as a 0.25 mL dose by intramuscular injection.

Children and adolescents 2 to 17 years

NACI recommends live attenuated influenza vaccine (LAIV) use for healthy children and adolescents 2 to 17 years of age who do not have contraindications to this vaccine. Only the quadrivalent formulation of LAIV (FluMist® Quadrivalent [AstraZeneca]) will be available in Canada in the 2015−2016 season. The 2015−2016 Statement has been updated to reflect that the evidence supporting the use of live attenuated influenza vaccines was based on the trivalent formulation of LAIV. Based on expert opinion, the comparative efficacy data which supported the preferential recommendations for the trivalent formulation of LAIV are also applicable to the quadrivalent formulation of LAIV because the manufacturing processes and immunologic mechanism of the quadrivalent LAIV and the trivalent LAIV products are the same. This expert opinion is supported by the results of the non-inferiority studies comparing trivalent and quadrivalent formulations of LAIV, which were required by regulatory bodies to authorize the use of the quadrivalent LAIV formulation. Comparative vaccine efficacy and effectiveness data of TIV or QIV, and the quadrivalent formulation of LAIV are not available.

Decreased effectiveness of quadrivalent LAIV was seen in the United States against the influenza A (H1N1) strain during the 2013−2014 influenza season. Thermal stability tests have shown that the reduced stability likely resulted in strain degradation when experiencing deviations in temperature during storage or transport. Undocumented temperature deviations are unlikely to occur in Canada as, by contract, the manufacturer is required to maintain the required temperatures throughout transport to provincial and territorial depots.

Based on a review of available evidence, NACI continues to recommend preferential use of LAIV in children 2 to 17 years of age who do not have contraindications to this vaccine. NACI will continue to monitor this issue.

All age groups

Table 2 summarizes the choice of influenza vaccine for selected age and risk groups. **Table 3** identifies the recommended dosage and route of influenza vaccine for the 2015−2016 season, by age.

Table 2: Choice of influenza vaccine for selected age and risk groups (for persons without a contraindication to the vaccine)

Recipient by age group	Vaccine types available for use[1]	Comments
Children 6 to 23 months of age	• TIV • QIV • Adjuvanted TIV	Given the burden of influenza B disease, QIV should be used. If QIV is not available, either unadjuvanted or adjuvanted TIV should be used.
Children 2 to 17 years of age	• TIV • QIV • LAIV	NACI recommends LAIV for healthy children and adolescents 2 to 17 years of age who do not have contraindications to this vaccine. LAIV is contraindicated for: children less than 24 months of age, due to increased risk of wheezing; individuals with severe asthma[2]; children and adolescents <18 years of age who are receiving aspirin or aspirin-containing therapy; pregnant women; and persons with immune compromising conditions, due to underlying disease, therapy, or both. LAIV, TIV or QIV can be used in children with chronic health conditions, including asthma that is not severe[2] and cystic fibrosis without immune suppression.
Adults 18 to 59 years of age	• TIV • QIV • LAIV	Any of these three vaccines may be used, unless contraindicated, for healthy adults in this age group. TIV and QIV are the preferred products for adults with chronic health conditions. LAIV is not recommended for adults with immune compromising conditions.
Adults 60 to 64 years of age	• TIV • QIV	Either of these vaccines can be used, unless contraindicated, for adults in this age group.
Adults ≥65 years of age	• TIV • QIV • Adjuvanted TIV	Any of these three vaccines may be used, unless contraindicated, for healthy adults in this age group.
Pregnant women	• TIV • QIV	LAIV is not recommended because of the theoretical risk to the fetus from administering a live virus vaccine.

[1] TIV = trivalent inactivated influenza vaccine (for intramuscular [IM] administration); QIV = quadrivalent inactivated influenza vaccine; LAIV = live attenuated influenza vaccine

[2] An individual with severe asthma is defined as someone who is currently on oral or high dose inhaled glucocorticosteriods, is active wheezing, or has had medically attended wheezing in the seven days prior to vaccination.

Table 3: Influenza vaccine: Recommended dosage and route, by age, for the 2015–2016 season

Age group	TIV[1,2] without adjuvant or QIV[1,2] IM[1]	MF59-adjuvanted TIV (Fluad Pediatric™ or Fluad®) IM	LAIV[1] (FluMist® Quadrivalent) IN	Number of doses required
6 to 23 months	0.5 mL[3]	0.25 mL	—	One or two[4]
2 to 8 years	0.5 mL	—	0.2 mL (0.1 mL per nostril)	One or two[4]
9 to 17 years	0.5 mL	—	0.2 mL (0.1 mL per nostril)	One
18 to 59 years	0.5 mL	—	0.2 mL (0.1 mL per nostril)	One
60 to 64 years	0.5 mL	—	—	One
≥65 years	0.5 mL	0.5 mL	—	One

[1] TIV = trivalent inactivated influenza vaccine; QIV = quadrivalent inactivated influenza vaccine; LAIV = live attenuated influenza vaccine; IM = intramuscular; IN = intranasal

[2] Influvac® ≥18 years; Fluviral® ≥6 months; Agriflu® ≥6 months; Vaxigrip® ≥6 months; Fluzone® ≥6 months; Flulaval® Tetra ≥6 months; and Fluzone® Quadrivalent ≥6 months.

[3] This information differs from the product monograph. As noted in the statement, recommendations for use and other information in this statement may differ from that set out in the product monographs/leaflets of the Canadian manufacturers (1).

[4] Children 6 months to less than 9 years of age who have never received the seasonal influenza vaccine, require two doses of influenza vaccine, with a minimum interval of four weeks between doses. Eligible children less than 9 years of age, who have properly received one or more doses of seasonal influenza vaccine in the past, should receive one dose per influenza vaccination season thereafter.

Additional information

The target groups for influenza and pneumococcal polysaccharide vaccines overlap considerably. Health care providers should take the opportunity to vaccinate eligible persons against pneumococcal disease when influenza vaccine is given.

A Canadian study conducted during the 2012−2013 season followed a cohort of children and adolescents 2 to 18 years of age with cystic fibrosis, following administration of trivalent LAIV, to evaluate the safety of LAIV in this population (5). The vaccine was found to be well tolerated, and provided reassurance that LAIV is safe for use in this population. Children with cystic fibrosis may receive LAIV if the individual is not being treated with immunosuppressive drugs, such as prolonged systemic corticosteroids, and meets the other criteria for LAIV administration.

The definition for oculo-respiratory syndrome (ORS) has been updated. ORS is defined as the presence of bilateral red eyes plus one or more respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that start within 24 hours of vaccination, with or without facial oedema. Few cases have been identified since the 2000−2001 influenza season. ORS is not considered to be an allergic response and, when it occurs, it should be reported as an adverse event following immunization (AEFI) to local public health officials.

Although, as a general rule, two live vaccines are given four weeks apart, there is no evidence that this interval is needed for live intranasal influenza vaccines and other live vaccines. Based on expert opinion, NACI recommends that LAIV can be given together with, or at any time before or after, the administration of any other live attenuated or inactivated vaccine.

Two recommendations from previous statements merit repetition. Immunization should not be delayed because of minor acute illness, with or without fever. If significant nasal congestion is present that might impede delivery of LAIV to the nasopharyngeal mucosa, inactivated vaccines can be administered or LAIV may be deferred until resolution of the illness. Egg allergic individuals may be vaccinated against influenza

using inactivated TIV or QIV, without prior influenza vaccine skin testing, and with the full dose, irrespective of a past severe reaction to egg, and without any particular consideration including immunization setting. As with all vaccine administration, however, immunizers should have the necessary equipment and be prepared to respond to a vaccine emergency at all times.

Finally, for the 2015−2016 influenza season, Intanza® will no longer be available on the Canadian market.

Conclusion

Recommendations for influenza vaccination are updated annually as this field is in rapid development. Vaccination remains the safest, longest lasting and most effective way to prevent influenza.

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Conflict of interest

None

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