

<b>Section 15:</b>	Influenza Immunization Program Standard	<b>Standard #:</b>	<b>15.100</b>
<b>Created by:</b>	Provincial Immunization Program, Standards and Quality		
<b>Approved by:</b>	Provincial Immunization Program, Standards and Quality		
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### **Preamble**

Alberta Health Services (AHS) Provincial Immunization Program Standards and Quality, Provincial Population & Public Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information relating to provincial immunization program standards and quality. These standards are based on currently available evidence based information, Alberta Health (AH) policy, and provincial and national guidelines. Immunizers must be knowledgeable about the specific vaccines they administer.

### **Background**

Influenza is a respiratory infection, primarily caused by influenza A and B viruses, that occurs in Canada each year in the late fall and winter months. Influenza occurs globally with annual epidemics resulting in approximately one billion cases of influenza, three to five million cases of severe illness and 290,000 to 650,000 deaths, with an annual attack rate estimated at 5-10% in adults and 20-30% in children. In Canada, although the burden of influenza can vary from year to year, it is estimated that there are an average of 12,200 hospitalizations related to influenza and approximately 3,500 deaths attributable to influenza occurring annually. Children aged 5 years up to and including 9 years of age generally have the highest rates of influenza infection; however, rates of serious illness and death are highest in children less than 2 years of age, individuals over the age of 65 years and those with underlying medical conditions.

Influenza circulation was at a historical low in the 2020-2021 influenza season when public health measures, such as masking and social distancing, suppressed spread. Alberta had no influenza cases that season.

Annual immunization with influenza vaccine is the most effective way to prevent or minimize influenza infection or its complications. The vaccine is safe and well-tolerated; it cannot cause influenza illness because inactivated influenza vaccines do not contain live virus and live attenuated influenza vaccines contain weakened viruses.

In the fall of 2009, Alberta introduced a universal influenza immunization program with all Albertans 6 months of age and older eligible to receive provincially funded vaccine. In Alberta service delivery is focused on increasing the immunization rates of high-risk populations who are most at risk of influenza-associated morbidity and mortality. The influenza immunization program is the largest immunization program provided within Alberta Health Services (AHS).

The Provincial Immunization Program Standards and Quality team, under the leadership of the Director of Communicable Disease Control (CDC) and the lead Medical Officer of Health for CDC, manages overall program planning for the AHS Influenza Immunization Program. The provincial AHS CDC team sets the immunization standards, and zone Public Health staff deliver the influenza immunization program in partnership with community providers.

## **Purpose**

The purpose of this standard is to provide principles and guidelines for the consistent administration of influenza vaccines.

## **Applicability**

This standard applies to all AHS staff and community providers administering provincially funded influenza vaccine.

## **Definitions:**

**Annual Dose** – Refers to the dose of influenza vaccine individuals 9 years of age and older receive each influenza season.

**Community Providers** – Refers to physicians, community pharmacists, long term care/continuing care facilities and private occupational health and safety companies.

**Dose 1 of 2 Influenza Vaccine** – Refers to the first dose of influenza vaccine given to children less than 9 years of age who require 2 doses given at a minimum of 4 weeks apart if they have never received seasonal influenza vaccine in a previous year.

**Dose 2 of 2 Influenza Vaccine** – Refers to the second dose of influenza vaccine given to children less than 9 years of age who require 2 doses given at a minimum of 4 weeks apart if they have never received seasonal influenza vaccine in a previous year.

**National Advisory Committee on Immunization (NACI)** – an expert group that makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom immunization should be targeted. NACI publishes the Statement on Seasonal Influenza Immunization annually.

**Influenza Immunization Program Letter** - outlines the major aspects of the influenza immunization program. Sent to all partners participating in the Influenza Immunization Program.

**Influenza Immunization Program Registration Form** – the document may be used by zones to be completed by immunizing partners wishing to participate in the Alberta Influenza Immunization Program. Once the registration form has been reviewed immunizing partners will receive additional information including the Influenza Immunization Program Letter.

**The Alberta Immunization Outreach Program** - written by Alberta Health, this document outlines the roles and responsibilities for immunization providers participating in Alberta's Immunization Outreach Program.

## **Competency**

In November 2008 the Public Health Agency of Canada published the Immunization Competencies for Health Professionals with a goal of promoting safe and competent practices for immunization providers. The following competencies outlined in that document are applicable to this standard:

- Communication – Communicates effectively about immunization, as relevant to the practice setting(s).
- Storage and handling of Immunization agents – Implements AHS and National Storage and Handling Guidelines when storing, handling, or transporting vaccines.
- Administration of Immunizing Agents – Prepares and administers immunization agents correctly.
- Adverse Events Following Immunization – Anticipates, identifies, and manages adverse events following immunization, as appropriate to the practice setting.
- Documentation – Documents information relevant to each immunization encounter in accordance with national guidelines for immunization practices and jurisdictional health information processes.
- Populations Requiring Special Considerations – Recognizes and responds to the unique immunization needs of certain population groups.

## **Section 1: General Considerations**

Alberta will continue with a universal influenza immunization program.

Universal influenza immunization has the potential to protect healthy adults and children from disease, decrease the spread of influenza in the community and prevent serious complications and death from influenza in vulnerable populations. This can result in potential economic benefits related to fewer lost work days and decreased health care utilization. A universal influenza immunization program with a focus on immunizing the most Albertans, and in particular those at highest risk of disease complications early in the influenza season, is best for reduction in health care services and reducing mortality and morbidity of Albertans.

The receipt of influenza vaccination is an essential component of the standard of care for all health care providers for their own protection and that of their patients. Health care providers who have direct patient contact should consider annual influenza vaccination as part of their responsibilities to provide the highest standard of care.

Immunization remains our primary tool for the prevention of influenza infection and illness. Antivirals do not replace annual influenza immunization.

## **Section 2: Eligibility for Influenza Immunization**

All individuals 6 months of age and older who live, work, go to school or are visiting in Alberta are eligible to receive provincially funded influenza vaccine. Persons without a ULI should be directed to attend an AHS Public Health Influenza Clinic.

AH procures the influenza vaccines, and determines eligibility and reporting requirements for influenza vaccine for the current season. AHS, working with community partners, provides influenza vaccine to Albertans. In some instances specific influenza vaccines are targeted to certain populations, e.g., seniors, residents of Long Term Care (LTC) facilities.

## 2.1. High Risk

Persons at high risk of influenza-related complications or hospitalization include:

- Pregnant women
- Persons 65 years of age and older
- Individuals of any age who are residents of nursing homes and other chronic care facilities
- All children 6 months up to and including 59 months of age
- Indigenous Peoples
- Adults and children with chronic health conditions including those persons who are morbidly obese
- Individuals living in chronically disadvantaged situations.

Immunization programs should focus on those persons at high risk of influenza-related complications and those capable of transmitting influenza to individuals at high risk. However, influenza vaccine is recommended and provided free of charge for all Albertans.

- **Pregnant Women**

The rates of influenza related hospitalization increase with gestational period after the first trimester; however, increased mortality from seasonal influenza has not been found in pregnant women. Immunization of pregnant women has the additional advantage of potentially protecting the fetus through transplacental antibody passage or through breast milk in lactating women. Studies show vaccine effectiveness against lab-confirmed influenza in infants of immunized mothers followed for 6 months was 63%. There is evidence immunization of pregnant women protects newborns from influenza and influenza-related hospitalization and that infants born during the influenza season to immunized women are less likely to be low birth weight, small for gestational age and premature.

Inactivated influenza vaccines (excluding Fluzone High-Dose®) are considered safe for pregnant women at ALL stages of pregnancy and for breastfeeding women. To date, studies have not shown evidence of harm to the mother or fetus associated with influenza immunization. Live influenza vaccines are considered safe for breastfeeding women. They are contraindicated in pregnant women.

- **Persons 65 years of age and older**

Hospitalization of adults 65 years of age and older attributed to influenza is estimated at 125-228 per 100,000 healthy people and influenza-attributed mortality rates increase with increased age.

- **Individuals of any age who are Residents of Nursing Homes and Other Chronic Care Facilities**

Residents of nursing homes and other chronic care facilities often have one or more chronic health conditions and live in institutional environments that may facilitate the spread of influenza.

- **Children**

Children 0 to 24 months of age are at increased risk of influenza-associated hospitalization compared to healthy older children and young adults. Hospitalization rates in children less than 2 years are estimated at 90 to 1000 admissions per 100,000 healthy children. Children 24 months up to and including 59 months of age have an estimated influenza attack rate of 10 to 40%. Additionally, children in this age range are efficient transmitters of influenza virus. Immunization of this age group may protect high risk groups who are unable to be immunized or those who do not respond well to the influenza vaccine.

- **Indigenous Peoples**

Based on historical information and findings identified during the 2009 influenza pandemic, Indigenous status has been associated with increased risk of influenza-related complications including death. Therefore NACI recommends the inclusion of Indigenous Peoples (First Nation, Métis, Inuit), among high-priority recipients of influenza vaccine.

- **Adults and Children with Chronic Health Conditions**

A number of chronic health conditions as identified by NACI are associated with increased risk of influenza-related complications, and influenza can lead to exacerbation of the chronic disease. Influenza immunization can induce protective antibody levels in a substantial proportion of adults and children with immune compromising conditions, although vaccine effectiveness may be lower in these people as compared to healthy individuals.

Information on the association between obesity and influenza-related complications continues to evolve. NACI recommends the inclusion of those who are morbidly obese (Body Mass Index [BMI] greater than or equal to 40) among high-priority recipients of influenza vaccine.

- **Populations with Insecure Housing or Otherwise Marginalized**

Individuals in this group would also be a focus for influenza immunization as higher rates of chronic disease put this population at increased risk of influenza-related complications. They may not access influenza immunization in the same way as the general population and therefore strategies to increase immunization rates may need to be developed.

### **Section 3: Influenza Vaccine**

In addition to the information outlined in this section, immunizers should refer to the AHS Immunization Program Standards Manual which can be accessed at the link below for specific details including but not limited to vaccine composition, indications, administration and dosage, contraindications and precautions, possible reactions, adverse reactions and reporting, vaccine storage and handling. <http://www.albertahealthservices.ca/10802.asp>.

Influenza vaccine is manufactured annually to include standardized amounts of the HA protein from representative seed strains of the two human influenza A subtypes (H3N2 and H1N1) and one (trivalent) or two (quadrivalent) of the influenza B lineages (Yamagata or Victoria).

As new influenza vaccines are developed, licensed and become available in Canada, they are incorporated into the provincial influenza immunization program based on AH purchasing decisions. AH makes recommendations on preferred vaccines for specific age groups based on efficacy, seroprotection and antibody response to influenza vaccines being studied, and the burden of disease in that age group.

#### **3.1 Inactivated Vaccine**

Immunization with inactivated influenza vaccines **cannot** cause influenza disease in the vaccine recipient because the vaccine does not contain live viruses. Immunization with live influenza vaccines does not cause influenza disease in vaccine recipients because the virus is attenuated or weakened.

Inactivated influenza vaccine is available in single dose (prefilled syringe format) or multi-dose vials. Multi-dose vial formulations of inactivated influenza vaccine that are authorized for use in Canada contain minute quantities of thimerosal, which is used as a preservative to keep the product sterile. Large retrospective studies have demonstrated that there is no association between childhood immunization with thimerosal containing vaccines and neurodevelopmental outcomes, including autism spectrum disorders.

### 3.2 Live Vaccine

Live vaccine will not be available in the provincially funded influenza program. For additional information related to live influenza vaccine refer to the NACI Statement and/or specific product monograph.

#### **Section 4: Immunogenicity and Efficacy**

Annual immunization is required because the body's immune response from immunization diminishes within a year. Also, because influenza viruses change often, the vaccine is reviewed each year and updated as necessary to keep up with the changing viruses.

The production and persistence of antibodies in an individual after immunization depend on several factors, including their age, prior and subsequent exposure to influenza antigens and the presence of immunodeficiency states. **Humoral antibody levels**, which correlate with vaccine protection, are generally achieved **2 weeks** after immunization.

Influenza vaccines are safe and well tolerated in healthy children. Young children have a high burden of illness and their vaccine-induced immune response is not as robust as older children. On the basis of studies that suggest a moderate improvement in antibody response in young children without an increase in reactogenicity, NACI recommends the use of a 0.5mL dose for all recipients of inactivated influenza, standard dose, unadjuvanted vaccine including young children.

Booster doses of influenza vaccine are not required in the same influenza season. However children 6 months of age to less than 9 years of age who have not previously received seasonal influenza vaccine require 2 doses of influenza vaccine, with a minimum of 4 weeks between doses. Only one dose of vaccine per season is recommended for everyone else. Two doses of influenza vaccine in older adults does not appear to improve the immune response to the vaccine compared to one dose.

Repeated annual administration of influenza vaccine has not been demonstrated to impair the immune response of the recipient to influenza virus. Even if the vaccine strains have not changed, re-immunization reinforces optimal protection for the coming influenza season. Systematic reviews have also demonstrated that influenza vaccine decreases the incidence of pneumonia, hospital admission and death in the elderly and reduces exacerbations in persons with chronic obstructive pulmonary disease. In observational studies immunization reduces physician visits, hospitalization and death in high-risk persons less than 65 years of age, reduces hospitalizations for cardiac disease and stroke in the elderly, and reduces hospitalization and deaths in persons with diabetes mellitus.

#### **Section 5: Precautions**

More detailed information on Contraindications and Precautions related to Influenza Vaccine can be found in the AHS Biological Product Information, Influenza Vaccines.

##### **5.1 Guillain-Barré Syndrome (GBS)**

Studies suggest that the absolute risk of GBS in the period following influenza immunization is about 1 excess case per million vaccinees above the background GBS rate. The background rate of GBS due to any cause was estimated at 2.02 (Ontario) and 2.30 (Quebec) per 100,000 person years.

The potential benefits of influenza immunization in preventing serious illness, hospitalization and death substantially outweigh these estimates of risk for vaccine-associated GBS. In fact, influenza infection itself is associated with GBS – the risk of GBS following influenza infection is greater than the GBS risk after influenza immunization.

GBS occurred in adults in association with the 1976 swine influenza vaccine, and evidence is consistent with a causal relation between the vaccine and GBS during that season. In an extensive review of studies since 1976, the United States Institute of Medicine concluded that the evidence was

inadequate to accept or reject a causal relation between GBS in adults and influenza vaccines administered after the swine influenza vaccine program in 1976.

A Canadian study that examined health-care data from Ontario from 1992-2004 showed a small but statistically significant temporal association between receiving influenza immunization and subsequent hospital admissions for GBS. This same study found no statistically significant increase in hospital admissions due to GBS since Ontario introduced its universal influenza immunization program.

Therefore, it is reasonable to avoid immunizing persons who are not at high risk for severe influenza complications who are known to have experienced GBS within 6 weeks after a previous influenza immunization.

## 5.2 Oculorespiratory Syndrome (ORS)

During the 2000/2001 influenza season, Health Canada received an increased number of reports of vaccine-associated symptoms and signs that were subsequently described as oculorespiratory syndrome (ORS). Fewer cases of ORS have been reported to Health Canada subsequent to the 2000/2001 influenza season.

ORS is defined by the following symptoms occurring within 24 hours of immunization:

- bilateral red eyes, **and**
- one or more of the following respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat) **with or without** facial swelling.

Recommendations for subsequent immunization following a report of ORS are based on a risk/benefit assessment and the severity of symptoms as perceived by the individual who experienced the symptoms. The following are the recommendations regarding influenza immunization for individuals who have previously experienced ORS symptoms:

- Individuals who previously experienced mild to moderate ORS symptoms may receive the influenza vaccine.
- Individuals who previously experienced severe ORS symptoms that did **not** include lower respiratory symptoms may also receive the influenza vaccine.
- For individuals who previously experienced severe ORS that included lower respiratory symptoms within 24 hours of receiving the influenza vaccine (e.g., wheezing, chest tightness, difficulty breathing), the Medical Officer of Health should be consulted to review the risks and benefits of further influenza immunization.
- Individuals who experience severe difficulty swallowing or other severe symptoms not included in the ORS case definition (e.g., throat constriction) should be reported to the Medical Officer of Health using the Alberta Adverse Event Reporting Process. The Medical Officer of Health should be consulted prior to the individual receiving subsequent doses of vaccine.

Studies indicate that re-immunization following ORS is safe. Approximately 5-45% of individuals who have experienced ORS may have a recurrence attributable to the vaccine, but usually in a milder form. Overall, the risk of ORS recurrence is minimal compared to the risks of influenza. Information regarding the occurrence of vaccine associated ORS during the previous influenza immunization season should be provided to individuals as part of the informed consent.

### **Related Resources**

Supporting documents to implement a safe and effective influenza immunization program listed below are available for **providers of influenza vaccine** shortly before the relevant influenza season on the AHS website at [Influenza Immunization Health Professionals | Alberta Health Services](#).

These documents must be reviewed by all immunizers prior to administering influenza vaccine as part of their annual influenza orientation. Documents include:

- AH Alberta Immunization Outreach Program document [AIP - Alberta Outreach Immunization Program](#)
- NACI Statements
- Product Monographs
- AHS Influenza Vaccine Biological Pages
- AHS Vaccine Storage and Handling Standard
- Influenza Client Immunization Record and Care After
- ORS Algorithm
- Influenza Vaccine Information Sheet
- Influenza Immunization Orientation Powerpoint
- Consent for Influenza Immunization
- Adverse Event Reporting <http://www.albertahealthservices.ca/10802.asp>
- Other relevant immunization resources can be found at the following link: <http://www.albertahealthservices.ca/info/Page10802.aspx>

## References

1. Government of Canada.:Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine 2023-2024 Ottawa, ON: Public Health Agency of Canada. [National Advisory Committee on Immunization \(NACI\) statement: Seasonal influenza vaccine for 2023-2024 - Canada.ca](#)
2. National Advisory Committee on Immunization. Canadian immunization guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada. <http://www.phac-aspc.gc.ca/naci-ccni/index-eng.php>
3. National Advisory Committee on Immunization (2006-01-03). Oculo-respiratory syndrome following influenza vaccination: Review of post-marketing surveillance through four influenza seasons in Canada. Ottawa, ON: Public Health Agency of Canada. <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/05vol31/dr3121a-eng.php>