Standard on the Contraindications and Precautions Related to Immunization

Alberta Health Services
Communicable Disease Control

Section 5.0	Contraindications and Precautions	**Standard # 05.100**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	June 1, 2015	**Revised**	March 3, 2025

Preamble

AHS Provincial Immunization Program Standards and Quality, Provincial Population & Public Health 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

Vaccines are safe and an important strategy in communicable disease control to prevent or reduce many communicable diseases. Vaccines undergo stringent testing through clinical trials to ensure they are safe and efficacious. Additionally, there are measures in place for ongoing monitoring of side effects related to vaccines.

Prior to administering any vaccine, the healthcare provider should assess the individual's state of health and other factors such as past immunization experience, known allergies, current health and any chronic conditions that may increase the risk of a serious adverse event following the immunization. Sometimes vaccines cannot be given or need to be delayed due to contraindications or precautions. Individuals may have concerns that lead to hesitation or refusal to be immunized. It is important for immunizers to correctly identify contraindications, distinguish them from precautions and seek expert advice as needed.

Purpose

Use this standard as a resource for immunizers to ensure a consistent approach to client assessment prior to vaccine administration. It summarizes information available related to contraindications and precautions. This standard does not replace information contained in the individual vaccine biological pages. Use it in conjunction with the following resources:

- Standard For Recommended Immunization Schedules
- AHS Immunization Policy Suite for Consent to Treatment(s)/Procedure(s) - Consent to Treatment/Procedure | Insite (albertahealthservices.ca)
- Standard for the Administration of Immunizations
- Vaccine Biological Pages
- Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression
- Standard for Reporting and Follow-Up of Adverse Events Following Immunization
- Standard for Immunization of Transplant Candidates and Recipients

Applicability

This standard applies to all immunizers providing provincially funded vaccine to members of the public.

Definitions:

Contraindication: Situation in which a vaccine should **not** be given because the risk of harm or of an adverse event outweighs potential therapeutic benefit of the vaccine. Contraindications may be temporary (for example, pregnancy is a contraindication to live vaccine) and the vaccine may be given later.

Precaution: Conditions that may increase the risk of an adverse event following immunization or that may compromise the ability of a vaccine to produce immunity. Generally, vaccines are deferred when a precaution is present. However, there may be circumstances when the benefits of administering the vaccine outweigh the potential harm, or when reduced vaccine immunogenicity may still result in significant benefit to an individual. A risk benefit assessment is required.

Competency

In 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 for this standard:

- Explains how vaccines work using basic knowledge of immune system.
- Demonstrates an understanding of the rationale and benefit of immunization, as relevant to the practice setting.
- Applies the knowledge of the components and properties of immunizing agents for safe and effective practice.
- Communicates effectively about immunization as relevant to the practice setting(s).
- Recognizes and responds to the unique immunization needs of certain population groups.

Section 1: Contraindications and precautions / fit to immunize

Prior to administration, assess the individual's state of health and other factors that may increase the risk of a serious adverse event following the immunization. Along with this assessment, consider the following references in the decision to immunize: Alberta Immunization Policy, the Canadian Immunization Guide, and the manufacturer's product monograph or directional leaflet.

Where recommendations in the *Alberta Immunization Policy* differ from the manufacturer's recommendations or the *Canadian Immunization Guide*, follow the *Alberta Immunization Policy* recommendations. Seek direction from the zone MOH/designate if a clear decision on whether to administer vaccine cannot be reached. Medical consultation may also be needed if there are questions pertaining to the health status of the individual.

The following is a general summary of areas to assess for each client at every immunization appointment before vaccine is given.

- The Fit to Immunize Tool is available for staff to use as a general guide for client assessment prior to immunization.

1.1 Current or recent illness

- Generally, individuals with minor or moderate acute illness may receive vaccine. There is no increase in risk of adverse events and no interference with the response to the vaccine.
- Immunizing a person who is severely ill needs to be carefully assessed. The benefits of protection and opportunity to immunize need to be weighed against the possibility that a vaccine-related adverse event could complicate their medical management, or that events related to the illness may be misperceived as vaccine-related. Expert consultation is recommended.

1.2 Chronic health conditions

Certain health conditions may require alteration of immunization technique or schedule, depending on the condition and the vaccine to be given. Consult with the physician or MOH/designate when required. See the following standards:

- Standard for the Administration of Immunizations
- Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression
- Standard for Immunization of Transplant Candidates and Recipients
- Immunization for Adult HSCT Transplant Recipients
- Immunization for Child HSCT Transplant Recipients

- Immunization for Adult SOT Candidates and Recipients
- Immunization for Children Expecting SOT Before 18 Months of Age
- Immunization for Children Expecting SOT After 18 Months of Age

1.2.1 Asthma

- Do not administer live attenuated influenza vaccine (LAIV) to individuals with severe asthma or those with medically attended wheezing in the seven days prior to immunization.
- Severe asthma is defined as currently on a high dose inhaled steroid.
    - High dose inhaled steroid is defined as an individual taking greater than 500 mcg per day of inhaled steroid regardless of age and drug (AHS MOH recommendation).
- LAIV can be given to people with stable, non-severe asthma.
- LAIV is not currently available as part of the Alberta provincial immunization program.

1.2.2 Immunocompromised individuals

- Avoid live vaccines in individuals who are immunocompromised due to the risk of disease caused by the vaccine strains. However, in certain cases the benefits may outweigh the risk. If there is uncertainty about the individual's immune status, seek approval from the most responsible health practitioner before immunization. For more information see:
    - Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression
    - Standard for Immunization of Transplant Candidates and Recipients
    - Immunization for Adult HSCT Transplant Recipients
    - Immunization for Child HSCT Transplant Recipients
    - Immunization for Adult SOT Candidates and Recipients
    - Immunization for Children Expecting SOT Before 18 Months
    - Immunization for Children Expecting SOT After 18 Months
- A person who is immunocompromised may not respond as well as a person who is healthy to an inactivated vaccine. However, inactivated vaccine is unlikely to cause harm to the client. Refer to Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression for more detail.
- Caution is needed when immunizing an individual with a live attenuated vaccine if they have close contacts who are immunocompromised.

1.2.3 Possible family or medical history of immunodeficiency disorders

Individuals who may have immunodeficiency disorders, such as known or suspected family history of congenital immunodeficiency disorder, undiagnosed maternal HIV infection, or history of failure to thrive and recurrent infections, should not receive live vaccines until investigation rules out immunodeficiency disorder. Immunodeficiency may be undiagnosed in young children presenting for routine immunizations.

1.2.4 Tuberculosis, active, untreated

Measles, Mumps, Rubella (MMR), Measles, Mumps, Rubella-Varicella (MMR-Var) and varicella (VZ) vaccines are contraindicated in individuals with active, untreated tuberculosis as a precautionary measure. Although tuberculosis may be exacerbated by natural measles infection, there is no evidence that measles or varicella containing vaccines have such an effect.

1.2.5 Bleeding disorders

Prior to immunization, optimize control of bleeding disorders for individuals with bleeding disorders such as hemophilia or Von Willebrand disease. They may be at risk of hematoma formation from intramuscular (IM) injections but there is the potential for increased risk of infection from their disease or frequent exposure to blood products. Individuals who require immunization with large volumes of vaccine or biologicals (for example HBIG, RIG or IG) should be assessed by their most responsible health practitioner for the need for clotting factor concentrates prior to immunization.

- Give IM injections with care.
- Optimize control of bleeding disorder before immunization.

- Give IM injections with a small gauge needle and apply firm pressure for 5 to 10 minutes.
- See Standard for the Administration of Immunizations for further details.

Individuals receiving long-term anticoagulation with either warfarin or heparin, are not considered to be at higher risk of bleeding complications. They may be safely immunized through IM or subcutaneous (SC) routes without discontinuation of anticoagulation therapy. There is a lack of evidence on whether there is an increased risk of bleeding complications following immunization with the newer types of anticoagulants such as antiplatelet agents. There is no reason to expect that there is a greater risk of bleeding complications than with other anticoagulants. A history of an IM hematoma or abnormal/unexplained bruising following immunization should prompt investigation of a possible bleeding disorder prior to immunization.

1.3 Medications

- Antibiotic therapy does not interfere with inactivated or live vaccines except for oral typhoid vaccine.
- Infants who have received immunoprophylaxis with respiratory syncytial virus (RSV) monoclonal antibody, for example palivizumab (Synagis), may be immunized with all routine vaccines (including rotavirus vaccine). The RSV monoclonal antibody is specific for the prevention of RSV infection and is not expected to interfere with the response to vaccines. An interval of 48 hrs is preferred for monitoring of AEFI, however vaccines may be given concurrently or at any interval before/after the RSV monoclonal antibody.
- Anticoagulation therapy does not need to be discontinued before administering immunization and the individual can be safely immunized through either the IM or SC route, as recommended for the vaccine product.

1.3.1 Chronic salicylate therapy in children

- Individuals receiving low doses of salicylate therapy, such as 3 to 5 mg/kg/day of acetylsalicylic acid (ASA) are not considered to be at increased risk of bleeding complications following immunization
- Children taking daily low doses (3 to 5 mg/kg/day) of ASA, can safely receive varicella vaccine if the child is NOT immunocompromised.
- Do not administer live attenuated influenza vaccine to children 2 to 17 yrs. who are receiving ASA or ASA-containing therapy, due to the association of Reye syndrome with ASA and wild-type influenza infection.

1.3.2 Antivirals

Antiviral therapy does not interfere with response to inactivated vaccines or most live vaccines with the following exception:

- Do not administer varicella-containing vaccine to individuals on antiviral medication for varicella zoster virus such as acyclovir, valacyclovir or famciclovir. These medications should be:
  - Discontinued at least 24 hours before administration of the vaccine.
  - Restarted at least 14 days following immunization.
- Shingrix vaccine may be given while an individual is receiving antiviral medication.

1.3.3 Immunosuppressive Therapy

- Inactivated vaccines may be administered to immunocompromised individuals if indicated: however, the magnitude and duration of the vaccine-induced immunity are reduced.
- Live vaccines are not generally recommended due to the risk of disease caused by the vaccine strains. However, in some less severely immunocompromised individuals, the benefits of live vaccines may outweigh the risks. Approval from the individual's attending physician must be obtained before proceeding with live vaccines.
- Refer to the Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression for more detail.

1.4 Congenital malformation of gastrointestinal tract or history of intussusception

Rotavirus vaccine is contraindicated in infants with a history of intussusception or uncorrected congenital malformation of the gastrointestinal tract such as Meckel's diverticulum that would predispose for intussusception. See Rotavirus Vaccine Biological page.

1.5 Neurological disorders

Neurologic disorders appear at different ages and may affect immunization decisions. Disorders that usually begin during infancy, such as cerebral palsy, spina bifida, seizure disorder, neuromuscular diseases and inborn errors of metabolism may have symptom onset before the receipt of the vaccines routinely recommended in infancy. Other conditions such as autism spectrum disorders, acute demyelinating encephalomyelitis, Guillain-Barré syndrome (GBS), transverse myelitis and multiple sclerosis are diagnosed in childhood and adulthood over the same time as routine vaccines are administered and may occur before or after the administration of vaccines.

- Disorders whose onset precedes immunization are generally not contraindications to subsequent immunization.
- Vaccines are safe to give when there is a history of a febrile seizure. There are no long-term sequelae associated with uncomplicated febrile seizures. Children with a history of febrile seizures have no increased risk of developing a seizure disorder, such as epilepsy.
    - There is no evidence that antipyretics prevent febrile seizures and therefore there is no need to recommend prophylactic antipyretic use.
    - History of febrile seizures or any seizure in a first-generation family member (parents or siblings) is not a contraindication to immunization.
- Do a case-by-case assessment with the MOH/most responsible health practitioner prior to further immunization for individuals who have had an afebrile seizure temporally associated with vaccine.
- Defer immunization for 24 hours for individuals with a significant head injury to ensure any sequelae have resolved.

1.6 Recent administration of human immune globulin or other blood products

Blood products and immune globulins may contain antibodies that interfere with the immune response to certain measles or varicella-containing live vaccines.

- See Standard For Recommended Immunization Schedules for detail on required intervals before giving a live vaccine after receipt of a blood product.

1.7 Live vaccine in the previous month

- Live vaccines must be administered at the same time or spaced at least four weeks apart.
    - Specialists recommending alternate spacing for specific high-risk individuals may be accommodated on a case-by-case basis.
    - Refer to the MMR, MMR-Var and varicella vaccine specific biological pages and the Standard for Recommended Immunization Schedules for specific recommendations for intervals between vaccines containing measles, mumps, rubella and varicella antigens.
- Live attenuated influenza vaccine (LAIV) may be administered any time before or after the administration of other live attenuated or inactivated vaccines.

1.8 Previous adverse events following immunization

Prior to immunization, assess the client's previous vaccine reactions. Vaccine safety and vaccine pharmacovigilance processes are intended to detect, assess, understand and communicate adverse events following immunization (AEFI) and are essential components of an immunization program. If reactions occur, they are usually mild, reasonably predictable and self-limiting. More serious or unexpected reactions can occur but are rare. It is therefore important for health care providers to monitor vaccine side effects and to report immediately all serious or unexpected AEFI.

Mild to moderate adverse events following immunization such as swelling, redness, fever or pain are expected, relatively common and self-limited. These are not a contraindication to immunization.

- Review the recommendations, consider current guidelines, consult the MOH/designate when required and proceed as appropriate if an adverse event has been previously reported.
- If an adverse event is reported during the assessment, follow the guidelines to report in the Standard for Reporting and Follow-Up of Adverse Events Following Immunization.
    - Follow Section 4: Guidelines for Public Health Immunization After an AEFI has been reported or submitted in the Standard for Reporting and Follow-Up of Adverse Events Following Immunization to determine whether or not to give vaccine while awaiting response to an AEFI report. Consultation with the zone MOH/designate may also be necessary.

1.8.1 Guillain-Barré syndrome (GBS)

GBS is an illness that involves acute onset of bilateral flaccid weakness or paralysis of the limbs with decreased or absent deep tendon reflexes.

- Individuals who develop GBS within six weeks of receipt of a tetanus-containing or influenza vaccine and where there is no other cause for the GBS identified, should not receive further doses of the same vaccine.
- Those who develop GBS outside the above timeframes may receive subsequent doses of the vaccine.
- There is no contraindication to immunization for individuals who have a history of GBS unrelated to immunization.

1.8.2 Oculo-respiratory syndrome

Oculo-Respiratory Syndrome (ORS) is a set of signs and symptoms of both the eyes and respiratory system that can occur following influenza immunization. Refer to vaccine-specific influenza biological pages as well as the Standard for Reporting and Follow-Up of Adverse Events Following Immunization for further details.

1.9 Allergies

Before any immunization, inquire about allergies and differentiate between minor allergic reactions and severe hypersensitivity reactions. A history of allergy is not necessarily a contraindication to immunization. However, reported anaphylaxis following a specific vaccine or exposure to one of the vaccine components, is generally a contraindication to further vaccine doses. Consult the manufacturer's product information to identify specific vaccine components if allergies are identified.

1.9.1 Anaphylaxis

- Anaphylaxis is rare following immunization, with estimated occurrence of 1.3 episodes per million doses of vaccine administered. However, anaphylaxis following immunization is potentially life-threatening and requires immediate medical attention.
- Advise individuals with no previous history of anaphylactic reactions to remain under observation for at least 15 minutes following receipt of vaccines.
- Extend the observation period to at least 30 minutes for individuals with a previous anaphylactic reaction to any agent such as vaccines, biologicals, drugs, food or bee stings.
- In low-risk situations, supervision can include having recipients remain within a short distance of the immunizer such as within a school.
- See the following for further details:
  - Anaphylaxis Management | Insite
  - Standard for Reporting and Follow-Up of Adverse Events Following Immunization

1.9.2 Latex allergy

- Some biological products have packaging such as vial stoppers, syringe plungers or needle shields made with natural rubber and may contain latex. Use special care for individuals with a previous latex anaphylactic reaction.
  - Do not administer vaccines supplied in vials or syringes that contain natural rubber, unless the benefit of immunization clearly outweighs the risk for a potential allergic reaction.
  - Use an equivalent biological product by a different manufacturer with latex-free packaging if available.
  - Seek medical consultation, if an equivalent biological product with latex-free packaging is not available. If the decision is to proceed with the biological product, administer in a controlled setting such as urgent care with an observation period of at least 30 minutes.
  - Biological products supplied in vials or syringes containing latex may be administered to individuals with latex allergies other than anaphylaxis such as contact sensitivity.

1.9.3 Hypersensitivity to egg and egg-related antigens

- Measles and mumps-containing vaccines:
  - Egg allergy is not a contraindication to immunization with measles/mumps containing vaccines, which are vaccines where the viruses are grown in chick embryo cell culture. The small amount of egg proteins contained in measles/mumps-containing vaccines is insufficient to cause an allergic reaction in people with egg allergy.
  - There is no increased risk of severe allergic reactions to MMR/MMR-Var vaccines.

- Prior egg ingestion is not a prerequisite for immunization with measles/mumps containing vaccines.
- Inactivated Influenza Vaccine (IIV) and live attenuated influenza Vaccine (LAIV):
  - Egg allergy is not a contraindication to immunization.
  - See Influenza Vaccine Quadrivalent Inactivated Biological Page and Influenza Vaccine High Dose Quadrivalent Inactivated Biological Page.

1.10 Pregnancy

- Live vaccines are generally contraindicated during pregnancy.
- Most routine inactivated vaccines may be administered to pregnant individuals when indicated.
  - Human papillomavirus (HPV) vaccine is not recommended for pregnant individuals.
- See vaccine specific biological pages for details.

1.11 Lactation

Routinely recommended vaccines may be safely administered to people who are breastfeeding. There is limited data available regarding the effects of maternal immunization on breastfed infants. However, there have been no reported adverse events thought to be vaccine related. Generally, there is no evidence that immunization during breastfeeding will adversely influence the maternal or infant immune response. Refer to vaccine specific biological pages for detailed information on lactation.

Infants of breastfeeding individuals and breastfeeding individuals initiating monoclonal antibody treatment after delivery should be immunized according to routinely recommended schedules. Transfer of monoclonal antibodies through breast milk is limited, and the minimal quantities that are ingested are likely to be broken down in the infant's gastrointestinal tract.

1.12 Limb integrity

Do not administer an immunizing agent in a limb that is likely to be affected by a lymphatic system problem such as lymphedema or mastectomy with lymph node curettage. The vastus lateralis is an alternative site for all ages. Individuals who present with A-V fistula (vascular shunt for hemodialysis), mastectomies, axilla lymphadenectomies, limb paralysis and upper limb amputations may have short term or long term circulatory or lymphatic system implications. This may impair vaccine absorption and antibody production, and lead to worsening of the condition.

1.13 Close contacts

A contraindication or precaution may not specifically affect the individual being immunized but could exist because of a close contact who may be adversely affected by use of a biological, for example, a live attenuated vaccine.

Section 2: Common concerns which are not usually contraindications

2.1 Age and weight

- Routine primary immunization begins at two months of age. When an infant is going to be at high risk for disease such as during travel, routine primary immunization may be started at six weeks of age. The exception is for meningococcal conjugate C vaccine, as the minimum age is eight weeks.
- Preterm or premature infants (born at less than 37 weeks gestation), have lower concentrations of maternal antibodies and a shorter duration of maternal protection. They are at greater risk for some vaccine-preventable diseases. Premature infants (in satisfactory clinical condition) should be immunized at the same chronological age (based on birth date, not corrected gestational age) as full-term infants using the routine immunization schedule . Do not reduce or divide vaccine doses for premature infants.
  - Premature infants born after 28 weeks of gestation have maternally derived antibodies, but at lower concentrations and for a shorter duration than full-term newborns as passive transfer of maternal antibodies occurs after the 28th week of gestation.
  - Premature infants of less than 28 weeks gestation are not expected to have significant amounts of maternal antibody. They may experience increased frequency and severity of vaccine preventable illnesses and should receive timely immunization.

- Infant weight is not a limitation to start immunization. Most preterm and low birth weight (less than 2500 g) babies produce sufficient vaccine-induced immunity and tolerate most vaccines as well as term infants.
- Premature and very low birth weight babies (less than 1500 g) still hospitalized at the time of immunization may experience a transient increase or recurrence of apnea and bradycardia following immunization. It is recommended that hospitalized premature infants have continuous cardiac and respiratory monitoring for 48 hours after their first immunization.

2.2 Family history of adverse events following immunization

Adverse events following vaccines are not known to be inherited, except febrile seizures, and are therefore not a contraindication for the individual being immunized.

2.3 Recent surgery or upcoming surgery

- Minor surgery, including dental procedures, is not a contraindication to immunization regardless of whether the procedure is done before or after immunization.
- Individuals awaiting splenectomy should ideally be immunized at least 14 days prior to or 14 days following the spleen being removed. See Standard for the Immunization of Individuals with Chronic Diseases and/or Immunosuppression.

2.4 Topical anesthetic patches/creams

- Topical anesthetics, such as EMLA can be used prior to immunization.
- Give the immunization in the appropriate site even if the topical anesthetic is misplaced.
- See Standard for the Administration of Immunizations for detail on the use of topical anesthetic products.

2.5 Recent exposure to an infectious disease

- If the client is fit to immunize at the time of the clinic visit, vaccines may be given. For contacts of a vaccine preventable disease who are not immune, the MOH/designate may provide guidance on when to give the immunization.
- Provide counseling on incubation periods and expected reactions to immunization.
- Previous disease does not always confer lifelong immunity. Refer to vaccine specific biological pages.

2.6 Lactose

- Lactose is an ingredient in some vaccines. It does not have the potential to cause an immunogenic response.
- Dairy allergy is usually related to the milk protein and not lactose.
- Lactose intolerance is not a contraindication to receiving vaccines which contain lactose.

Related documents

- Fit to Immunize Assessment

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