



Standard on the Contraindications and Precautions Related to Immunization

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Created by:	Province-wide Immunization Program, Standards and Quality	
Approved by:	Dr. Gerry Predy, Senior Medical Officer of Health, Alberta Health Services	
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Preamble

AHS Province-wide Immunization Program Standards and Quality, Population, Public and Aboriginal Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information relating to province-wide 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 and that there are measures in place to monitor side effects related to vaccines.

A contraindication is a condition in a recipient that **increases** the risk for a serious adverse reaction or a situation where the risks of vaccine outweigh any potential therapeutic benefit. Examples of contraindications are known anaphylaxis to a vaccine or a vaccine component or immune compromising conditions related to therapy or disease.

A precaution is a condition in a recipient that **may increase** the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce an optimal immune response. The majority of contraindications and precautions are temporary, and immunizations often can be administered later if one or more exist.

All vaccine providers should assess the current health and any chronic conditions of the client to identify contraindications and precautions to the vaccine before each dose is given.

Purpose

This standard is an important resource for immunizers to use for a consistent approach to client assessment prior to vaccine administration. It summarizes information available related to contraindications and precautions. This standard is not intended to replace information contained in the individual vaccine biological pages. It can be used in conjunction with the following standards (including but not limited to):

- *Standard for Recommended Immunization Schedules*
- AHS Immunization Policy Suite for Consent to Treatment(s) / Procedure(s)
<http://insite.albertahealthservices.ca/2270.asp>

- *Standard for the Administration of Immunizations*
- *Vaccine Biological Pages*
- *Standard for 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 with the health conditions covered in this standard.

Definitions:

Contraindication:

Situation in which a vaccine should **not** be given because the risk of an adverse event outweighs any potential therapeutic benefit of the vaccine. The only true permanent contraindication to all vaccines is a history of anaphylactic reaction to a previous dose of vaccine or to a vaccine component. Many contraindications are temporary (e.g., pregnancy is a contraindication to live vaccine) and the vaccine can usually be given at a later time.

Precaution: A condition that may increase the risk of an adverse reaction following immunization or that may compromise the ability of the vaccine to produce immunity. In general, vaccines are deferred when a precaution is present. However, there may be circumstances when the benefits of giving the vaccine outweigh the potential harm, or when reduced vaccine immunogenicity may still result in significant benefit (e.g., providing inactivated vaccine to an immunocompromised individual). A risk benefit assessment is required.

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 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 as needed 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

The following is a summary of the most common contraindications and precautions. It does not encompass every possible contraindication for each vaccine. It is important that an assessment of possible contraindications and precautions is done prior to each dose of vaccine. Consult with the Medical Officer of Health (MOH)/designate as required. Refer to *vaccine specific biological pages* for further detail.

The following is a general summary of areas that should be assessed for each client at every immunization appointment before vaccine is given. The Fit To Immunize Assessment Tool is also available for staff to use as a general guide for client assessment prior to immunization.

1. Current or Recent Illness:

- A moderate or severe illness with or without fever is a reason to defer most vaccines until the person has recovered from the acute phase of the illness. This precaution avoids possible confusion between a symptom of the disease and an adverse effect from the vaccine.
- A minor illness with or without fever; a recent viral infection from which the client is recovering; antibiotic therapy (with the exception of some live oral vaccines – e.g., oral typhoid); and recent exposure to a communicable disease are not generally contraindications or reasons to defer immunization.

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. Consultation with the physician or MOH/designate should be sought when required.

- See *Standard for the Administration of Immunizations* for detail related to specific injection techniques.
- See *Standard for the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression* for detail on specific health conditions such as Hematopoietic Stem Cell Transplant (HSCT), Solid Organ Transplant (SOT), immunocompromised individuals, etc.

2.1. Asthma

- Live Attenuated Influenza Vaccine (LAIV) should not be administered to individuals with severe asthma or those with medically attended wheezing in the seven days prior to immunization. See *influenza specific biological pages* for details.
- Severe asthma is defined as currently on oral or high dose inhaled glucocorticosteroids or active wheezing.
 - 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 stable, non-severe asthmatics.

2.2. Immunocompromised Persons

- In general, individuals who are immunocompromised, whether from disease or from therapy, should not receive live vaccines because of the risk of disease caused by the vaccine strains. However, there may be situations where the benefit of vaccine outweighs the risk. When considering immunization of an immunocompromised person with a live vaccine, approval from the individual's attending physician and MOH/designate should be obtained before immunization.
- An immunocompromised person may not respond as well as a healthy individual 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.

2.3. Family History of Immunodeficiency Disorders

People who have a family history of immunodeficiency disorders (e.g., known or suspected congenital immunodeficiency disorder, HIV infection, or failure to thrive and recurrent infection), should not be immunized with a live vaccine until they have been fully investigated and immunodeficiency disorder has been ruled out. Immunodeficiency states may be undiagnosed in young children presenting for routine immunizations, which include live vaccines. This is particularly important to consider in infants receiving live vaccines (e.g., travel vaccines) before 12 months of age since underlying conditions are less likely to be diagnosed in younger children.

2.4. Tuberculosis, active, untreated

Measles, Mumps, Rubella (MMR), Measles, Mumps, Rubella-Varicella (MMR-V), varicella, and herpes zoster (shingles) 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.

2.5. Transplant Recipients

Transplant candidates and recipients need special consideration when determining their immunization requirements. There are some vaccines which may be contraindicated for these individuals. See Standard for Immunization of Transplant Candidates and Recipients and individual biological pages for details.

2.6. Bleeding Disorders

Individuals with bleeding disorders (e.g., hemophilia or Von Willebrand disease) may differ from the general population with respect to the risk of hematoma formation from intramuscular (IM) injections, and the potential for increased risk of infection from their disease or frequent exposure to blood products. Control of bleeding disorders should be optimized prior to immunization. Individuals with bleeding disorders who may require immunization with large volumes of vaccine or biologicals (e.g., HBIG, RIG, IG) should be assessed by their attending physician on an individual basis for the need for clotting factor concentrates prior to immunization. See Standard for the Administration of Immunizations for additional details on administering vaccines to individuals with bleeding disorders.

Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications, provided instructions found in Section 3 of the Vaccine Administration Standards are followed. They may be safely immunized through either the IM or subcutaneous (SC) route as recommended without discontinuation of their 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 but there is no reason to expect that there is a greater risk of bleeding complications than with other anticoagulants.

A history of an intramuscular hematoma following immunization or abnormal/unexplained bruising should prompt investigation of a possible bleeding disorder prior to immunization.

3. Medications

There may be some medications that individuals are taking which can present a precaution or a contraindication for some vaccines. Some examples include:

- **Immunosuppressive medication/therapy**

Individuals who are immunosuppressed either from disease or therapy should generally not receive live vaccine. Some inactivated vaccines may be recommended although the individual will likely have a lower immunogenic response. Refer to *Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression* for details.

- **Chronic Salicylate Therapy in Children**

- Individuals receiving low doses of salicylate therapy (e.g., 3 to 5 mg/kg/day of acetylsalicylic acid [ASA]) are not considered to be at increased risk of bleeding complications following immunization.
- If child is taking daily low doses (3 to 5 mg/kg/day) of ASA, varicella immunization can safely be given if the child is NOT immunocompromised.⁶
- Live Attenuated Influenza Vaccine should NOT be given to children 2-17 yrs. who are receiving ASA or ASA-containing therapy due to the association of Reye syndrome with ASA and wild-type influenza infection.(NACI Statement on Seasonal Influenza Vaccine for 2014-15).

- **Antivirals**

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

- Varicella vaccine and herpes zoster vaccine may have reduced effectiveness if given concurrently with antivirals active against varicella zoster virus (e.g., acyclovir, valacyclovir, famciclovir). Individuals taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella or herpes zoster vaccine and should not restart antiviral therapy until 14 days after immunization. If therapy cannot be discontinued for this timeframe, consult with the zone MOH. Refer to *varicella vaccine specific biological* page for details.
- LAIV should not be administered until 48 hours after antiviral agents active against influenza (e.g., oseltamivir and zanamivir) are stopped, and antiviral agents should not be administered until at least 14 days after receipt of LAIV unless medically indicated. If antiviral agents are administered within this time frame (from 48 hours before to 14 days after LAIV), re-immunization should take place at least 48 hours after the antivirals are stopped. Refer to *LAIV vaccine specific biological* page for details.

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 (e.g., Meckel's diverticulum) that would predispose for intussusception. See *Rotavirus vaccine specific biological* page for details.

5. Neurological

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 known to be diagnosed in childhood and adulthood

over the same time period as routine vaccines are administered and may occur before or after the administration of vaccines.

- Neurologic conditions whose onset clearly precedes immunization are generally not contraindications to subsequent immunization.
- Vaccines are safe to give when there is a history of a febrile seizure. Children with a history of febrile seizures have no increased risk of developing a seizure disorder, such as epilepsy. Oral analgesics/antipyretics (e.g., acetaminophen or ibuprofen) can be used for treatment of minor adverse reactions such as fever or injection site discomfort that might occur following immunization. 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.
- Significant head injury – immunization should be deferred for 24 hours to ensure any sequelae have resolved.

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 a live vaccine. See *Standard for Recommended Immunization Schedules* for detail on intervals that must be respected before giving a live vaccine after receipt of a blood product.

7. Live Vaccine in the Previous Month:

- Live vaccines must be administered concurrently or be separated by at least 4 weeks. Live attenuated influenza vaccine (LAIV) may be administered any time before or after the administration of other live attenuated or inactivated vaccines. 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.

8. Previous Adverse Reaction:

- An essential component of an immunization program is vaccine safety and the activities and processes to detect, assess, understand and communicate adverse events following immunization (AEFI) – vaccine pharmacovigilance. If reactions occur, they are usually mild, fairly 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. Prior to immunization, an assessment of the client's reactions to previous vaccines should be conducted.
- Mild to moderate vaccine associated adverse events (e.g., swelling, redness, fever, pain) are expected, relatively common and self-limited. These are not a contraindication to immunization.
- If an adverse reaction has been previously reported, the provider should review the recommendations, consider current guidelines, consult the MOH/designate when required and proceed as appropriate.
- If an adverse reaction is being reported during the assessment, follow the guidelines to report in the *Standard for Reporting and Follow-Up of Adverse Events Following Immunization*.
- Follow the *Guidelines for 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 may also be necessary.

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. It may be a contraindication to receiving vaccines as outlined below.

- Individuals who develop GBS within 6 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

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 *Standard for Reporting and Follow-Up of Adverse Events Following Immunization* for further details.

9. Allergies:

An allergic reaction is an acquired hypersensitivity considered to be related either to the vaccine components or the antigen itself. Individuals may report an allergy to a number of vaccine components, such as gelatin, latex, neomycin or thimerosal. Anaphylactic reactions to these components are extremely rare. When mild hypersensitivity reactions occur, vaccines that are administered subcutaneously or intramuscularly are generally safe.

- Allergy to vaccine components must be ascertained prior to vaccine administration.
- Anaphylaxis to a vaccine component is a contraindication to further administration with the same vaccine or a vaccine with the same components. In situations where the need for the vaccine and/or a biologic outweighs the risks of anaphylaxis (e.g., post exposure prophylaxis) case by case consultation with the MOH/designate is required.
- The amount of egg/chicken protein in measles/mumps containing vaccines has been found to be insufficient to cause an allergic reaction in egg-allergic individuals.
 - Studies of egg allergic individuals have shown that there is no increased risk of severe allergic reaction to MMR/MMR-Var vaccines.
- Egg allergic individuals may be immunized with inactivated influenza vaccine (TIV or QIV) or live attenuated influenza vaccine (LAIV).
- Advise vaccine recipients to remain in the waiting area for at least 15 minutes after immunization administration.
- Advise vaccine recipients who have had an anaphylactic reaction to any agent, vaccine related or not, to wait for 30 minutes post immunization.
- Referral to an allergist may be indicated prior to immunization
- See *Standard for Reporting and Follow-Up of Adverse Events Following Immunization*

9.1. Latex Allergy

- Latex is sap from the commercial rubber tree. Latex is processed to form natural rubber latex and dry natural rubber. Both products contain the same plant impurities (plants peptides and proteins) found in natural latex and are believed to trigger allergic reactions.
- Dry natural rubber is used in some syringe plungers, vial stoppers and needle shields.
- Synthetic rubber and synthetic latex do not contain natural rubber or natural latex and therefore do not contain the impurities linked to allergic reactions.

- The most common type of reaction to latex is contact dermatitis, which is NOT a contraindication to immunization with a vaccine containing latex in the packaging.
- If an individual reports anaphylaxis to latex, consultation with the MOH/designate is required prior to immunization with a vaccine containing latex in the packaging. There may be an alternate vaccine product available that is latex free that could be provided.

10. Pregnancy:

Pregnancy is a temporary precaution or contraindication to immunization. There is very little data related to giving vaccines to a pregnant individual.

- For most inactivated vaccines, pregnancy is a precaution, rather than a contraindication, to immunization; however, human papillomavirus (HPV) vaccine is not recommended for pregnant women due to inadequate safety and immunogenicity data. Refer to *vaccine specific biological pages* for details on pregnancy.
- Live vaccines are generally contraindicated during pregnancy due to the theoretical risks to the fetus. Live vaccine would be considered for a pregnant woman only if the risk of disease is high and outweighs the theoretical risk to the fetus. This decision is always made in consultation with the physician and MOH/designate.
- Immunosuppressive therapy given to a mother during pregnancy can cause immunosuppression of infants. Consultation with zone MOH/designate is necessary to assess live vaccine eligibility.
- If a pregnant woman is inadvertently immunized with a live vaccine, check appropriate product monograph for instructions on reporting to manufacturer.

11. Lactation:

Routinely recommended vaccines may be safely administered to breastfeeding women. There are 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.

- Immunosuppressive therapy given to a mother during lactation can cause immunosuppression of infants. Consultation with the zone MOH may be necessary to assess live immunization of the infant in these situations.

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) and those who have had mastectomies, axilla lymphadenectomies, limb paralysis and upper limb amputations may have short term or long term circulatory (e.g., lymphatic systems) implications that may impair vaccine absorption and antibody production.

Section 2: Common Concerns which are Not Usually Contraindications

The following is a list of concerns which are commonly raised in a clinic setting, but are not usually contraindications to immunization. Each situation should be assessed on a case by case basis and consultation should be sought from the MOH/designate when required.

1. 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. Family history of adverse event following immunization
 - Adverse reactions to vaccines are not known to be inherited, except febrile seizures, and are therefore not usually a concern for the individual being immunized.
3. Prematurity
 - Infants born prematurely regardless of birth weight should be immunized at the same chronological age and according to the same schedule and precautions as full term infants. An exception is preterm infants who weigh less than 2000 grams born to mothers with hepatitis B, who require an additional dose (see hepatitis B biological page).
 - Antibody response to immunization is generally a function of post natal age and not maturity
 - Very low birth weight infants (1500g) may experience a transient increase or recurrence of apnea and bradycardia following immunization. This subsides within 48 hours and does not alter the overall clinical progress of the child. If a child remains hospitalized at the time of their first immunizations, it is recommended that they have continuous cardiac and respiratory monitoring for 48 hours following immunization.
4. Topical Anesthetic Patches/Creams (e.g., EMLA)
 - The use of topical anesthetics is not an issue with regards to immunization.
 - Placement of the product (cream or patch) should not interfere with appropriate siting for injection.
 - See *Standard for the Administration of Immunization* for detail on the use of topical anesthetic products
5. Recent Exposure to an Infectious Disease
 - Provided the client is fit to immunize at the time of the clinic visit, vaccines may be given according to recommendations outlined in the vaccine biological pages and notifiable disease follow-up guidelines. For non-immune contacts of vaccine preventable notifiable disease, the MOH/designate will have provided guidance on when immunization should be given to minimize the risk of exposure to an infectious contact.
 - Counseling on incubation periods and expected reactions to immunization should be provided to the client/parent
 - Previous disease does not always confer lifelong immunity; refer to vaccine specific biological pages.
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 the lactose.
 - Lactose intolerance is not a contraindication to receiving vaccines which contain lactose.

Related Documents

- Fit to Immunize Assessment Tool (September 12, 2016)

References

1. Centers for Disease Control and Prevention. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2011;60(2):
2. Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2015 February 25). *Contraindications and Precautions to Immunization*.
3. Alberta Health, Acute Care and Population Health Division, *Adverse Events Following Immunization (AEFI) Policy for Alberta Health Services Public Health (2014, January)*.
4. BC CDC Immunization Manual (2009) <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm> (accessed 2015Feb06)
5. National Advisory Committee on Immunization. (2012). *Canadian immunization guide (Evergreen Edition)*. Ottawa, ON: Public Health Agency of Canada. <http://www.phac-aspc.gc.ca/publicat/cig-gci/>