Contraindications and Precautions to Immunization

Revision Date: May 06, 2016

Definitions:

**Contraindications**
A situation in which a vaccine should not be used because the risk outweighs any potential therapeutic benefit.¹

Examples of contraindications to vaccines are:
- Anaphylaxis to a previous dose of the vaccine or any of its components.
- Individuals who are significantly immunocompromised related to disease or therapy.

**Precautions**
Conditions that may increase the risk of an adverse event following immunization or that may compromise the ability of a vaccine to produce immunity.¹ 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 a susceptible, immunocompromised individual.¹ See Special Situations for Immunization – Immunization of Specific Populations for more information.

See Biological Products for specific information on each vaccine.

Assessment Expected Prior to Administering Vaccines

Prior to administering any vaccine, 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,¹ the manufacturer’s product monograph or directional leaflet, and Alberta Health Services’ Guidelines. Where recommendations in Alberta Immunization Policy differ from the manufacturer’s recommendations or the Canadian Immunization Guide, Alberta Immunization Policy recommendations should be followed.

Assess the following factors prior to administering any vaccine:

- Past health history.
- History of allergy, particularly anaphylactic reactions to any substance.
- Current state of health, including any concerns with the immune system.
- Pregnancy/lactation.
- Receipt of blood transfusions or antibody-containing blood products within the past year.
- Receipt of vaccines within the previous four weeks.
- Type of vaccine to be administered (inactivated or live, attenuated).
- Current immunization record and previous adverse events following immunization (AEFI).
- Informed consent, including discussion of risks of disease, benefits of the vaccine, the expected vaccine side effects and possible adverse events following immunization.
- Compliance concerns.

If, after consideration of these factors, a clear decision on whether or not to administer vaccine cannot be reached, the public health nurse should seek direction from the local MOH/designate. Medical consultation may also be needed if there are questions pertaining to the health status of the individual. If further consultation is required, contact the Alberta Health, Immunization Program.

**Note:** It is important not to miss opportunities to administer immunization because inappropriate conditions or circumstances are thought to be contraindications or precautions for vaccines. Effective screening prior to immunization is necessary to ensure that information about health conditions is gathered before proceeding with immunization. Refer to: Canadian Immunization Guide¹ – Part 2 Vaccine Safety Contraindication, Precautions and Concerns – Common conditions and concerns for more detailed information.
Common Contraindications and Precautions

1. **Adverse Event Following Immunization (AEFI):**

   Follow the Medical Officer of Health recommendations for the reported AEFI.

   Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers* ²

2. **Allergies**

   Inquiring about allergies to differentiate between minor allergic reactions and severe hypersensitivity reactions should be routine prior to any immunization. A history of an allergy is not necessarily a contraindication to immunization. However, reported anaphylaxis following a specific vaccine or exposure to one of the components contained in the vaccine is generally a contraindication to further doses of the vaccine. The manufacturer’s product information should be consulted to identify specific vaccine components if allergies are identified. See *Biological Products* for specific vaccine information.

   - **Anaphylaxis:**
     
     - Anaphylaxis is rare following immunization with estimated occurrence of 1 – 10 episodes per million doses of vaccine administered.¹ However, anaphylaxis following immunization is potentially life-threatening and requires immediate medical attention.
     
     - Prevention and management of anaphylaxis is critically important and should be anticipated with every immunization.¹ The following measures need to be in place prior to administration of vaccines.
       
       - All provincially funded biologicals must be administered in settings where protocols for management of anaphylaxis are in place and can be effectively implemented. Consult *Alberta Health Services’ Guidelines*, as well as the *Canadian Immunization Guide*; *Early vaccine reactions including anaphylaxis*.¹ Equipment and medication outlined in these guidelines must be available in all settings whenever provincially funded biologicals are administered.
       
       - Individuals must be advised to remain under observation for at least 15 minutes following receipt of vaccines.¹ Those who have had a previous anaphylactic reaction to any agent (vaccines, biologicals, drugs, food, bee stings, etc.) should have the observation period extended to at least 30 minutes. In low risk situations, supervision can include having recipients remain within a short distance of the vaccinator (e.g., within a school).¹ Consult *Alberta Health Services’ Guidelines* for further details.

       - Anaphylaxis following immunization needs to be assessed by the local Medical Officer of Health (MOH).
       
       Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers* ²

   - **Other Allergic Reactions:**
     
     - Rash, including urticarial rashes, with onset more than one hour after immunization, are generally not a contraindication to further immunization.
     
     - Delayed hypersensitivity reactions may appear several hours to days after immunization.¹
       
       Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers* ²

   - **Specific Allergens**
     
     - **Latex Allergy**
       
       The packaging of some biological products (vial stoppers, syringe plungers or needle shields) is made with natural rubber that may contain latex. Special care and consideration are required if anaphylaxis to latex has occurred in the past as listed below:

       - Vaccines supplied in vials or syringes that contain natural rubber should not be administered unless the benefit of immunization clearly outweighs the risk for a potential allergic reaction.³
An equivalent biological product by a different manufacturer with latex-free packaging may be available.

If an equivalent biological product with latex-free packaging is not available, seek medical consultation. If the decision is to proceed with the biological product, it should be administered in a controlled setting (e.g., urgent care) with an observation period of at least 30 minutes.

For latex allergies other than anaphylaxis (e.g., contact sensitivity), biological products supplied in vials or syringes that contain latex may be administered.3

**Note:** Most vaccine vials contain synthetic rubber (latex-free) stoppers. Latex-free syringes are available.

- **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 (virus grown in chick embryo cell culture).1 The minute quantity of egg proteins contained in measles/mumps-containing vaccines appears to be insufficient to cause an allergic reaction in egg-allergic people.1
    - Studies of egg-allergic individuals have shown that there is no increased risk of severe allergic reactions to MMR/MMR-Var vaccines.1
    - Vaccine recipients reporting severe hypersensitivity reactions to any substance (including egg), should be kept under observation for at least 30 minutes following immunization.
    - Prior egg ingestion is not a prerequisite for immunization with measles/mumps-containing vaccines,1 and special measures are not needed for children who have not ingested egg prior to this immunization.
  - **Inactivated Trivalent Influenza Vaccine (TIV)**
    See the following for current information as it is updated annually:
    - Biological Products – Influenza Vaccines
    - Alberta Health Influenza Immunization Policy
  - **Live Attenuated Influenza Vaccine (LAIV)**
    See the following for current information as it is updated annually:
    - Alberta Health Influenza Immunization Policy

3. **Asthma, severe**
   Severe asthma is defined as currently on oral or high dose inhaled glucocorticosteroids or active wheezing.3
   
   - **Live Attenuated Influenza Vaccine (LAIV):** See the following for current information as it is updated annually:
     - Alberta Health Influenza Immunization Policy

4. **Biological Products**
   - **Inactivated Vaccines (Recombinant, Polysaccharide and Acellular Vaccines)**
     - Polysaccharide and conjugate vaccines containing the same antigen(s) should not be administered simultaneously and must be separated by specified intervals to be effective. See Biological Products for vaccine-specific information and Recommended Immunization for Infants, Children and Adults – Simultaneous Administration of Vaccines.
     - Persons who are immunocompromised or who are receiving immunosuppressive therapy may receive inactivated vaccines but the magnitude and duration of vaccine-induced immunity is often reduced.1
Live Vaccines

- Live parenteral vaccines not administered simultaneously, should be separated by an interval of at least four weeks or more before another live parenteral vaccine is administered.\(^1\) Varicella-containing vaccines are an exception as follows:
  - Individuals younger than 13 years should have an interval of at least three months between doses of varicella-containing vaccine. However, if rapid complete protection against varicella is required, the interval between doses may be shortened to a minimum of six weeks.
  - Individuals 13 years and older should have an interval of at least six weeks between doses of varicella vaccine.
  - Immunocompromised persons if eligible for varicella vaccine may receive two doses of univalent varicella vaccine with an interval of at least three months between doses.\(^1\)

See Biological Products –Varicella-containing Vaccines.

**Note:** If live parenteral vaccines are inadvertently administered too close together (less than four weeks apart), but not simultaneously, the immune response to the second vaccine may be affected by the first vaccine and is considered invalid. The second vaccine should be repeated at the recommended interval (four weeks or more, depending on the vaccine, after the invalid dose).\(^1\) Longer intervals between doses of varicella-containing vaccines doses are recommended. See Biological Products for specific details.

- Measles-containing vaccine: Active immunity may not develop due to interference from circulating maternal antibody. Therefore, any doses of measles-containing vaccine administered before 12 months of age should be repeated at 12 months of age or older.\(^4\)
- Live attenuated influenza vaccine (LAIV) may be administered simultaneously with other live parenteral vaccines or at any interval before or after other live parenteral vaccine.\(^3\)
- Live oral vaccines may be administered simultaneously with or at any interval before or after any other live vaccine regardless of the route of administration of the other vaccine.\(^1\)
- Pregnancy is generally a contraindication for immunization with a live vaccine.\(^1\)

**Tuberculin Skin Test (TST):**

- Live vaccines may suppress the tuberculin test response, resulting in a false negative reading.
- The TST may be administered at the same clinic visit as the live vaccine(s), but should be deferred for at least four weeks if a live vaccine has been administered recently.\(^5\)
- The TST should be deferred for four weeks following a major viral infection such as measles, mumps or chickenpox.\(^5\)

**Immune Globulin (IG) Preparations or Blood Products:**

Passive immunization with immune globulins or receipt of blood products can interfere with the response to measles or varicella-containing live viral vaccines. IG or blood products administered at the same time, shortly before or after the measles, mumps, rubella or varicella containing vaccines may reduce the effectiveness of the vaccine.\(^1\)

- The recommended interval between administration of immune globulin/antibody-containing blood product and subsequent immunization with live vaccines varies from 0 - 11 months, depending upon the product used and the dose administered. The *Canadian Immunization Guide Part 1 Blood products, human immune globulin and timing of immunization*\(^1\) provides guidelines for the interval between the administration of immune globulin preparations and MMR or varicella-containing vaccines and is included below. [www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php](http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php).
• If IG or blood products are administered less than 14 days after the receipt of MMR, MMR-Var or VZ vaccines, the vaccine should be repeated after the recommended interval as outlined in the *Canadian Immunization Guide*.

  o If a measles or varicella post-exposure is required within seven months of receipt of the blood product (e.g., whole blood, plasma or platelets), a case-by-case consultation with the local Medical Officer of Health is recommended.

  o Recombinant and high-purity plasma-derived clotting factor concentrates are free of immune globulins. Intermediate-purity plasma-derived clotting factor concentrates will likely contain some immune globulins but much smaller amounts than immune globulin products. A case-by-case conference with the physician providing care is recommended before proceeding with immunization.

  o Rh immune globulin (RhIg) may interfere with the response to rubella and varicella vaccines.

    ▪ Women who receive RhIg and are non-immune to rubella should receive MMR as soon as possible after delivery and have serological testing for rubella three after the receipt of the vaccine.

    ▪ Women who receive RhIg and are non-immune to varicella should receive varicella vaccine three months after the RhIg.

Guidelines for the interval between administration of immune globulin (Ig) preparations or blood products and measles-mumps-rubella (MMR), measles-mumps-rubella-varicella (MMRV) or univalent varicella vaccine to maximize immunization effectiveness

<table>
<thead>
<tr>
<th>Immune globulin or blood product</th>
<th>Dose, route</th>
<th>Interval between receipt of Ig or blood product and subsequent administration of MMR, MMRV or univalent varicella vaccine (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard immune globulin (human)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune globulin (Ig)</td>
<td>0.02 - 0.06 mL/kg, IM</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>0.25 mL/kg, IM</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>0.50 mL/kg, IM</td>
<td>6</td>
</tr>
<tr>
<td>Intravenous immune globulin (IVIg)</td>
<td>300 - 400 mg/kg, IV</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>1,000 mg/kg, IV</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>2,000 mg/kg, IV</td>
<td>11</td>
</tr>
<tr>
<td><strong>Blood transfusion products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma and platelet products</td>
<td>10 mL/kg, IV</td>
<td>7</td>
</tr>
<tr>
<td>Whole blood</td>
<td>10 mL/kg, IV</td>
<td>6</td>
</tr>
<tr>
<td>Packed red blood cells</td>
<td>10 mL/kg, IV</td>
<td>5</td>
</tr>
<tr>
<td>Reconstituted red blood cells</td>
<td>10 mL/kg, IV</td>
<td>3</td>
</tr>
<tr>
<td>Washed red blood cells</td>
<td>10 mL/kg, IV</td>
<td>0</td>
</tr>
<tr>
<td><strong>Specific immune globulin (human)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cytomegalovirus immune globulin (CMVIg)</td>
<td>150 mg/kg, IV</td>
<td>6</td>
</tr>
<tr>
<td>Hepatitis B immune globulin (HBlg)</td>
<td>0.06 mL/kg, IM</td>
<td>3</td>
</tr>
<tr>
<td>Rabies immune globulin (Rablg)</td>
<td>20 IU/kg, IM</td>
<td>4</td>
</tr>
<tr>
<td>Rh immune globulin (RhIg)</td>
<td>300 mcg, IM</td>
<td>3[Footnote 3]</td>
</tr>
<tr>
<td>Tetanus immune globulin (TIg)</td>
<td>250 units, IM</td>
<td>3</td>
</tr>
<tr>
<td>Varicella immune globulin (VarIg)</td>
<td>125 IU/10 kg, IM</td>
<td>5</td>
</tr>
<tr>
<td><strong>Specific immune globulin (humanized monoclonal antibody)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory syncytial virus monoclonal antibody (palivizumab) (RSVAb)</td>
<td>15 mg/kg/4 weeks, IM</td>
<td>0</td>
</tr>
</tbody>
</table>

5. Guillain-Barré Syndrome (GBS)

- **Influenza:**
  - Following a review of studies, the United States Institute of Medicine concluded that the 1976 swine influenza vaccine was associated with an elevated risk of GBS. However, evidence was inadequate to accept or reject a causal relation between GBS in adults and seasonal influenza immunization.1
  - More recent studies suggest that the absolute risk of GBS is about one excess case per one million vaccines. The risk of GBS associated with influenza immunization must be balanced against the risk of GBS associated with influenza infection itself.1

Generally, it is recommended to avoid subsequent influenza vaccine if persons are known to have had GBS within six weeks of a previous influenza immunization.1

*See Biological Products – Influenza Vaccines for more information.*
Tetanus:

- GBS has been reported following tetanus toxoid-containing vaccine. The Institute of Medicine has concluded that the available evidence favors a causal relationship between tetanus toxoid and GBS, although very rare.\(^7\)
- Individuals who develop GBS within six weeks of receipt of a tetanus-containing vaccine, should not receive further doses.\(^1\)
- Those who develop GBS outside the six-week interval may receive subsequent doses of tetanus-containing vaccine.

6. Immunocompromised Individuals

- Generally, immunocompromised individuals should not receive live vaccines due to the risk of disease caused by the vaccine strains.\(^1\)
- If there is uncertainty about the individual’s immune status, consultation with the attending physician is recommended.
- Individuals who may have immunodeficiency disorders due to family history or symptoms such as failure to thrive or recurrent infections should not receive live vaccines until they have been investigated and T-cell dysfunction has been ruled out.\(^1\)
- Immunosuppressive therapy:
  - Prior to immunosuppressive therapy, immunization should be reviewed and if possible any vaccines required should be administered before immunosuppressive therapy begins.\(^1\)
  - Otherwise, delay vaccines until immunosuppressive therapy has been completed\(^1\) and immune system has recovered. Consultation with the attending physician is recommended.
  - Consultation with an immunologist is advised prior to administration of live vaccines to an infant who may have been exposed to monoclonal antibodies (e.g., rituximab, infliximab, adalimumab) during pregnancy or breastfeeding.\(^1\)

See Immunization of Specific Populations for more information.

7. Intussusception or Congenital Malformation of Gastrointestinal Tract

- Rotavirus vaccine is contraindicated in infants with a history of intussusception or uncorrected congenital malformation of the gastrointestinal tract that would predispose for intussusception.\(^1\)

8. Medications

- Antibiotic therapy does not interfere with inactivated vaccines or provincially funded live vaccines.
- Anticoagulation therapy does not need to be discontinued before administering immunization.
- Antiviral therapy:
  - Varicella-containing vaccine and herpes zoster vaccine should not be administered to individuals on antiviral medication for varicella zoster virus (e.g., acyclovir, valacyclovir, famciclovir).\(^1\) These medications should be discontinued from at least 24 hours before administration of the vaccine and not restarted until at least 14 days following immunization.\(^1\)
  - LAIV should not be administered until 48 hours after antiviral agents against influenza (e.g., oseltamivir and zanamivir) are stopped and should not be administered until at least 14 days after receipt of LAIV unless medically indicated.\(^1\) See Biological Products – Influenza Vaccine FLUMIST® for more information.

9. Pregnancy

- Live vaccines are generally contraindicated during pregnancy.
- Most routine inactivated vaccines may be administered to pregnant women when indicated. However, human papillomavirus vaccine (HPV) is not recommended for pregnant women.
10. Surgery or Concurrent Illness

- Minor surgery, including dental procedures, is not a contraindication to immunization regardless of when the procedure is done (i.e., before or after immunization).

- 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. Exceptions are listed below:
  - Influenza vaccine: Significant nasal congestion might impede delivery of LAIV to the nasopharyngeal mucosa. The vaccine can either be deferred or TIV can be administered instead.
  - Rotavirus vaccine: Defer the vaccine for infants with moderate to severe gastroenteritis unless a deferral will result in scheduling of the first dose beyond the recommended age limit. See Biological Products – Rotavirus Vaccine for further information.

- The risks and benefits of immunizing a severely ill person need 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 the medical management of the person or that events related to the illness may be misperceived as vaccine-related events. Expert consultation is recommended in these situations.

- Recent exposure to an infectious illness (e.g., chickenpox) is not a contraindication to immunization.

References


