COMMON CONDITIONS AND CONCERNS

There are a number of conditions that may be raised as a concern about receiving a vaccine, that in fact should not delay or preclude immunization. For example, routine administration of vaccines should not be postponed in persons with minor illnesses, such as an upper respiratory tract infection, otitis media, mild gastrointestinal illness, or concurrent antibiotic therapy. Repeated infectious illnesses are common in early childhood and will not interfere with the efficacy of vaccines. Generally, if a person is well enough to present for immunization in the outpatient setting, he/she is well enough to be immunized.

Opportunities for immunization should not be lost because of unfounded concerns. Information and reassurance can generally allay reservations about receiving vaccines in these circumstances. The following identifies some of the common concerns and implications for immunization.

ACUTE ILLNESS (WITH OR WITHOUT FEVER)

In general, people with minor or moderate acute illness may receive vaccines. There is no increase in risk of adverse events following immunization and no interference with response to vaccine. There are three exceptions –

- If significant nasal congestion is present that might impede delivery of LAIV to the nasopharyngeal mucosa, TIV can be administered or LAIV could be deferred until resolution of the illness.
- In infants with moderate-to-severe gastroenteritis, rotavirus vaccine should be deferred until the condition improves unless deferral will result in scheduling of the first dose beyond the recommended age limit.
- Administration of oral cholera and travellers' diarrhea vaccine should be postponed in persons with acute gastrointestinal illness.

The risks and benefits of vaccinating a severely ill person need to be carefully assessed. The benefits of protection in a high risk exposure situation or when the window of opportunity is short (i.e., when travel or immunocompromise are imminent) need to be assessed against the risks that a vaccine-related adverse event (particularly fever) could complicate the management of the person. It is possible that systemic adverse events may complicate the medical management of an acute illness or that events associated with the acute illness may be misperceived as vaccine-related adverse events. Expert opinion is strongly recommended in this situation.

ADVERSE EVENT FOLLOWING PREVIOUS IMMUNIZATION

There are numerous adverse events following a previous immunization that may lead to concern regarding another immunization.

Extensive limb swelling following immunization

A severe injection site reaction to one vaccine is not associated with an increased risk of injection site reactions to other vaccines. Repeating a dose of a vaccine that was previously associated with a large injection site reaction may result in a similar reaction; however, there is no increased risk of systemic adverse events. A large injection site reaction may occur in a child after the fourth or fifth dose of a diphtheria toxoid-tetanus toxoid-acellular pertussis-containing vaccine. The presence of a large injection site reaction to a previous dose is not a contraindication to continuing the recommended schedule.

Severe injection site reactions occasionally occur in adults following receipt of diphtheria toxoid-tetanus toxoid-containing vaccine (Td). Further routine doses of Td vaccine should not be given for at least 10 years.

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Hypotonic-hyporesponsive episode (HHE) following immunization

HHE may occur following immunization with pertussis-containing vaccine but occurs less frequently following receipt of current acellular pertussis-containing vaccines. There is evidence that there are no adverse consequences to these events.

Febrile seizure or syncope following immunization

Parents may hesitate to have their child have a vaccine if he/she had a history of a post-immunization febrile seizure. Likewise, people may hesitate to have a vaccine if they had an episode of syncope following a previous vaccine (such as may occur with HPV vaccine in a young girl).

Vaccines are safe to given when there is a history of a febrile seizure. For MMR vaccine for example, the risk of febrile seizures within 2 weeks following MMR vaccination was 1.56 per 1000 children overall, 3.97 per 1000 for siblings of children with a history of febrile seizures, and 19.47 per 1000 for children with a personal history of febrile seizures. This means when a child has a history of a febrile seizure 98% will *not* have a febrile seizure following an MMR vaccine. Children with a history of febrile seizures have no increased risk of developing a seizure disorder, such as epilepsy. Oral analgesics/antipyretics (such as acetaminophen or ibuprofen) can be used for treatment of minor adverse reactions such as fever or injection site discomfort that might occur following vaccination. There is no evidence that antipyretics prevent febrile seizures.

Vaccines are safe to give when there is a history of fainting after a vaccine. The likelihood of fainting can be reduced by measures that lower stress in those awaiting immunization, such as short waiting times, comfortable room temperature, preparation of vaccines out of view of recipients, and privacy during the procedure. People should be immunized while seated. Refer to Vaccine Administration Practices in Part 1 for additional information.

Inconsolable crying following immunization

Persistent or inconsolable crying and an unusual, high-pitched cry (most typically after pertussis vaccination) are not associated with any sequelae and are likely to be pain responses at the site of injection in young infants. Refer to Vaccine Administration Practices in Part 1 for comfort measures that can be taken.

Ocular-respiratory syndrome (ORS)

Oculo-respiratory syndrome is a usually transient condition characterized by bilateral conjunctivitis, facial edema, and upper respiratory symptoms that has been known to occur primarily after receiving influenza immunization. Symptoms typically appear 2 to 24 hours after vaccination and resolve within 48 hours of onset. If ORS occurred with lower respiratory symptoms, subsequent influenza vaccine is contraindicated. Refer to Influenza vaccine in Part 4 for additional information.

ALLERGIES

A history of allergies is one of the most common concerns that people have about vaccines. There are many types of allergic reactions and it is important to differentiate among them when considering implications for immunization.

Allergic reactions can be either immediate or delayed. An immediate hypersensitivity reaction usually occurs within moments or up to one hour after vaccine. It is IgE mediated (Type 3) and can be either mild (e.g. hives) or severe, such as anaphylaxis. Refer to Early Vaccine Reactions Including Anaphylaxis in Part 2 for additional information.

Delayed hypersensitivity reactions may appear several hours to days after immunization. These reactions include an Arthus or Type 3 reaction (a local vasculitis due to deposition of IgG-based immune complexes in dermal blood vessels) or more typically, a cell-mediated, delayed hypersensitivity or Type 4 reaction (typically a contact dermatitis). These are typically local reactions to a component of the vaccine.

Severe arthus-type injection site reactions are occasionally reported following receipt of diphtheria toxoid or tetanus toxoid-containing vaccines. There may be extensive painful swelling around the injection site, often involving the arm from shoulder to elbow and generally beginning 2 to 8 hours after injection. Persons experiencing severe injection site reactions should not receive further routine doses of Td vaccine for at least 10 years.

On close questioning, it may become evident that people think they have an allergy to a vaccine or vaccine component but it is not an allergy. Most adverse skin events associated with vaccines, for example, are simply a normal inflammatory response to a foreign substance. As these inflammatory reactions are not related to allergy, patients can receive subsequent vaccinations safely. People can be reassured if they have a mild hypersensitivity reaction, such as a contact dermatitis from either the vaccine or one of its components. People with a suspected moderate to severe hypersensitivity reaction, should be referred to an allergist for further testing. Suspected hypersensitivity should not be an ongoing reason to not administer vaccine. It should be investigated by an allergist to clarify whether the person may proceed with vaccination or not.

Egg allergy

Anaphylactic egg allergy is rare. People with egg allergy may be immunized with MMR or MMRV vaccines in the routine manner. The amount of egg/chicken protein in these vaccines have been found to be insufficient to cause an allergic reaction in egg-allergic individuals. Egg-allergic individuals may be vaccinated against influenza using TIV, without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, with the following conditions. Those with mild reactions such as hives, or those who tolerate eggs in baked goods may be vaccinated in regular vaccination clinics. Those who have suffered from anaphylaxis with respiratory or cardiovascular symptoms should be vaccinated in a medical clinic, allergy office or hospital where appropriate expertise and equipment to manage respiratory or cardiovascular compromise is present. These individuals should always be kept under observation for 30 minutes. Referral to a specialist with expertise in allergies may be necessary in occasional circumstances where there is strong concern about proceeding with the recommendation above and the individual is at risk of complications from influenza. If the individual is not in a high-risk group, the need for vaccination may be reassessed. Data are not currently available to support these recommendations for LAIV.

OTHER ALLERGIES

People may report an allergy to a number of vaccine components, such as gelatin, latex, neomycin or thimerosol. Anaphylactic reactions to these components are extremely rare. When mild hypersensitivity reactions occur, vaccines that are administered subcutaneously or intramuscularly are generally safe. A thimerosol allergy is extremely rare. If there is a documented history of a delayed hypersensitivity reaction to thimerosal (such as a large local reaction or an eczematous rash), immunization with thimerosal-containing vaccines can proceed. In the rare instance of individuals with proven delayed hypersensitivity to thimerosol, they should be advised that long-lasting local or systemic cutaneous reactions can occur. They should report any reaction of concern following immunization so that it can be managed appropriately. Refer to Table 2 and Contents of Immunizing Agents Available for Use in Canada in Part 1 for additional information.

BLEEDING DISORDER

People with bleeding disorders should receive all recommended immunizations according to routine schedules when appropriate safety measures have been taken. Control of bleeding disorders should be optimized prior to immunization. Vaccine providers should ensure that there are no symptoms or signs compatible with an undiagnosed bleeding disorder (e.g. unexplained bruising). If such indicators are present before immunization, a diagnosis should be established before commencing immunization. When administering a parenteral vaccine, consider use of a small gauge needle and apply pressure for 5-10 minutes after the immunization. Refer to Immunization of Persons with Chronic Diseases in Part 3.

BREASTFEEDING

Following routine immunization of either a mother or her infant during breastfeeding there is no reduction in maternal or infant response to vaccines and no increase in the risk of adverse events for either mother or infant. There is some evidence that breastfeeding may have a beneficial effect in infants after vaccination and is associated with less fever and pain. BCG, smallpox and yellow fever vaccines are generally contraindicated in breastfeeding women but may be considered in high-risk situations.

CONCERNS ABOUT IMMUNIZATION

Concern about exposure to too many antigens

Parents often have a concern about exposing their young child to too many antigens when multiple vaccines are recommended at one time. It is useful to identify that the human immune system has an enormous capacity to respond to antigens; infants can respond to about 10,000 different antigens at any one time – and may do so when crawling on the floor. Immunization does not significantly add to the vaccinee's daily exposure to antigens. The vaccines given to young infants in Canada engage less than 0.01% of an infant's immune response capacity. Generally, vaccinees have similar immune responses whether vaccines are given at the same time or at different visits. Concomitant administration of most routine vaccines at the same visit does not result in increased rates of adverse reaction.

Concern about multiple injections

Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children without contraindications. There are no contraindications to giving multiple injections at the same visit and all opportunities to immunize should be utilized. Live viral vaccines given by injection may be either given concomitantly or a minimum interval of 4 weeks apart to address the hypothetical risk of interference from the vaccine given first on the vaccine given later. Generally if two live parenteral vaccines are indicated, it is preferable to them concomitantly to avoid the need for a follow up visit. Concomitant administration of vaccines may be critical when preparing for international travel. Refer to recently administered live viral vaccines.

People may need to be reassured that concomitant administration of most routine vaccines at the same visit does not result in decreased antibody responses or increased rates of adverse reaction. Giving multiple vaccines at one visit helps to ensure that people are up to date with the vaccines required for their age and risk factors.

Concern about thimerosol

It is not unusual for people to voice concerns about thimerosol and the effect it can have on brain tissue. Thimerosol is used as a preservative in some vaccines, but not in a dose that would cause safety concerns. If no allergic history is present, there is no legitimate safety reason to avoid the use of thimerosol-containing products, for children or adults, including pregnant women

CONCURRENT MEDICATION, INCLUDING BIOLOGICS

Antibiotic therapy

Antibiotic therapy, does not interfere with response to inactivated vaccines or most live vaccines with the following exceptions: Live, oral typhoid vaccine should be delayed until 48 to 72 hours after receipt of the last dose of antibiotics active against *Salmonella typhi*. BCG vaccine should not be administered to individuals receiving drugs with anti-tuberculous activity, including fluoroquinolones.

Anticoagulation

Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized through either the intramuscular or subcutaneous route (as recommended for the vaccine product)without discontinuation of anticoagulation therapy. Give intramuscular administration with a small gauge

needle (23 gauge or smaller) and apply firm pressure to the injection site for 5 to 10 minutes. There is a paucity 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 believe that they need to be treated any differently from those receiving other anticoagulants.

Antiviral therapy

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 (such as acyclovir, valacyclovir, famciclovir). People 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 vaccination.
- 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), revaccination should take place at least 48 hours after the antivirals are stopped.

Recent administration of blood products containing antibodies

Passive immunization with human immune globulin or receipt of most blood products can interfere with the immune response to certain live vaccines. Measles-containing or varicella vaccines should be given at least 14 days prior to administration of an immune globulin preparation or blood product, or delayed until the antibodies in the immune globulin preparation or blood product have degraded. A risk-benefit assessment is needed for post-partum women who have received Rh immune globulin (RhIg) and require MMR or varicella vaccine (refer to Immunization in Pregnancy and Breastfeeding in Part 3 for additional information). Herpes zoster vaccine should be delayed until 3 months after a dose of intravenous immune globulin.

Salicylates

It is generally safe to be immunized when taking salicylates (acetylsalicylic acid, aspirin, or ASA) although some exceptions apply. LAIV is contraindicated in children and adolescents (2-17 years of age) currently receiving salicylates (e.g. ongoing treatment with aspirin-containing therapy) because of the association of Reye's syndrome with ASA and wild-type influenza infection. TIV is a good alternative. ASA-containing products should be delayed for 4 weeks after receipt of LAIV in children less than 18 years of age.

Another exception is varicella immunization. Varicella-containing vaccine manufacturers recommend avoidance of salicylate therapy for 6 weeks after varicella immunization because of an association between wild-type varicella, salicylate therapy and Reye's syndrome. Health care providers should weigh the theoretical risks associated with varicella vaccine against the known risks associated with wild-type varicella. Because adverse events have not been reported with the use of salicylates after varicella immunization, people with conditions requiring chronic salicylate therapy should be considered for immunization, with close subsequent monitoring. Refer to Immunization of Persons with Chronic Diseases in Part 3 for additional information.

NEUROLOGIC DISORDER

There is no evidence of increased risk of adverse events following immunization in persons with neurologic disorders. Such persons may be at increased risk of complications from vaccine preventable diseases such as influenza and should be immunized appropriately with the exception of people who experience an episode of GBS with onset within 6 weeks after immunization.

PREMATURE BIRTH

Premature infants respond adequately to vaccines used in infancy and are not at significantly increased risk of adverse events. In general, immunize premature infants per the routine immunization schedule, according to child's chronological age with the exception of hepatitis B vaccination of preterm infants with a birth weight of less than 2,000 grams. The response to hepatitis B vaccine may be diminished in such infants; refer to Hepatitis B Vaccine in Part 4 for additional information. Hospitalized premature infants should have continuous cardiac and respiratory monitoring for 48 hours after their first immunization.

SKIN DISORDERS

Vaccines are generally safe for people with skin disorders. For comfort, administer vaccine into non-affected area. There are two exceptions to this. Smallpox vaccine is contraindicated in those with eczema (atopic dermatitis) in non-outbreak situation; refer to Smallpox Vaccine in Part 4. BCG vaccine is contraindicated when there is extensive skin disease or burns; refer to Bacille Calmette-Guerin Vaccine in Part 4.

Table 2 provides a reader-friendly summary of common conditions and vaccine concerns that could be used as an educational tool when obtaining informed consent for immunization.

Table 2: Common conditions and vaccine concerns and implications for immunization

Condition or concern	Implications for immunization
Acute illness, minor (including upper respiratory infection, diarrhea)	Safe[1] with the following exceptions: • **LAIV:** If significant nasal congestion is present that might impede delivery of LAIV to the nasopharyngeal mucosa, TIV can be administered or LAIV could be deferred until resolution of the illness. • **Rotavirus vaccine:** If moderate-to-severe gastroenteritis, defer until condition improves unless deferral will result in scheduling of the first dose beyond the recommended age limit.**Oral cholera** vaccine: defer until acute gastrointestinal illness resolved. • **Oral cholera and travellers' diarrhea vaccine** should be postponed in persons with acute gastrointestinal illness
Acute illness, severe	Need to consider risk-benefit. Refer to Acute Illness in text.
Adverse event following previous immunization	
Extensive limb swelling following immunization	Safe, even when it crosses a joint.
Febrile seizure or syncope after previous immunization	Safe; refer to Vaccine Administration Practices in Part 1 for general precautions.
Hypotonic-hyporesponsive episode (HHE)	Safe; no long term consequences from an HHE episode.
Inconsolable crying	Safe; refer to Vaccine Administration Practices in Part 1 for general comfort measures.

Condition of concern	Implications for immunization
Oculo-respiratory syndrome (ORS)	Safe except: • **Influenza vaccine:** contraindicated if ORS is present with lower respiratory involvement. Refer to Influenza Vaccine in Part 4.
Allergies	
Allergies, known	Safe for most **non-anaphylactic allergies** with the following considerations: • **Vaccine components:** If suspected hypersensitivity or non-anaphylactic allergy to vaccine components, investigation is indicated which may involve immunization in a controlled setting. Consultation with an allergist is advised. **Diphtheria toxoid or tetanus toxoid-containing vaccines:** If there is a history of a severe Arthus-type reactions following diphtheria toxoid or tetanus toxoid-containing vaccines, recipients should not receive further routine doses of Td vaccine for at least 10 years. Refer to Part 4 Tetanus Toxoid for additional information.See specific allergies below.If a history of anaphylaxis to any component of a vaccine, refer to Contraindications Table 1. Refer to Contents of Immunizing Agents Available for Use in Canada in Part 1 for lists of immunizing agents available for use in Canada and their contents.
Egg allergy	Vaccines in those with a ***non-anaphylactic egg allergy*** is generally safe with the following considerations: • **Live attenuated Influenza vaccine (LAIV):** is not recommended due to a lack of data ***Anaphylactic egg allergy*** is rare. When present it is a contraindication to vaccines containing egg with the following exceptions: • **Trivalent Influenza Vaccine (TIV):** Egg allergic individuals may be vaccinated against influenza using TIV without prior influenza vaccine skin test and with the full dose, with consideration being given to the most appropriate setting for the vaccine administration (Refer to Egg Allergy in text for details). • **MMR and MMRV vaccines:** The amount of egg/chicken protein in these vaccines have been found to be insufficient to cause an allergic reaction in egg-allergic individuals.
Gelatin allergy	Generally safe. Most gelatin allergies are non-anaphylactic and gelatin-containing vaccines may be given. Anaphylactic allergy to gelatin is extremely rare. For an anaphylactic allergy see Contraindications Table 1.
Latex allergy	Generally safe. For non-anaphylactic latex allergies (e.g., history of contact dermatitis to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex may be given. Anaphylactic allergy to latex is very rare. For an anaphylactic allergy see Contraindications Table 1.

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Condition or concern	Implications for immunization
Neomycin allergy	**Generally safe. Neomycin allergy is most often a contact dermatitis (i.e., a delayed hypersensitivity reaction) which is not a contraindication for administration of vaccines containing neomycin.** For an anaphylactic allergy see Contraindications Table 1.
Thimerosal allergy	Generally safe. A local or delayed-type hypersensitivity reaction to thimerosal is not a contraindication to receipt of a vaccine that contains thimerosal. Thimerosol allergy is extremely rare. In the rare instance of individuals with proven delayed hypersensitivity to thimerosol, they should be advised that long-lasting local or systemic cutaneous reactions can occur with repeat injection. They should report any reaction of concern following immunization so that it can be managed appropriately For an anaphylactic allergy see Contraindications Table 1.
Bleeding disorder	Safe with the following measures: • Optimize control of bleeding disorder before immunization. • Give intramuscular administration with a small gauge needle (23 gauge or smaller) and apply firm pressure to the injection site for 5 to 10 minutes. Refer to Immunization of Persons with Chronic Diseases in Part 3
Breastfeeding	Generally safe with the following considerations: • **BCG vaccine:** Exercise caution because it is not known whether BCG is excreted in human milk. • **Japanese encephalitis vaccine**; should only be given if the risk of disease outweighs the unknown risk of vaccination to the woman and her breastfeeding infant. • **Yellow fever vaccine:** Generally, breastfeeding mothers should not receive yellow fever vaccine. • **Smallpox vaccine** is contraindicated for breastfeeding mothers in non-outbreak situations; special precautions required if needed for post-exposure prophylaxis. Refer to Smallpox Vaccine in Part 4. Refer to Immunization in Pregnancy and Breastfeeding in Part 3.
Concerns about immunization	
Exposure to too many antigens	Combination vaccines are safe. Most children are exposed to thousands of antigens a day.
Multiple injections	Multiple injections of vaccines are safe. • For live viral parenteral vaccines, it is *preferable* to give concomitantly (otherwise need to give at least 4 weeks apart). • Oral and intranasal live vaccines can be given at the same time as, or any time before or after, other live vaccines Refer to Vaccine Administration Practices in Part 1 for measures to address potential anxiety and discomfort.
Vaccine contains thimerosal	Vaccines that contain thimerosal are safe in children, adults and during pregnancy

Condition of concern	Implications for immunization
Concurrent medication, including biologics	
Antibiotic therapy	Generally safe with the following exceptions: • **Live typhoid vaccine:** Delay immunization if on antibiotics active against *Salmonella typhi* until 48 to 72 hours after last dose, refer to Typhoid Vaccine in Part 4. • **BCG vaccine:** Delay immunization if receiving antibiotic therapy active against mycobacteria (including quinolones), delay BCG immunization until antibiotic therapy completed. Refer to Bacille Calmette-Guerin Vaccine in Part 4.
Anticoagulation	Generally safe with the following considerations: • Give intramuscular administration with a small gauge needle (23 gauge or smaller) and apply firm pressure to the injection site for 5 to 10 minutes. Less data for risk with newer anticoagulants such as antiplatelet agents. Refer to Immunization of Persons with Chronic Diseases in Part 3
Antiviral therapy	Generally safe with the following exceptions: • **LAIV, herpes zoster and varicella:** Consider timing of administration if antiviral drug active against virus in vaccine. Recommended interval between these vaccines and antiviral drugs are vaccine and antiviral specific. Refer to vaccine specific chapters in Part 4.
Blood products containing antibodies (immunoglobulins; transfusion of reconstituted red blood cells, platelets or plasma)	Generally safe to give vaccine with the following exceptions: • **MMR, varicella-containing vaccine or herpes zoster vaccine:** Consider timing of vaccines; recommended interval between blood product and these vaccines are vaccine and blood product specific. Refer to Recent Administration of Human Immune Globulin Products in Part 1 and vaccine specific chapters in Part 4. • Risk benefit assessment is needed for post-partum women who have received Rh immune globulin (RhIg) and require MMR or varicella vaccine. Refer to Immunization in Pregnancy and Breastfeeding in Part 3.
Salicylates	Generally safe with the following exceptions: • **LAIV:** *If on salicylate therapy:* LAIV is contraindicated.[2] Use TIV instead. *For intermittent salicylate use:* In children and adolescents, avoid salicylates for 4 weeks after receiving LAIV.[2] • **Varicella-containing vaccine:** *For chronic salicylate therapy:* Varicella-containing vaccine may be considered with close monitoring *For intermittent salicylate use:* Avoid salicylates for 6 weeks after receiving varicella-containing vaccine.[2] Refer to Immunization of Persons with Chronic Diseases in Part 3.

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Condition or concern	Implications for immunization
Inflammatory eye disease requiring steroid therapy	Generally safe with the following exception: • **Smallpox vaccine:** In a non-outbreak situation, defer svaccination until condition resolves or course of steroids completed. Refer to Smallpox Vaccine in Part 4.
Measles infection	Generally safe with the following exception: • **Varicella-containing vaccine:** Delay vaccination for 4-weeks. Refer to Varicella (Chickenpox) Vaccine in Part 4.
Neurologic disorders	
History or family history of febrile seizure	Safe; refer to Vaccine Administration Practices in Part 1 for general precautionary measures.
History of Guillain-Barre Syndrome (GBS)	Safe unless GBS occurred within 6 weeks of receiving previous dose of same vaccine. See Contraindications Table 1.
History of syncopal episodes	Vaccinate in a safe environment which could include being vaccinated lying down, remaining seated in immunization clinic setting, and being accompanied when leaving clinic. Refer to Early Vaccine Reactions Including Anaphylaxis in Part 2 and Vaccine Administration Practices in Part 1.
Multiple Sclerosis (MS)	Safe
Premature birth	Vaccines are safe when given to infants who weighed 1500 grams or more at birth.[3] Refer to Immunization of Infants Born Prematurely in Part 3.
Skin disorder	Vaccines are generally safe; for comfort, administer vaccine into non-affected area. **Smallpox vaccine** is contraindicated in those with eczema (atopic dermatitis) in non-outbreak situation; refer to Smallpox Vaccine in Part 4. If extensive skin disease or burns, **BCG vaccine** is contraindicated; refer to Bacille Calmette-Guerin Vaccine in Part 4.

[1] Safe: defined in the context of therapeutic products, such as vaccines, as "...the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." From: US Food and Drug Administration, *Code of Federal Regulations Title 21*.

[2] Salicylates are avoided in these instances to decrease the risk of Reyes syndrome.

[3] Infants born prematurely (especially those weighing less than 1,500 grams at birth) are at higher risk of apnea and bradycardia following vaccination. Hospitalized premature infants should have continuous cardiac and respiratory monitoring for 48 hours after their first immunization.

BCG = Bacille Calmette-Guérin vaccine
LAIV = live attenuated influenza vaccine
MMR = measles-mumps-rubella vaccine
MMRV = measles-mumps-rubella-varicella vaccine

CONCERNS ABOUT CONDITIONS IN CLOSE CONTACTS OF VACCINEES

Vaccination provides protection at both an individual and population level. Some people may have conditions that preclude vaccination, but they can be protected by having the people around them vaccinated. Immunization of household contacts of immunosuppressed persons, pregnant women, and neonates provides important protection against transmission of disease in the household.

Up-to-date routine immunizations are recommended for household contacts of pregnant women, immunocompromised persons, and neonates with the following exceptions:

- TIV is preferred over LAIV for those in close contact with severely immunocompromised persons.
- If there are household contacts who have received live, oral polio vaccine in another country within the last 6 weeks, they should not have contact with immunocompromised persons.
- If a vaccine recipient develops a varicella-like rash, the rash should be covered and the vaccinee should avoid direct contact with the immunocompromised person for the duration of the rash
- Smallpox vaccine should not be administered to household contacts of an immunocompromised person in a non-emergency situation.
- Special precautions should be taken for unvaccinated pregnant household and other close contacts of persons receiving smallpox vaccine in order to eliminate viral transfer to these contacts.

Table 3 summarizes conditions in persons who may be in close contact with vaccinees and provides information for vaccine providers and vaccine recipients about the appropriateness and safety of vaccines in these circumstances.

Table 3: Conditions in close contacts of vaccinee

Condition in close contact	S/C to be immunized with the following exceptions
Close contact is immunocompromised	• **TIV** is preferred for household contacts of severely immunocompromised persons. • If **LAIV** received, vaccinee should avoid close association with severely immunocompromised person for at least 2 weeks. • Following **varicella vaccine**, if the vaccine recipient develops a varicella-like rash, the rash should be covered and the vaccinee should avoid direct contact with the immunocompromised person for the duration of the rash • Live, **oral polio vaccine**[2] contraindicated. • If a household contact (traveller or immigrant) has received live, **oral polio vaccine** within the last 6 weeks; they should avoid contact with immunocompromised persons. Refer to Poliomyelitis Vaccine in Part 4. • **Smallpox vaccine** should not be administered to household contacts of an immunocompromised person in a non-emergency situation • Refer to Immunization of Immunocompromised Persons in Part 3.
Close contact is a neonate/infant	• Defer **smallpox vaccine** (if non-outbreak situation). If smallpox vaccine is received, vaccine should avoid close contact with the neonate until the scab at the vaccination site falls off. • Refer to Immunization of Immunocompromised Persons in Part 3.

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Condition in close contact	"Safe"[1] to be immunized with the following exceptions:
Close contact is a pregnant women	• Defer **smallpox vaccine** (if non-outbreak situation) • If **smallpox vaccine** needed in an outbreak situation, avoid contact with the pregnant woman until the scab at vaccination site falls off. • Refer to Immunization in Pregnancy and Breastfeeding in Part 3.

[1] Safe: defined in the context of therapeutic products, such as vaccines, as "...the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." From: US Food and Drug Administration, *Code of Federal Regulations Title 21 sec 600.3.*

[2] Oral polio vaccine is not recommended or available in Canada

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PART 2

EARLY VACCINE REACTIONS INCLUDING ANAPHYLAXIS

This chapter is intended as a guide for the initial management of vaccine recipients who develop vaccine reactions within a two hour period following immunization in a non-hospital setting (e.g., public health clinic, medical office). For a vaccine recipient with severe, life-threatening anaphylaxis, establishment of intravenous (IV) access for drug and fluid administration will be necessary, and endotracheal intubation and other manoeuvres may be required. These interventions are generally best performed by ambulance personnel or in a hospital's emergency department.

Since the publication of the *2006 Canadian Immunization Guide:*

- The intramuscular route has been preferentially recommended for injection of epinephrine for anaphylaxis management.
- The recommended steps for basic management of anaphylaxis in a non-hospital setting have been updated according to the *World Allergy Organization Guidelines for the assessment and management of anaphylaxis* published in 2011 and updated in 2012.
- Recommendations for adjunctive treatment of anaphylaxis have been revised.
- The dosing guidelines for epinephrine have been revised, and there is now more information regarding the use of auto-injectors.
- When a vaccine has been given subcutaneously an additional dose of epinephrine is no longer recommended at the injection site, as this is not part of the WAO guidelines and there is no evidence to support it.
- The recommended items in an anaphylaxis management kit have been revised.

FAINTING, ANXIETY OR BREATH-HOLDING

Fainting (vasovagal syncope), anxiety and breath-holding episodes are benign reactions to vaccination which occur more commonly than anaphylaxis.

FAINTING

During fainting, the individual suddenly becomes pale, loses consciousness and collapses to the ground. Fainting is sometimes accompanied by brief clonic seizure activity (i.e., rhythmic jerking of the limbs) which generally requires no specific treatment or investigation. Fainting is managed by placing the vaccinee in a recumbent position. Recovery of consciousness occurs within a minute or two, but the person may remain pale, diaphoretic and mildly hypotensive for several minutes.

The likelihood of fainting is reduced by measures that lower stress in those awaiting immunization, such as short waiting times, comfortable room temperature, preparation of vaccines out of view of recipients, and privacy during the procedure. To reduce injuries due to fainting, people should be immunized while seated. For those at risk of fainting, consider a recumbent position. Foster a safe environment and

educate vaccinees on avoiding unsafe activities, such as stair climbing or driving immediately after immunization. For example, school immunization programs may wish to institute a pairing policy (two students remain together) so vaccinees are not alone for the first 10 to 15 minutes after leaving the immediate clinic location, in case they faint and fall or begin to experience symptoms of anaphylaxis.

ANXIETY

People experiencing anxiety may appear fearful, pale and diaphoretic and complain of lightheadedness, dizziness and numbness, as well as tingling of the face and extremities. Hyperventilation is usually evident. Treatment consists of reassurance and rebreathing using a paper bag until symptoms subside.

BREATH-HOLDING

Breath-holding episodes occur in some young children when they are upset and crying hard. The child suddenly becomes silent but remains agitated. Facial flushing and perioral cyanosis deepens as breath-holding continues. Some episodes end with resumption of crying, but others end with a brief period of unconsciousness during which breathing resumes. No treatment is required beyond reassurance of the child and parents.

SWELLING AND URTICARIAL RASH AT THE INJECTION SITE

Swelling and urticarial rash (i.e., hives) at the injection site can occur but are not always caused by an allergic reaction. The swelling or hives should be observed for at least 30 minutes in order to ensure that the reaction remains localized, and if so, the vaccinee may leave after this observation period. Ice can be applied to the injection site for comfort. If the hives or swelling disappear and there is no evidence of any progression to other parts of the body and there are no other symptoms within the 30 minute observation period, further observation is not necessary. However, **if any other symptoms arise, even if considered mild (e.g., sneezing, nasal congestion, tearing, coughing, facial flushing), or if there is evidence of any progression of the hives or swelling to other parts of the body during the observation period, epinephrine should be given** (refer to the steps for basic management of anaphylaxis in a non-hospital setting).

A mild local reaction resolving by itself within a few minutes is not indicative of an allergic reaction and does not require special observation or specialized assessment prior to subsequent vaccination.

ANAPHYLAXIS

Anaphylaxis is a serious, potentially life-threatening allergic reaction to foreign antigens; it has been proven to be associated with vaccines. Anaphylaxis is rare with an estimated range of occurrence of 1-10 episodes per million doses of vaccine administered. Anaphylaxis is preventable in many cases and treatable in all. It should be anticipated in every vaccinee.

PRE-VACCINATION SCREENING

Prevention of anaphylaxis is critically important. Pre-vaccination screening includes screening for a history of anaphylaxis and identification of potential risk factors. It should include questions about possible allergy to any component of the vaccine(s) being considered in order to identify if there is a contraindication to administration.

POST-VACCINATION SCREENING

Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of vaccine. Therefore, vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a safer interval when there is a specific concern about possible vaccine allergy. In low-risk situations, observation can include having vaccinees remain within a short distance of the vaccinator

(e.g., within the school when immunization is carried out in that setting) and return immediately for assessment if they feel unwell. As noted above, a pairing policy is recommended in school settings.

SIGNS AND SYMPTOMS OF ANAPHYLAXIS

In anaphylaxis, signs and symptoms develop over several minutes and by definition involve at least two body systems (e.g. the skin, respiratory, gastrointestinal or circulatory systems). The cardinal features of anaphylaxis are:

- itchy, urticarial rash
- progressive, painless swelling (angioedema) about the face and mouth, which may be preceded by itchiness, tearing, nasal congestion or facial flushing
- respiratory symptoms, including sneezing, coughing, wheezing, laboured breathing and upper airway swelling (indicated by hoarseness and/or difficulty swallowing) possibly causing airway obstruction
- gastrointestinal symptoms, including crampy abdominal pain and vomiting
- sudden reduced blood pressure or symptoms of end-organ dysfunction (e.g., hypotonia and incontinence). In infants, symptoms may also include fussiness, irritability, drowsiness or lethargy

Skin and mucosal symptoms are reported to occur in 80% to 90% of anaphylaxis cases and respiratory symptoms occur in up to 70%. Cardiovascular system symptoms such as chest pain, palpitations, or tachycardia occur in up to 45% and central nervous system symptoms of uneasiness, altered mental status, dizziness, or confusion occur in up to 15%. Gastrointestinal symptoms like nausea, vomiting and diarrhea may occur in up to 45% of anaphylaxis cases. Features of severe anaphylaxis include obstructive swelling of the upper airway, marked bronchospasm and hypotension. Hypotension can progress to cause shock and collapse. Unconsciousness is rarely the sole manifestation of anaphylaxis; it occurs only as a late event in severe cases.

The rate of progression or the severity of the anaphylactic episode can be difficult to predict at the start of anaphylaxis; however, rapid development of anaphylaxis following vaccination indicates that a more severe reaction is likely. Symptoms vary from one person to another and only a few symptoms may be present. Death can occur within minutes.

RISK FACTORS FOR SEVERE ANAPHYLAXIS

Anaphylaxis is a rare complication of immunization. Risk factors for increased severity of anaphylaxis include very young or old age; pregnancy; asthma; cardiovascular disease; and concurrent use of certain medications (i.e., angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARB] or beta-blockers). Even in these populations, however, anaphylaxis is rare.

ANAPHYLAXIS MANAGEMENT KITS

Appropriate preparation is important for a good outcome in anaphylaxis. **Anaphylaxis management kits should be readily available wherever vaccines are administered.** Epinephrine in an auto-injector or in a vial may be used to treat anaphylaxis; however, vials of epinephrine must be available for treatment of infants weighing less than 15 kg (refer to Epinephrine for additional information). Epinephrine solutions for injection (vials or auto-injectors) have a short shelf-life (generally 12 to 18 months) and past this time, will start to break down to inactive substances. Epinephrine and other emergency supplies should be checked on a regular basis and replaced when outdated. Refer to the list of essential items in an anaphylaxis management kit.

List of recommended items in an anaphylaxis management kit

Essential Items

- A clear, concise summary of the anaphylaxis emergency management protocol
- Laminated table of dosage recommendations for epinephrine and diphenhydramine hydrochloride (e.g. Benadryl) by weight and by age*
- Two vials of aqueous epinephrine 1:1000
- A range of autoinjectors of epinephrine labelled by age and weight (optional)
- One vial of injectable diphenhydramine hydrochloride
- Two – 1 cc syringes with attached needles (1 – 25 gauge,1 inch needle; 1 – 25 gauge, 5/8 inch needle)
- One – 25 gauge, 5/8 inch needle (extra)
- Two– 25 gauge, 1 inch and 1.5 inch needles (extra for larger adults)
- Scissors
- Alcohol swabs
- One nasopharyngeal airway and one oropharyngeal airway for each age range anticipated in the clinic
- Pocket mask
- Stethoscope and sphygmomanometer
- Tongue depressors
- Flashlight
- Wristwatch with second hand to measure pulse
- Cell phone if no easy access to onsite phone

Additional Items

(Depending on local circumstances, such as availability of ambulance personnel)-:

- IV lines and fluids, and related equipment (e.g., tourniquet)
- Oxygen and related equipment

*Refer to Table 1 and Table 2 for recommended dosing information.

MANAGEMENT OF ANAPHYLAXIS

Anaphylaxis is a medical emergency and rapid recognition and management can be life-saving. Every vaccine provider should be familiar with the signs and symptoms of anaphylaxis and be prepared to act quickly.

Protocols

Advance preparation for emergency management of anaphylaxis is essential. It is recommended that vaccine providers develop, post, and regularly rehearse a written anaphylaxis emergency management protocol. Protocols should specify the necessary emergency equipment, drugs and dosages, and medical personnel necessary to safely and effectively manage anaphylaxis. Refer to Steps for basic management of anaphylaxis for a summary of the basic management of anaphylaxis in a non-hospital setting.

Steps for basic management of anaphylaxis in a non-hospital setting
(Steps 1, 2, 3 should be done promptly and simultaneously)

1. **Assess** circulation, airway, breathing, mental status, skin, and body weight (mass). Secure an oral airway if necessary. **Direct someone to call 911**(where available) or emergency medical services.

2. **Position** the vaccine recipient on their back or in a position of comfort if there is respiratory distress; elevate the lower extremities. Place the vaccinee on their side if vomiting or unconscious. Pregnant anaphylactic vaccinees should be placed semi-recumbent on their left side with their legs elevated.

3. **Inject epinephrine intramuscularly in the mid-anterolateral aspect of the thigh:** 0.01 mg/kg body weight of 1:1000 (1 mg/mL) solution
   - ADOLESCENT or ADULT: maximum - 0.5 mg
   - CHILD: maximum - 0.3 mg

   Record the time of the dose.

   Repeat every 5 to 15 minutes as needed, for a maximum of three doses.

4. **Stabilize vaccinee;** perform cardiopulmonary resuscitation if necessary, give oxygen and establish intravenous access if available and give adjunctive treatment (i.e. diphenhydramine hydrochloride or Benadryl®) if indicated.

5. **Monitor** vaccinee's blood pressure, cardiac rate and function, and respiratory status.

6. **Transfer to hospital for observation.**

Adapted from Simons FE, Arudusso LR, Bilo MB et al. World Allergy Organization guidelines for the assessment and management of anaphylaxis. J Allergy Clin Immunol 2011;127(3):593e1-22.

Rapid assessment and positioning

Rapid intervention is of paramount importance. Assess airway, breathing and circulation; establish an airway if needed. When assessing the airway, look specifically at the lips, tongue and throat for signs of swelling. Position the person flat on the back, unless he/she is vomiting or unconscious (then place on the side) or in respiratory distress (may need to elevate head and chest for comfort). Legs should be elevated to help maintain blood pressure. Direct someone to call 911 or emergency medical services for transportation to hospital.

Epinephrine

Prompt administration of epinephrine is the priority and should not be delayed. Epinephrine is the treatment of choice for management of anaphylaxis in community and health care settings as it prevents and relieves upper airway swelling, hypotension and shock. In addition, it causes increased heart rate, increased force of cardiac contractions, increased bronchodilation, and decreased release of histamine and other mediators of inflammation. Epinephrine reaches peak plasma and tissue concentrations rapidly.

Failure to administer epinephrine promptly may result in greater risks to the anaphylactic vaccinee than using epinephrine improperly. If uncertain, err on the side of treatment; there are no contraindications to the use of epinephrine. If time is lost early in the treatment of an acute anaphylactic episode, subsequent management can become more difficult.

Epinephrine 0.01 mg/kg body weight of a 1:1000 (1 mg/mL) solution should be administered into the mid-anterolateral aspect of the thigh; the deltoid muscle of the arm is not as effective as the thigh in absorbing epinephrine. Scissors may be needed to cut clothing to establish access. If

scissors are not readily available, epinephrine may be administered through clothing. Although there is a slightly increased risk of infection, timely administration of epinephrine is the priority. The risk of infection can be addressed once the person has stabilized. Refer to Table 1 for epinephrine dosing guidelines. For infants less than 7 months of age, the dose of epinephrine should be determined by weight, if possible. For example, an infant weighing 4 kg (8.8 lb) should receive 0.04 mg of epinephrine in 0.04 mL of 1:1000 (1 mg/mL) solution.

Table 1: Dose of epinephrine (1:1000, 1 mg/mL solution), by age or weight

Age	Weight [1]	Dose by injection	Dose by auto-injector
0 – 6 months	Up to 9 kg (20 pounds)	0.01 mg/kg body weight	Not applicable
7 - 36 months	9 - 14.5 kg (20 - 32 lb)	0.1 - 0.2 mg	Not applicable
37 - 59 months	15 - 17.5 kg (33 – 39 lb)	0.15 - 0.3 mg [2]	Junior dose of 0.15 mg
5 - 7 years	18 - 25.5 kg (40 – 56 lb)	0.2 - 0.3 mg [2]	Junior dose of 0.15 mg
8 - 12 years	26 - 45 kg (57 – 99 lb)	0.3 mg [2]	If , less than 30 kg (66 lbs) give Junior dose If 30 kg or more: Give standard dose
13 years and older	46 + kg (100 + lb)	0.5 mg [3]	Give standard dose of 0.3mg

Adapted from Immunization Action Coalition, Medical Management of Vaccine Reactions in Children and Teens. Accessed June 2012. (http://www.immunize.org/catg.d/p3082a.pdf)
[1] Rounded weight at the 50th percentile for each age range
[2] Maximum dose for children 12 years of age and younger
[3] Maximum dose for adolescents

An epinephrine auto-injector (Allerject™, Anapen®, EpiPen® or Twinject®) may be used if the person who administers it is knowledgeable about proper use and the correct dose of epinephrine for age or body weight is available in the auto-injector. The junior dose is intended for children who weigh 15-30 kg. The "junior" or pediatric preparations contain 0.15 mg (0.3 mL) of epinephrine 1:2000 per dose (EpiPen® Jr.; Anapen Jr. 150) or 0.15 mg (0.15 mL) of epinephrine 1:1000 per dose (Twinject® 0.15 mg). The standard dose is intended for children and adults weighing 30 kg or more. The standard preparations contain 0.3 mg (0.3 mL) of epinephrine 1:1000 per dose.

Mild and transient effects such as pallor, tremor, anxiety, palpitations, headache and dizziness occur within minutes after injection of a recommended dose of epinephrine. These effects confirm that a therapeutic dose has been given.

Ensure the person lies down. Fatality can occur within seconds if the vaccinee stands or sits suddenly after epinephrine. People should remain in a recumbent position following receipt of an epinephrine injection and be monitored closely.

Adjunctive treatment

As an optional *adjunct* to epinephrine, a dose of diphenhydramine hydrochloride (e.g., Benadryl®) may be given to relieve itching, flushing, urticaria, and nasal and eye symptoms. Generally the injectable format is used although oral tablets or liquid elixir may also be used; in all formats the dosing is the same. Refer to Table 2 for diphenhydramine hydrochloride dosing guidelines. Diphenhydramine is generally not recommended for infants under 12 months of age, and should be used with caution between 12-23 months because it may cause drowsiness or paradoxical excitement. When given to children, dosage should be determined by weight (1mg/kg).

Table 2: Dose of diphenhydramine hydrochloride, by age

Age	Weight (pounds)	Dose of diphenhydramine hydrochloride
12-23 months[1]	7-12 kg (15-25 lbs)	6.25 - 12.5 mg
2 to 4 years	12-25 kg (25-55 lbs)	12.5 - 25 mg
5 to 11 years	25-45 kg (55-99 lbs)	25 - 50 mg
12 years and older	45 kg + (99 lbs or more)	50 mg

[1] Use with caution in children 12 – 23 months due to risk of sedation or paradoxical excitement.

When indicated, give high-flow supplemental oxygen (6 to 8 L/minute) by face mask or oropharyngeal airway (if available) to people with cyanosis, dyspnea or any other severe reaction requiring repeated doses of epinephrine.

People on beta-blockers may be more resistant to epinephrine.

Transfer to hospital

All vaccinees receiving emergency epinephrine must be transported to hospital immediately for evaluation and observation. Since the symptoms of an anaphylactic reaction can reoccur after the initial reaction (biphasic anaphylaxis) in up to 23% of adults and up to 11% of children, hospitalization is recommended for monitoring. Generally, patients are hospitalized overnight or monitored for at least 12 hours. A biphasic course of anaphylaxis is more likely to occur if the administration of epinephrine is delayed.

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PART 2

ANAPHYLACTIC HYPERSENSITIVITY TO EGG AND EGG-RELATED ANTIGENS

This chapter summarizes the recommendations for vaccines with respect to anaphylactic hypersensitivity to egg and egg-related antigens. Since the publication of the *2006 Canadian Immunization Guide* recommendations regarding influenza vaccination of persons with egg allergy have been revised and recommendations for tick-borne encephalitis vaccine have been added.

GENERAL CONSIDERATIONS

Egg allergy is one of the most common food allergies of childhood, with a prevalence of 1% to 3% in children under 3 years of age. It is often associated with eczema in infants and asthma in young children. As most children outgrow their egg allergy, the prevalence in adulthood is much lower and is estimated at 0.1%. The most common egg allergy is to egg white. Cross-sensitivity with egg yolk and chicken protein has been described.

Vaccines that contain small quantities of egg protein can cause hypersensitivity reactions in some people with allergies to eggs. In Canada, there are several vaccines manufactured by processes involving hens' eggs or their derivatives, such as chick cell cultures. This manufacturing process may result in the following vaccines containing trace amounts of residual egg and chicken protein:

- measles-mumps-rubella (MMR) vaccines
- measles-mumps-rubella-varicella (MMRV) vaccine
- influenza vaccines
- tick-borne encephalitis (TBE) vaccine
- RabAvert®rabies vaccine
- yellow fever (YF) vaccine

Hypersensitivity reactions occurring following receipt of these vaccines varies considerably in relation to the amount of residual egg and chicken protein in the vaccine.

Anaphylaxis after vaccination is rare. It may occur in people with anaphylactic hypersensitivity to eggs and in those with no history of egg allergy, due to other components in the vaccine. Due to this lack of predictability, immunization should always be performed by personnel with the capability and facilities to manage anaphylaxis post-vaccination. Refer to Early Vaccine Reactions Including Anaphylaxis in Part 2 for additional information regarding management of anaphylaxis in non-hospital settings.

PRE-VACCINATION SCREENING

Individuals should be asked about allergies to egg or chicken prior to vaccination with influenza, TBE, YF, or RabAvert®rabies vaccines. Prior egg ingestion is not a prerequisite for immunization with egg protein-containing vaccine. It should be noted that any vaccine is contraindicated in people who have had an anaphylactic reaction to a previous dose of the vaccine. Referral to an allergy specialist is recommended.

Atopic diseases are not a contraindication to immunization with egg protein-containing vaccine.

MEASLES AND MUMPS-CONTAINING VACCINE

Anaphylaxis after vaccination with MMR vaccine is rare. Studies of egg-allergic subjects have shown that there is no increased risk of severe allergic reactions to MMR vaccine. For example, a 1994 study reported no anaphylactic reactions in 500 children with a history of egg allergy immunized with MMR vaccine. Numerous other studies had the same outcome. A literature review conducted in 2000 concluded that administration of MMR vaccine is safe in children with egg allergy and egg allergy should not delay measles vaccination.

The trace amount of egg protein in MMR and MMRV vaccines appears to be insufficient to cause an allergic reaction in egg-allergic individuals. Skin testing is *not* recommended prior to vaccination as it does not predict reaction to the vaccine. **MMR or MMRV vaccine can be administered in the routine manner to people who have a history of anaphylactic hypersensitivity to hens' eggs.** Hypersensitivity reactions that do occur following MMR and MMRV vaccine are usually due to other components of the vaccine, such as gelatin or neomycin.

INFLUENZA VACCINE

Anaphylaxis after vaccination with influenza vaccine is a rare consequence of hypersensitivity to a vaccine component. All influenza vaccines in Canada are currently manufactured by a process involving hens' eggs which may result in the vaccine containing trace amounts of residual egg protein. Although the ovalbumin (egg protein) content in influenza vaccines manufactured in eggs may vary from year to year, vaccines marketed in Canada are approved under a specification for ovalbumin content that is associated with low risks of adverse events.

Numerous studies have demonstrated that egg-allergic persons can safely receive trivalent inactivated influenza vaccine (TIV). People with egg allergy, especially those with chronic conditions such as asthma, benefit from receiving TIV. Because of the lack of data, the use of live attenuated influenza vaccine (LAIV) in egg-allergic persons is not recommended at this time.

Egg-allergic individuals may be vaccinated against influenza using TIV, without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, with the following conditions. Those with mild reactions such as hives, or those who tolerate eggs in baked goods may be vaccinated in regular vaccination clinics. Those who have suffered from anaphylaxis with respiratory or cardiovascular symptoms should be vaccinated in a medical clinic, allergy office or hospital where appropriate expertise and equipment to manage respiratory or cardiovascular compromise is present. These individuals should always be kept under observation for 30 minutes.

REFERRAL

Referral to a specialist with expertise in allergies may be necessary in occasional circumstances where there is strong concern about proceeding with the recommendation above and the individual is at risk of complications from influenza. If the individual is not in a high-risk group, the need for vaccination may be reassessed.

SECOND DOSE IN YOUNG CHILDREN

Egg-allergic children who require a second dose of TIV during the same influenza season can, if the first dose is tolerated well, be given a second dose of the same product used for the initial administration, which need not be from the same vaccine lot.

COUNSELLING

The vaccine provider should discuss the risks of reactions, as should be done for any immunization, including the potential risk for an anaphylactic reaction after the observation period.

POST-VACCINATION OBSERVATION

All egg-allergic individuals receiving TIV should be observed post-vaccination for a 30 minute time period, which may be extended (e.g., to 60 minutes) as a precautionary measure for higher risk individuals. Appropriate emergency treatment and resuscitative equipment should be immediately available to manage potential severe reactions or anaphylaxis. Refer to Early Vaccine Reactions Including Anaphylaxis in Part 2 for additional information regarding management of anaphylaxis in non-hospital settings.

RABIES VACCINE

RabAvert® rabies vaccine is grown in chick embryo cell culture. Imovax® rabies vaccineis manufactured using human diploid cell cultures and therefore egg protein contamination is not an issue. **For pre-exposure vaccination, Imovax® rabies vaccine should be given to persons with a history of hypersensitivity reactions to egg or egg products** as a precautionary measure. For post-exposure prophylaxis, the use of Imovax® vaccine is preferred for persons with a history of hypersensitivity to egg. If Imovax® vaccine is not available, RabAvert® vaccine should be administered with strict medical monitoring and facilities for emergency treatment of anaphylactic reactions readily available.

TICK-BORNE ENCEPHALITIS VACCINE

Individuals with prior anaphylactic reactions to eggs or egg products should be vaccinated with TBE vaccine only under close clinical monitoring with readiness for emergency treatment.

YELLOW FEVER VACCINE

Yellow fever (YF) vaccine is prepared from virus grown in chick embryos and is the vaccine most likely to contain sufficient amounts of egg or chicken proteins to cause an allergic reaction in egg-allergic or chicken-allergic individuals. There have been several reports of anaphylactic reactions to YF vaccine in egg-allergic or chicken-allergic individuals; therefore, **YF vaccine should not be routinely administered to egg-allergic or chicken-allergic individuals.**

A 2010 case report documented a protocol for administration of YF vaccine in escalating doses to an egg-allergic individual with positive skin tests to YF vaccine. In a 2009 study of 7 egg-allergic subjects with strong local urticarial reaction to a 0.1 mL intradermal test dose of YF vaccine, the test dose was found to be sufficient to induce a protective antibody response. Referral of egg-allergic or chicken-allergic individuals to an allergy specialist is recommended as YF vaccination may be possible after careful evaluation, skin testing and graded challenge or desensitization.

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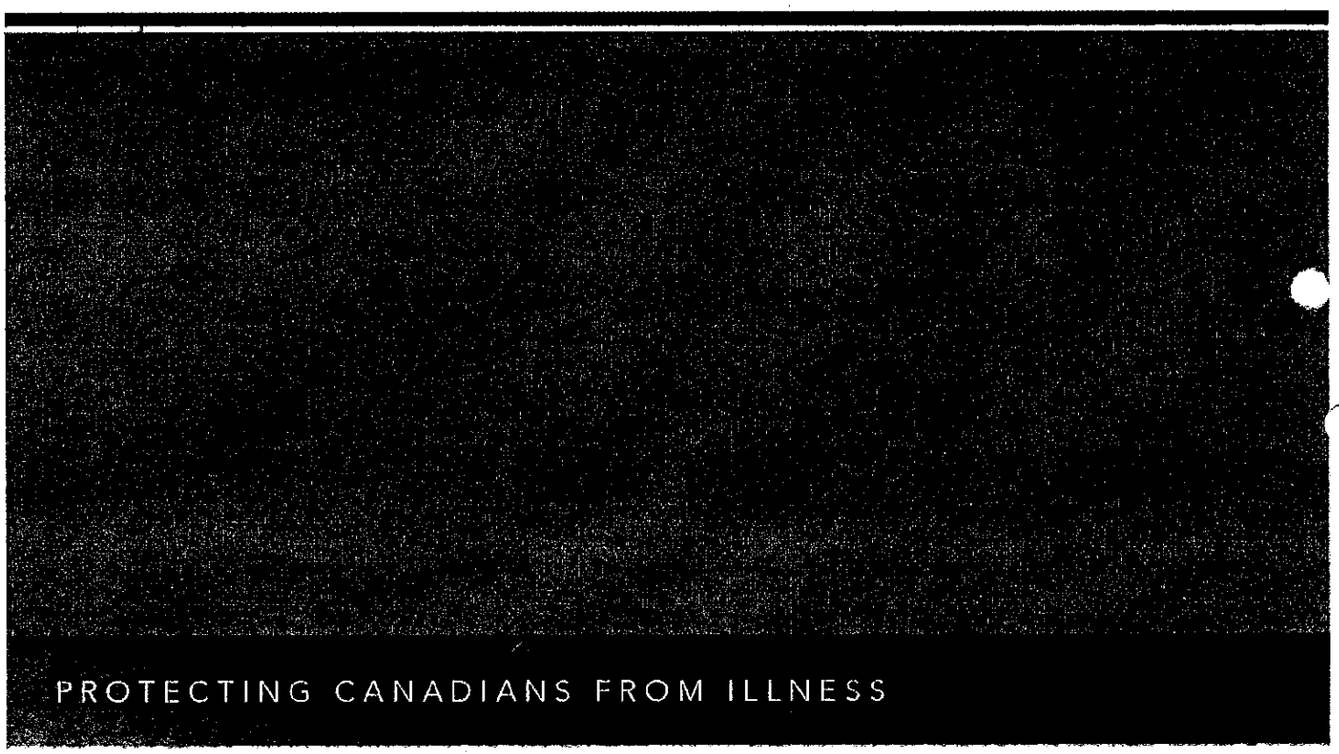
CANADIAN IMMUNIZATION GUIDE

PART 3



PROTECTING CANADIANS FROM ILLNESS

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FOLIO 924

TO PROMOTE AND PROTECT THE HEALTH OF CANADIANS THROUGH LEADERSHIP, PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.
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IMMUNIZATION OF ADULTS

Prevention of infection by immunization is not just for children; adults require immunization to address waning immunity against some vaccine preventable diseases and to establish immunity against other diseases more common in adults. In addition, immunization of adults prevents infection and, therefore, subsequent exposure of young children and others at increased risk of vaccine preventable diseases. For example, adults who are in contact with infants should be prioritized to receive pertussis and influenza vaccination to reduce the risk of transmission of these infections to infants who are too young to be fully protected. Some vaccines are needed by all adults and other vaccines may be required due to individual risk resulting from occupation, travel, underlying illness, lifestyle or age.

In recent years, new vaccines such as herpes zoster and human papillomavirus have become available for adults. Despite these advances, the vaccination rates of adults in Canada are low, resulting in many adults remaining vulnerable to vaccine preventable diseases.

Common reasons for incomplete immunization in adulthood include:

- lack of recognition of the importance of adult immunization
- lack of recommendation from health care providers
- lack of health care provider knowledge about adult immunization and recommended vaccines
- misrepresentation/misunderstanding of the risks of vaccine and benefits of disease prevention in adults
- lack of understanding of vaccine safety and efficacy
- missed opportunities for vaccination in health care providers' offices, hospitals and nursing homes
- lack of publicly-funded vaccine and reimbursement to vaccine providers
- lack of coordinated immunization programs for adults
- lack of regulatory or legal requirements
- fear of injections
- lack of availability of up-to-date records and recording systems

Adult immunization is an emerging issue that has seen an increasing emphasis in clinical care and health professional training programs.

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HEALTH CARE PROVIDER RESPONSIBILITIES

Health care providers have a responsibility to ensure that adults under their care have continuing and updated protection against vaccine preventable diseases through appropriate immunization. When considering immunization, the person's medical history will inform whether other immunizations are needed in addition to routinely recommended vaccines. Refer to Immunization of Persons with Chronic Diseases and Immunization of Immunocompromised Persons in Part 3 for further information on how health conditions may modify vaccine recommendations.

Health care providers should provide adults under their care with factual information about immunization, including:

- information about vaccines
- expert recommendations regarding the use of vaccines
- benefits and risks of vaccination
- cost of the vaccine if it is not publicly funded
- possible consequences of declining a vaccine
- where vaccine can be obtained if the health care provider is unable to provide the vaccine

When more than one dose of a vaccine is required for optimal protection, the health care provider should arrange follow-up to encourage completion of the vaccine series.

STRATEGIES TO IMPROVE VACCINE UPDATE ADULTS

All adults should be counselled concerning their immunization status. Opportunities for general immunization counselling of adults include:

- new patient/client encounters
- periodic health examinations
- pregnancy and the immediate post-partum period
- visits for chronic disease management
- assessment of new immigrants
- parents attending their child's vaccination visits
- hospitalization, especially when diagnosed with a chronic disease
- management protocols on admission to nursing homes, long-term care institutions, and acute care institutions
- management protocols on admission to health professional training programs
- new employee assessments in day care, health care and health care-related facilities
- persons requesting specific vaccination(s)
- persons with evidence of risk taking behaviour, such as illicit drug use or a sexually transmitted infection
- individuals requesting advice concerning travel

Health care providers should regularly review individuals under their care to ensure that the person's immunization status is up to date and that they have been made aware of new vaccines. Practitioners should routinely audit immunization records during clinical encounters; scheduling record audits on a set birthday, for example, to coincide with a mid-decade birthday (i.e., 25, 35 years of age, etc.), is one effective reminder strategy. Health care institutions should have policies addressing immunization issues for patients/clients and personnel.

Strategies to increase the uptake of immunization by adults include: community education, patient/client reminders, incentives, patient/client-held records, legal or regulatory requirements, and programs that decrease costs. Educational programs for health care providers are also effective, as are organizational

changes, such as immunization clinics and the participation of non-physician staff in the execution of prevention strategies or immunization programs.

A sample adult immunization record and information resources for adult immunization are available on the Immunize Canada website (http://www.immunize.ca/en/specific-groups/adults.aspx).

RECOMMENDED IMMUNIZATION FOR ADULTS

All adults in Canada without contraindications should be routinely immunized against vaccine preventable diseases. Routinely recommended adult immunizations are summarized in Table 1. Recommended immunization schedules for adults who have no record or an uncertain immunization history, as well as for booster dosing of those who have completed a primary series are available in Table 5 and Table 6 in Recommended Immunization Schedules in Part 1.

In addition to routinely recommended immunization, certain vaccines are recommended for adults in specific risk situations. These recommendations are summarized in Table 2. Health care workers and international travellers require assessment of immunization status, completion of routinely recommended vaccine series, and booster doses as necessary. Table 7 in Recommended Immunization Schedules in Part 1 highlights recommended immunizations for adults considered at-risk. Refer to Immunization of Travellers, Immunization of Workers, Immunization of Immunocompromised Persons, and Immunization of Persons with Chronic Diseases in Part 3; and vaccine-specific chapters in Part 4 for additional information.

DIPHTHERIA, TETANUS

All adults in Canada should be immunized against diphtheria and tetanus. Booster doses of diphtheria and tetanus toxoid-containing vaccine are recommended every 10 years. Refer to Diphtheria Toxoid and Tetanus Toxoid in Part 4 for additional information.

HERPES ZOSTER (SHINGLES)

Herpes zoster vaccine may be given to adults 50 to 59 years of age and is routinely recommended for adults 60 years of age and older. Adults aged 50 years and older who are known to be varicella zoster virus seronegative should receive two doses of varicella (chickenpox) vaccine rather than herpes zoster (shingles) vaccine. It should be that varicella zoster virus antibody is not usually measured in adults 50 years of age and older; therefore, most adults should be considered immune to varicella and offered herpes zoster vaccine as appropriate based on their age. Refer to Herpes Zoster (Shingles) Vaccine in Part 4 for additional information.

HUMAN PAPILLOMAVIRUS

Bivalent or quadrivalent human papillomavirus (HPV) vaccine is recommended for women up to and including 26 years of age and may be given to those 27 years of age and older who are at ongoing risk of exposure. Quadrivalent HPV vaccine is recommended for men up to and including 26 years of age and may be administered to men 27 years of age and older who are at ongoing risk of exposure. Refer to Human Papillomavirus Vaccine in Part 4 for additional information.

INFLUENZA

Seasonal influenza vaccine is encouraged annually for all adults and is recommended annually for adults 65 years of age and older as well as adults of all ages in specific risk situations, including healthy adults in close contact with children less than 5 years of age or other high-risk individuals (refer to Table 2). Refer to Influenza Vaccine in Part 4 for additional information.

MEASLES, MUMPS, RUBELLA

Combined measles-mumps-rubella vaccine (MMR) is recommended for vaccination of adults susceptible to one or more of these viruses. One dose is recommended for most susceptible adults born in or after 1970. Those who are at the greatest risk of measles or mumps exposure (travellers to destinations

outside of North America, health care workers, students in post-secondary educational settings, and military personnel) should receive 2 doses, at least 4 weeks apart. Adults born before 1970 can be assumed to have acquired natural immunity to measles and mumps and do not need vaccine unless: non-immune military personnel or health care workers (2 doses, at least 4 weeks apart) or non-immune travellers (1 dose) or non-immune students (consider 1 dose). Rubella-susceptible adults, regardless of age, should receive 1 dose. If rubella vaccine is indicated for a pregnant woman, it should be provided after delivery, preferably prior to discharge from hospital. Refer to Measles Vaccine, Mumps Vaccine and Rubella Vaccine in Part 4 for additional information including criteria for determining susceptibility/immunity to measles, mumps and rubella.

MENINGOCOCCAL

Healthy adults up to and including 24 years of age should receive meningococcal conjugate vaccine if not received in adolescence. Either monovalent or quadrivalent conjugate meningococcal vaccine may be used depending on local epidemiology and programmatic considerations. Adults with specific risk conditions (refer to Table 2) should receive two doses of quadrivalent conjugate meningococcal vaccine, 8 weeks apart, followed by booster doses every 5 years. Refer to Meningococcal Vaccine in Part 4 for additional information.

PERTUSSIS

All adults (18 years of age and older) should receive one dose of acellular pertussis-containing vaccine (Tdap) if not previously received during adulthood. This can be administered regardless of the interval since the last dose of tetanus and diphtheria toxoid-containing vaccine. In particular, adults who have not previously received Tdap vaccine in adulthood, and who anticipate having regular contact with an infant, should be prioritized to receive a dose of Tdap vaccine, ideally administered at least 2 weeks before contact with the infant. Refer to Pertussis Vaccine in Part 4 for additional information.

PNEUMOCOCCAL

A single dose of pneumococcal 23-valent polysaccharide vaccine (Pneu-P-23) is recommended for adults 65 years of age and older, and for younger adults with specific risk factors, (refer to *Table 2*) One lifetime re-immunization with Pneu-P-23 vaccine should be considered for those at highest risk of invasive pneumococcal disease.

Hematopoietic stem cell transplant (HSCT) recipients should receive a primary series of 3 doses of pneumococcal 13-valent conjugate vaccine (Pneu-C-13) starting 3 to 9 months after transplant, after discussion with transplant specialists, followed by a booster dose of Pneu-P-23 vaccine12 to 18 months post-transplant (6 to 12 months after the last dose of Pneu-C-13 vaccine). For other immunosuppressed adults (including those with HIV; anatomic or functional asplenia; sickle cell disease or other hemoglobinopathies; congenital immunodeficiencies; malignant neoplasms including leukemia or lymphoma; who are on immunosuppressive therapies; or who are either a recipient or a candidate for solid organ or islet cell transplant), give 1 dose of Pneu-C-13 vaccine followed 8 weeks later by 1 dose of Pneu-P-23 vaccine. Refer to Pneumococcal Vaccine in Part 4 and Immunization of Immunocompromised Persons in Part 3 for additional information.

POLIO

All adults in Canada should be immune to polio. For previously unimmunized adults, administer a primary series of inactivated poliomyelitis vaccine (IPV)-containing vaccine if a primary series of tetanus and diphtheria toxoid-containing vaccine is being given or if the adult is at increased risk for exposure to poliovirus (refer to Table 2). Otherwise administer IPV vaccine with routine tetanus and diphtheria toxoid-containing vaccine booster doses. A single lifetime booster dose of IPV-containing vaccine is recommended for adults previously immunized with polio vaccine who are at increased risk of exposure (refer to Table 2). Refer to Poliomyelitis Vaccine in Part 4 for additional information.

VARICELLA

Two doses of univalent varicella vaccine are recommended for susceptible adults 18 to 49 years of age. Adults (under 50 years of age) who have received only one dose of varicella vaccine should be offered a second dose. Refer to Varicella (Chickenpox) Vaccine in Part 4 for additional information.

Table 1: Adult Immunization – Recommendations for routine immunization in healthy adults at low risk [1]

Vaccine	Recommendations for routine immunization
Diphtheria Tetanus	Primary series for previously unimmunized adults Booster dose every 10 years
Herpes zoster (shingles)	60 years of age and older – 1 dose 50 to 59 years of age – may be given 1 dose
HPV	Women up to and including 26 years of age – bivalent (HPV2) or quadrivalent (HPV4) vaccine Men up to and including 26 years of age –HPV4 vaccine
Measles Mumps	Susceptible adults born in or after 1970 – 1 dose Born before 1970 – consider immune
Meningococcal conjugate	Adults up to and including 24 years of age not immunized in adolescence – 1 dose
Pertussis	One dose of acellular pertussis-containing vaccine (Tdap) in adulthood Adults who will be in close contact with young infants should be immunized as early as possible
Pneumococcal 23-valent polysaccharide (Pneu-P-23)	65 years of age and older – 1 dose
Polio	Primary series for previously unimmunized adults when a primary series of tetanus and diphtheria toxoid-containing vaccine is being given or with routine tetanus and diphtheria-toxoid containing vaccine booster doses
Rubella	Susceptible adults – 1 dose If vaccine is indicated, pregnant women should be immunized after delivery
Varicella (chickenpox)	Susceptible adults up to and including 49 years of age – 2 doses; if previously received 1 dose should receive a second dose Known seronegative adults 50 years of age and older – 2 doses – routine testing is not advised

[1] Refer to vaccine-specific chapters in Part 4 for additional information. Refer to Table 2 for recommendations for adults with risk factors.

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Table 2: Adult immunization – recommendations for specific risk situations[1]

Vaccine	Recommendations for risk situations
Bacille Calmette-Guérin (BCG)	Consider use for adults: • who may be repeatedly exposed to persons with untreated, inadequately treated or drug-resistant active tuberculosis (TB) in conditions where protective measures against infection are not feasible and if early identification and treatment of latent TB infection are not available • who are long-term travellers to high prevalence countries (in exceptional circumstances as noted above)
Cholera and travellers' diarrhea	Consider use for **cholera prevention** in adult travellers to cholera-endemic area(s) at high-risk of exposure, including those with occupational risk for exposure (e.g., health care or humanitarian workers in endemic countries) Consider use for **prevention of travellers' diarrhea** in adults: • with chronic diseases at risk for complications • at increased risk of acquiring travellers' diarrhea • who are immunosuppressed
***Haemophilus influenzae* type b** (Hib)	Recommended for adults with increased risk of invasive Hib disease: • congenital immunodeficiencies • malignant hematologic disorders • HIV • anatomic or functional asplenia • all transplant recipients • cochlear implant recipients Following HSCT adults should receive 3 doses of Hib vaccine at least 4 weeks apart starting 6 to 12 months post-transplant
Hepatitis A	Recommended for adults: • travelling to hepatitis A (HA) endemic areas • who are immigrants from HA endemic areas • who are household or close contacts of children adopted from HA endemic countries • in communities or populations at risk of outbreaks or in which HA is highly endemic • who are household or close contacts of proven or suspected cases of HA • with occupational or lifestyle risk for exposure • with chronic liver disease from any cause, including those infected with hepatitis C • with hemophilia A or B receiving plasma-derived replacement clotting factors • for post-exposure or outbreak management

Vaccine	Recommendations for risk situations
Hepatitis B	Recommended for adults: • who have immigrated to Canada from areas where there is a high prevalence of HB • who are household or sexual contacts of acute hepatitis B (HB) cases and HB carriers, including close contacts of children adopted from HB endemic countries if the adopted child is HBsAg positive • with occupational or lifestyle risk for exposure • travelling to HB endemic areas • in communities/populations in which HB is highly endemic • who are residents of institutions for the developmentally challenged or inmates of correctional facilities • with chronic liver disease, including those infected with hepatitis C • with chronic renal disease, including chronic dialysis • hemophiliacs and other people who receive repeated infusions of blood or blood products • who have undergone hematopoietic stem cell transplantation or are awaiting solid organ transplant • who have congenital immunodeficiencies • who are HIV-infected • for post-exposure management
HPV	May be given to men and women 27 years of age and older at ongoing risk of exposure*
Influenza	Recommended annually for adults: • at high risk of influenza-related complications • capable of transmitting influenza to individuals at high risk • who provide essential community services • in direct contact during culling operations with poultry infected with avian influenza
Japanese encephalitis	Recommended for adults: • with occupational risk for exposure • travelling to endemic area(s) during transmission season with specified exposure risks Booster dose 12 months after primary immunization for persons at continuous risk
Measles **Mumps**	Recommended for adults born in or after 1970: • If susceptible and at increased risk of exposure (travellers to destinations outside of North America, health care workers, students in post-secondary educational settings, and military personnel) - 2 doses, at least 4 weeks apart. Recommended for adults born before 1970 if: • non-immune military personnel or health care workers - 2 doses, at least 4 weeks apart

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Vaccine	Recommendations for risk situations
	• non-immune travellers - 1 dose • non-immune students - consider 1 dose Recommended for early post-exposure management of measles
Meningococcal quadrivalent conjugate	Recommended for adults: • with occupational risk for exposure (i.e., laboratory workers and the military) • who are travellers for whom meningococcal vaccine is recommended or required, including travellers to sub-Saharan African and pilgrims to the Hajj in Mecca, Saudi Arabia • at high risk of meningococcal disease due to medical conditions: o anatomic or functional asplenia (including sickle cell disease) o congenital complement, properdin, factor D or primary antibody deficiencies o acquired complement deficiency due to receipt of the terminal complement inhibitor eculizumab consider use for HIV-infected adults • who are close contacts of a case of invasive meningococcal disease caused by a vaccine preventable serogroup • for management of an outbreak caused by a vaccine preventable serogroup Booster doses every 5 years if risk is ongoing
Pneumococcal 23-valent polysaccharide (Pneu-P-23)	Recommended for adults: • who are residents of long-term care facilities • who are at increased risk of invasive pneumococcal disease (IPD) due to lifestyle factors: o persons with alcoholism o smokers o persons who are homeless • who are at high risk of IPD but without immunosuppression. Persons with: o asthma requiring regular medical care o chronic cerebral spinal fluid (CSF) leak o chronic neurologic condition that may impair clearance of oral secretions o cochlear implants (including those who are to receive implants) o chronic cardiac or pulmonary disease o diabetes mellitus o chronic kidney disease, including nephrotic syndrome o chronic liver disease (including hepatic cirrhosis due to any cause) • who are at high risk of IPD AND are immunosuppressed. These persons should receive Pneu-C-13 vaccine followed by Pneu-P-23 vaccine eight weeks later. Persons with: o asplenia (functional or anatomic)

Vaccine	Recommendations for risk situations
	o sickle cell disease or other hemoglobinopathies o congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions o HIV infection o immunosuppressive therapy including use of long-term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases o malignant neoplasms including leukemia and lymphoma o solid organ or islet cell transplant (candidate or recipient). Consider for individuals who use illicit drugs One lifetime booster dose for adults at highest risk of IPD.
Pneumococcal 13-valent conjugate (Pneu-C-13)	The following adults should receive 1 dose of Pneu-C-13 vaccine followed 8 weeks later by 1 dose of Pneu-P-23 vaccine. Adults with: • asplenia (functional or anatomic) • sickle cell disease or other hemoglobinopathies • congenital immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions • HIV infection • immunosuppressive therapy including use of long-term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases • malignant neoplasms including leukemia and lymphoma • solid organ or islet cell transplant (candidate or recipient) Following HSCT, adults should receive 3 doses of Pneu-C-13 vaccine at least 4 weeks apart followed by a dose of Pneu-P-23 vaccine 6 to 12 months after the last Pneu-C-13 dose (refer to Immunization of Immunocompromised of Persons in Part 3 for additional information)
Polio	Priority for adults who are: • travelling to, or receiving travellers from, areas where poliovirus is known or suspected to be circulating • health care workers who have close contact with patients who might be excreting wild type or vaccine type poliovirus • members of communities or specific population groups with disease caused by polio • people who come in close contact with those who may be excreting poliovirus (e.g., people working with

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Vaccine	Recommendations for risk situations
	refugees, or the military and people on humanitarian missions in endemic countries) • laboratory workers handling specimens that may contain poliovirus • family or close contacts of internationally adopted infants who may have been or will be vaccinated with OPV vaccine For previously unimmunized adults - primary series of IPV-containing vaccine For previously immunized adults - one lifetime booster dose of IPV-containing vaccine
Rabies (pre-exposure prophylaxis)	Recommended for adults: • with occupational risk of exposure • with lifestyle risk of exposure • travelling to high-risk areas with specified exposure risks Booster doses if required
Smallpox	Recommended for adults with occupational risk of exposure
Typhoid	Recommended for adults: • travelling to endemic area(s) with specified exposure risks • who have ongoing household or intimate exposure to an *S. typhi* carrier • with occupational risk of exposure Booster doses if at ongoing risk
Yellow fever	Recommended for adults: • less than 60 years of age travelling to areas where there is evidence of yellow fever transmission or if required for foreign travel • with occupational risk of exposure Consider use for adults aged 60 years and over travelling to areas where risk of yellow fever is the highest Re-immunization recommended every 10 years for immunocompetent people, if indicated

[1] Refer to vaccine-specific vaccine-specific chapters in Part 4 and the Immunization of Immunocompromised Persons and Immunization of Persons with Chronic Diseases in Part 3 for additional information

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IMMUNIZATION OF PERSONS WITH INADEQUATE IMMUNIZATION RECORDS

People may present to health care providers with inadequate or no immunization records. Vaccine providers should always attempt to obtain the person's immunization records from his or her previous health care provider.

Written or electronic documentation of immunization is preferred for both children and adults; however, in some instances, information obtained by telephone from the person's health care provider with the exact dates of immunization may be accepted. For children, parental recall of prior immunization, in the absence of documentation from the vaccine provider, correlates poorly with vaccines received and should not be accepted as evidence of immunization. One possible exception is seasonal influenza vaccine, due to the increased reliability of recall as to whether or not influenza vaccine was received less than one year previously.

Routine serologic testing to determine immunity of children and adults without immunization records is generally not practical. The following approach is recommended: Children and adults lacking adequate documentation of immunization should be considered unimmunized and started on an immunization schedule appropriate for their age and risk factors unless known to be immune by serologic testing. Refer to *Table 3* and *Table 5* in the *Recommended Immunization Schedules* in Part 1 for additional information. Refer to Canadian provincial/territorial immunization schedules for infants and children. (http://www.phac-aspc.gc.ca/im/is-vc-eng.php)

The following considerations are of note:

- Adverse effects of repeated immunization with the following vaccines have not been demonstrated: combined measles-mumps-rubella with or without varicella, inactivated polio, *Haemophilus influenzae* type b, meningococcal, hepatitis A, hepatitis B, univalent varicella and influenza vaccines regardless of possible prior receipt of these vaccines.

- In general, local reactions are greatest after the first dose of a live vaccine and then subside with subsequent vaccinations. In contrast, local reactions tend to increase with each subsequent dose of an inactivated vaccine.

- Persons who develop a serious adverse injection site reaction after administration of vaccines – particularly tetanus, diphtheria and pertussis – should be individually assessed before they receive additional doses of these vaccines. The benefit of continuing the vaccine series needs to be weighed against the risk of further adverse reactions. Serologic testing, if available and appropriate, may guide the need for continued immunization. There are no established serologic correlates for protection against pertussis; diphtheria and tetanus serology may be used as a proxy.

Refer to *Immunization of Persons New to Canada* in Part 3 for additional information about immunization of people who have recently arrived in Canada.

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IMMUNIZATION IN PREGNANCY AND BREASTFEEDING

Pregnancy provides an opportunity for evaluation of a woman's immunization status. Pregnant women are a vulnerable population. They have an altered immune response and, for some infections, are at increased risk of infection and at increased risk of severe outcomes once infected. Likewise the fetus, neonate and young infant are vulnerable.

One of the challenges of developing recommendations for pregnant and breastfeeding women is the lack of studies that would allow making evidence-based decisions. Only a few methodologically robust studies of vaccine administration in pregnant and breastfeeding women exist; most safety data available are derived from registries where outcomes are passively reported.

When considering vaccination for pregnant or breastfeeding women, it is important to distinguish between live and inactivated vaccines. There is no theoretical reason to suspect that inactivated vaccines would be associated with an increased risk of adverse events when administered during pregnancy or in breastfeeding women. Live vaccines, however, such as measles, mumps, rubella, varicella, and yellow fever, should generally not be given during pregnancy because of the theoretical risk of disease transmission to the fetus.

Ideally, the immunization status of women intending to become pregnant should be reviewed and vaccines updated as necessary prior to conception. Live vaccines, for example, can be given to non-pregnant women with the advice to avoid pregnancy for at least 28 days following immunization. In many instances, however, pregnancies are unplanned and immunization status will need to be assessed during the pregnancy.

MATERNAL BENEFITS

The objective of vaccination during pregnancy is to protect the mother and, potentially, the fetus and newborn. Pregnant women respond adequately to vaccines even though pregnancy is an immunologically altered state. Clinical trials of tetanus toxoid and inactivated polio vaccine administered during pregnancy have demonstrated normal adult immunologic responses. Vaccines recommended for the protection of a pregnant woman's health include:

- inactivated influenza vaccine
- hepatitis B vaccine for a woman with ongoing exposure risks
- hepatitis A vaccine for a woman who is a close contact of a person with hepatitis A or if travelling to an endemic area
- tetanus toxoid and reduced diphtheria toxoid-containing vaccine if indicated
- meningococcal vaccine in an outbreak setting or post-exposure

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- pneumococcal polysaccharide vaccine if in a high risk group due to underlying illnesses
- acellular pertussis-containing vaccine (Tdap) should be considered for pregnant women in the second half of pregnancy who have not previously received Tdap vaccine in adulthood, in situations where potential benefits outweigh risks, such as during a pertussis outbreak.

MATERNAL SAFETY

Inactivated vaccines are generally safe in pregnancy. Reactions following vaccination with inactivated vaccines are usually limited to the injection site. No increase in anaphylactic reactions or events that might induce preterm labour has been observed. Vaccines that contain thimerosal are considered safe in pregnancy and the National Advisory Committee on Immunization (NACI) has concluded that there is no safety reason to avoid the use of thimerosal-containing vaccines for pregnant women.

BENEFITS OF IMMUNIZATION IN PREGNANCY FOR THE FETUS/INFANT

The beneficial effects of maternal vaccination for the newborn have been well documented. Maternal vaccination protects the mother from a vaccine-preventable disease that she could transmit to her fetus or infant. In addition, protective concentrations of maternal antibodies are transferred to the fetus transplacentally, with the majority of transfer occurring during the third trimester. Maternal antibodies typically have a half-life of 3 to 4 weeks in the newborn, and progressively decrease during the first 6 to 12 months of life. Recommended infant immunization schedules take into consideration the potential effect that maternally transferred antibodies may have on infant vaccinations.

SAFETY OF IMMUNIZATION IN PREGNANCY FOR THE FETUS/INFANT

There is no theoretical reason to suspect that adverse events will occur in the fetus/infant following maternal vaccination during pregnancy with inactivated vaccines. There are no published data indicating that currently authorized inactivated vaccines are teratogenic or embryotoxic, or have resulted in specific adverse pregnancy outcomes.

In general, live attenuated viral or bacterial vaccines are contraindicated in pregnancy, as there is a theoretical risk to the fetus; however, when benefits outweigh risks, vaccination with a live attenuated vaccine may be considered (e.g., yellow fever vaccine).

IMMUNIZATION DURING PREGNANCY (refer to table 1)

RECOMMENDED VACCINES

Inactivated influenza vaccine

All pregnant women, at any stage of pregnancy, should be considered high priority for receiving inactivated influenza vaccine because of their increased risk of influenza-associated morbidity, evidence of adverse neonatal outcomes associated with maternal influenza, evidence that vaccination of pregnant women protects their newborns from influenza and influenza-related hospitalization, and evidence that infants born during the influenza season to vaccinated women are less likely to be premature, small for gestational age, and low birth weight. Live attenuated influenza vaccine should not be given to pregnant women.

There is good evidence demonstrating the safety of inactivated influenza vaccine during pregnancy. Active surveillance following influenza vaccination during pregnancy has not shown evidence of harm to the mother or fetus associated with influenza immunization. Although the cumulative sample size of

these studies is relatively small, particularly in the first trimester, passive surveillance has not raised any safety concerns despite widespread use of influenza vaccine in pregnancy over several decades. Surveillance following the use of both adjuvanted and unadjuvanted pH1N1 vaccine in more than 100,000 pregnant women in Canada and almost 500,000 pregnant women in Europe did not reveal any safety concerns.

Women who did not receive influenza vaccination during pregnancy should receive influenza vaccine post-partum before discharge from hospital if it is influenza season.

Refer to *Influenza Vaccine* in Part 4 for additional information.

Hepatitis B vaccine

All pregnant women should be routinely tested for hepatitis B surface antigen (HBsAg). A pregnant woman who has no markers of hepatitis B (HB) infection but who is at high risk of HB should be offered a complete HB vaccine series at the first opportunity during the pregnancy and should be tested for antibody response. HB vaccine can be used safely in pregnancy and should be administered when indicated, because acute HB in a pregnant woman may result in severe disease for the mother and chronic infection in the infant. The safety of combined hepatitis A-hepatitis B vaccine given during pregnancy has not been studied in clinical trials; however, there is no theoretical reason to suspect an increased risk of adverse events. Refer to *Hepatitis B Vaccine* in Part 4 for additional information.

VACCINES THAT MAY BE INDICATED

Hepatitis A vaccine

The efficacy and safety of hepatitis A vaccines given during pregnancy has not been studied in clinical trials, but there is no theoretical reason to suspect an increased risk of adverse events. Hepatitis A can cause severe disease in pregnancy, and the vaccine should be considered for pregnant women when potential benefits outweigh risks such as for post-exposure prophylaxis or for travel to high risk endemic area. Refer to *Hepatitis A Vaccine* in Part 4 for additional information.

Tetanus toxoid, diphtheria toxoid, acellular pertussis vaccines

Susceptible pregnant women may receive tetanus toxoid-reduced diphtheria toxoid-containing vaccine (Td) if indicated. Follow-up data on pregnant women who have received tetanus toxoid-containing vaccine (often in the first trimester) have not revealed an increased risk of adverse events. There is no theoretical reason to suspect an increased risk of adverse events following the administration of Td vaccine.

The safety and efficacy data related to use of tetanus toxoid-reduced, diphtheria toxoid-reduced, acellular pertussis vaccine (Tdap) during pregnancy is currently under review by NACI. NACI's current recommendation for pregnant women who have not previously received Tdap vaccine in adulthood is that Tdap vaccine should be administered immediately post-partum to ensure pertussis immunity and reduce the risk for transmission to the newborn. In particular situations where potential benefits outweigh risks, such as during pertussis outbreaks, Tdap vaccine should be considered for pregnant women in the second half of pregnancy who have not previously received Tdap vaccine in adulthood. Refer to *Tetanus Toxoid*, *Diphtheria Toxoid* and *Pertussis Vaccine* in Part 4 for additional information.

Poliomyelitis vaccine

Inactivated poliomyelitis vaccine (IPV) may be considered for pregnant women who require immediate protection and are at increased risk of exposure to wild poliovirus. Limited data have not revealed an increased risk of adverse events associated with IPV vaccine administered to pregnant women. There is no theoretical reason to suspect an increased risk of adverse events following IPV administration. Refer to *Poliomyelitis Vaccine* in Part 4 for additional information.

Pneumococcal vaccine

Pneumococcal polysaccharide 23-valent vaccine has been studied in pregnant women and found to be safe. However, a recent Cochrane review showed that there was insufficient evidence to support maternal pneumococcal immunization for the prevention of pneumococcal infection in the infant and protection of the infant is not an indication for maternal vaccination. Pneumococcal vaccine is recommended for pregnant women who, because of underlying medical conditions, are at high risk of invasive pneumococcal disease. Some experts suggest that a conjugate pneumococcal vaccine may be given as the initial dose followed by the Pneu-P-23 vaccine for adults less than 65 years of age at increased risk of IPD, as this may theoretically improve antibody response and immunologic memory. If this strategy is chosen, Pneu-C-13 vaccine should be administered first, followed at least 8 weeks later by Pneu-P-23 vaccine. Refer to *Pneumococcal Vaccine* in Part 4 and *Immunization of Immunocompromised Persons* and *Immunization of Persons with Chronic Diseases* in Part 3 for additional information.

Meningococcal vaccine

Conjugate meningococcal vaccines have not been studied in pregnancy; however, there is no theoretical reason to suspect adverse events will occur and may be given in circumstances when the benefits outweigh the risks. Conjugate meningococcal vaccine should be considered for pregnant women in circumstances such as travel to a high risk area; post-exposure prophylaxis against a vaccine preventable strain if indicated; or during an outbreak if indicated. Refer to *Meningococcal Vaccine* in Part 4 for additional information.

Rabies vaccine

If a pregnant woman has had a potential exposure to rabies, post-exposure prophylaxis should be given. If pre-exposure prophylaxis is indicated for work or travel purposes, in general, avoidance of risk should be considered and pre-exposure immunization delayed unless substantial risk of exposure remains. Refer to *Rabies Vaccine* in Part 4 for additional information.

Other inactivated vaccines

Cholera and travellers' diarrhea vaccine and Japanese encephalitis vaccines have not been studied in pregnant women. Administration of either vaccine to pregnant women may be considered in high risk situations only after evaluation of the benefits and risks. Inactivated parenteral typhoid vaccine should be used in high risk situations if protection against typhoid is required. Refer to vaccine specific chapters in Part 4 for additional information.

VACCINES NOT RECOMMENDED

Human papillomavirus vaccine (HPV)

HPV vaccine is not recommended for use in pregnancy because data on efficacy and safety of HPV vaccination in pregnancy are limited. No adverse outcomes of pregnancy or adverse events to the developing fetus have been reported. Initiation of the HPV vaccine series should be delayed until after completion of pregnancy. If a woman is found to be pregnant after initiating the vaccination series, completion of the series should be delayed until after pregnancy. If a vaccine dose has been administered during pregnancy, there is no indication for any intervention. Refer to *Human Papillomavirus Vaccine* in Part 4 for additional information.

GENERALLY CONTRAINDICATED VACCINES

Measles-mumps-rubella vaccine

Measles-mumps-rubella vaccine (MMR) (live attenuated vaccine) is generally contraindicated in pregnancy because there is a theoretical risk to the fetus. However, in some situations, potential benefits may outweigh risks such as during measles or rubella outbreaks, in which case vaccination may be considered. There is no evidence to date demonstrating a teratogenic or other risk from MMR vaccine. Inadvertent immunization with MMR vaccine is not a reason for pregnancy termination.

Pregnant women without documented evidence of prior immunization with a rubella-containing vaccine should be serologically screened for rubella antibodies. Those found to be non-immune serologically should be vaccinated with one dose of MMR vaccine in the immediate post-partum period, before discharge from hospital (unless they have received Rh immune globulin [RhIg] – refer to *Rh immune globulin and MMR vaccine*). Women who have been appropriately immunized post-partum do not need to be serologically screened for rubella antibodies either post-immunization or in subsequent pregnancies. Women who have been found to be serologically positive in one pregnancy do not need to be screened again in subsequent pregnancies.

Refer to *Measles Vaccine*, *Mumps Vaccine*, and *Rubella Vaccine* in Part 4 for additional information.

Univalent varicella vaccine

Varicella vaccine (a live attenuated vaccine) is contraindicated in pregnancy because there is a theoretical risk to the fetus; however, there is a lack of evidence to demonstrate a teratogenic or other risk from varicella vaccine. Inadvertent immunization with varicella vaccine is not a reason for pregnancy termination.

Pregnant women without documented evidence of prior immunization with 2 doses of varicella vaccine or evidence of varicella disease should be serologically screened for varicella antibodies. Those found to be non-immune to varicella should receive 2 doses of a univalent varicella vaccine, 6 weeks apart; the first dose should be given in the immediate post-partum period, before discharge from hospital (unless they have received Rh immune globulin [RhIg] – refer to *Rh immune globulin*). Once appropriately immunized, there is no need for serological confirmation of immunity.

Refer to *Varicella (Chickenpox) Vaccine* in Part 4 for additional information, including post-exposure prophylaxis with varicella zoster immune globulin for pregnant women exposed to varicella.

Other live attenuated vaccines

The use of other live attenuated vaccines during pregnancy must be evaluated on the basis of the individual risk and benefit. Live attenuated oral typhoid vaccine is contraindicated in pregnancy because of the lack of data on safety or efficacy; inactivated typhoid vaccine should be used if indicated. Live attenuated intranasal influenza vaccine should not be given to pregnant women; inactivated influenza vaccine should be used if indicated. Live oral polio vaccine (OPV) should not be administered to pregnant women; inactivated polio vaccine should be used if indicated. In addition, OPV is not available in Canada. BCG vaccine has not been studied in pregnant or breastfeeding women. BCG vaccine should not be given during pregnancy although no harmful effects of BCG vaccination on the fetus have been observed.

The use of other live attenuated vaccines during pregnancy must be evaluated on the basis of the individual risk and benefit. For instance, if a pregnant woman must travel to an area at high risk of yellow fever transmission and a high level of mosquito protection is not feasible, yellow fever (YF) vaccine may be administered when the risk of exposure is high and the travel cannot be postponed. In one study of women exposed to YF vaccine early in pregnancy there was slight increased risk noted for minor malformations (mainly skin) in the babies; no increased risk of major malformations was found. Since seroconversion rates following YF vaccine are lower during pregnancy; post-immunization serology should be considered. Inadvertent immunization with YF vaccine is not a reason for pregnancy termination.

Smallpox vaccine may be considered for a pregnant woman following high risk exposure.

Refer to vaccine specific chapters in Part 4 for additional information.

LIVE ATTENUATED VACCINES AND RH IMMUNE GLOBULIN

A risk benefit assessment is needed for post-partum women who have received RhIg and require MMR or varicella vaccine. Immune globulin administration may impair the efficacy of live attenuated vaccines, such as MMR and varicella, as measles, rubella, and varicella antibodies may be present in the RhIg preparation. The risk of lowered vaccine efficacy needs to be weighed against the need for protection. To optimize response to vaccine, rubella-, measles- or varicella-susceptible women who receive RhIg in the peri-partum period should generally wait 3 months before being vaccinated with MMR or varicella vaccine.

However, if there is a risk of exposure to rubella, measles, or varicella, a risk of recurrent pregnancy in the 3-month post-partum period, or a risk that vaccines may not be given later, MMR and/or univalent varicella vaccines may be given prior to discharge. In that context, serologic testing for rubella and varicella should be done 3 months later and non-immune women should be revaccinated. In the event that a post-partum woman receives MMR and/or varicella vaccines prior to receiving RhIg, serologic testing for rubella should be done 3 months later and the woman revaccinated if non-immune.

BIOLOGIC PRODUCTS DURING PREGNANCY

There is no known risk to the fetus or pregnant woman from administration of immune globulin for passive immunization. Immune globulin products should be administered to pregnant women as required.

In general, women should not receive immune modulators, such as infliximab or rituximab, during pregnancy. IgG immunoglobulins are known to pass the placental barrier and there is a risk that this treatment could deplete B-cells in both pregnant women and their fetus. It is particularly important not to administer live vaccines to pregnant women who receive monoclonal antibodies, such as TFN inhibitors. Refer to *Immunization of breastfed infants* for additional implications for the infant.

IMMUNIZATION OF HOUSEHOLD CONTACTS OF PREGNANT WOMEN

A pregnant household member is not a contraindication for routine vaccination of household contacts. Pregnancy should be used as an opportunity to update immunization of susceptible household contacts. MMR and varicella-containing vaccines should be administered when indicated to children and other household contacts of pregnant women. Infants living in households with a pregnant woman can be vaccinated with rotavirus vaccine, as indicated. The risk of infection and disease from rotavirus vaccine virus is low because most women of childbearing age have pre-existing immunity to rotavirus through natural exposure and rotavirus infection during pregnancy is not known to pose a risk to the fetus.

Extreme precautions should be taken for unvaccinated pregnant household and other close contacts of persons receiving smallpox vaccine in order to eliminate viral transfer to these contacts. Such precaution can include isolation of the vaccinee from his/her pregnant household contacts until the vaccine scab falls off.

IMMUNIZATION DURING BREASTFEEDING (refer to table 1)

IMMUNIZATION OF BREASTFEEDING WOMEN

In general, routinely recommended vaccines may be safely administered to breastfeeding women. There are limited data available regarding the effects of maternal vaccination on breastfed infants; however, there have been no reported adverse events thought to be vaccine-related. There is no evidence that immunization during breastfeeding will adversely influence the maternal or infant immune response.

Annual influenza vaccination is recommended for breastfeeding women. Live attenuated influenza vaccine has a similar or lower immune response than inactivated influenza vaccine in adults; inactivated vaccine is preferred if the breastfeeding woman has a chronic health condition.

Women who are breastfeeding can be vaccinated with Td, Tdap, pneumococcal, meningococcal, hepatitis A, hepatitis B, IPV, rabies, typhoid, MMR, varicella and cholera vaccines if indicated. HPV vaccine may be administered to breastfeeding women.

Japanese encephalitis (JE) vaccine has not been studied in breastfeeding women. Administration of JE vaccine to breastfeeding women who must travel to areas where the risk of JE infection is high should be immunized only if the risk of disease outweighs the unknown risk of vaccination to the woman and/or her breastfeeding infant.

There are a few instances when vaccination is not recommended during breastfeeding. Probable transmission of yellow fever vaccine strain virus from a mother to her infant through breastfeeding has been reported; therefore, breastfeeding mothers should not generally be vaccinated with yellow fever vaccine. It is not known whether BCG vaccine is excreted in human milk. Because live vaccine may be excreted in human milk, caution should be exercised when considering BCG vaccine while breastfeeding. Smallpox vaccine is not recommended for breastfeeding women because of the theoretical risk for contact transmission from mother to infant. If smallpox vaccine is used as post-exposure prophylaxis for a breastfeeding woman, breastfeeding and other close contact with the baby should be avoided until the scab has separated from the vaccination site.

Refer to vaccine specific chapters in Part 4 for additional information.

IMMUNIZATION OF BREASTFED INFANTS

In general, infants who are breastfed should receive all recommended vaccines according to the routine immunization schedule. In developed countries, there is no evidence that transfer of antibodies in human milk can affect the efficacy of live attenuated vaccines in breastfed infants.

The one exception to this recommendation is for breastfeeding women who are on immune modulators, such as monoclonal antibodies (such as infliximab or rituximab), or who were on these drugs during pregnancy. These drugs affect IgGs that can pass through the placental barrier. There is a potential for immunosuppression in the infant that persists after birth. Because human IgG is excreted in human milk, women should be advised to discontinue nursing until circulating drug levels are no longer detectable. Infants who have been exposed to monoclonal antibodies, either during pregnancy or from breastfeeding, should not receive BCG vaccine at birth and should have B-cell enumeration. B cell enumeration should be normal before vaccination with BCG or live vaccines. Consultation with an immunologist is advised

Table 1: Summary of recommendations for immunizing susceptible pregnant or breastfeeding women
(Vaccines are listed in alphabetical order)

VACCINE	USE IN PREGNANCY	USE IN BREASTFEEDING	COMMENTS
INACTIVATED VACCINES			
Cholera and travellers' diarrhea	Use if indicated in high risk situations[1]	Use if indicated	• No data on use during pregnancy or breastfeeding
Hepatitis A	Use if indicated in high risk situations[1]	Use if indicated	• No data on efficacy and safety during pregnancy Hep A vaccine should be considered for pregnant women when potential benefits outweigh risks such as for post-exposure prophylaxis or for travel to high risk endemic area
Hepatitis B	Use if indicated[1]	Use if indicated	• HB vaccine can be used safely in pregnancy and during breastfeeding
Human papillomavirus (HPV)	Currently not recommended	Use if indicated	• Limited data on use during pregnancy and breastfeeding
Influenza (inactivated)	Recommended	Recommended	
Japanese encephalitis	Use if indicated in high risk situations[1]	Use if indicated in high risk situations[1]	• No data on safety or efficacy during pregnancy or breastfeeding
Meningococcal conjugate	Use if indicated[1]	Use if indicated	• No data on use during pregnancy. Should be considered for pregnant women in circumstances such as travel to a high -risk area; post-exposure prophylaxis against a vaccine preventable strain; or during an outbreak. • Refer to *Meningococcal Vaccine* in Part 4 for a listing of high risk conditions.

VACCINE	USE IN PREGNANCY	USE IN BREASTFEEDING	COMMENTS
Pneumococcal conjugate 13-valent (Pneu-C-13)	Use if indicated for high risk conditions	Use if indicated for high risk conditions	• No data on use during pregnancy • Refer to *Pneumococcal Vaccine* in Part 4 for a listing of high risk conditions.
Pneumococcal polysaccharide (Pneu-P-23)	Use if indicated for high risk conditions	Use if indicated for high risk conditions	• Lack of evidence of risk to fetus or pregnancy • Refer to *Immunization of Persons with Chronic Diseases* and *Immunization of Immunocompromised Persons* in Part 3
Polio (inactivated)	Use if immediate protection needed and at increased risk of exposure to wild poliovirus	Use if indicated	• Lack of evidence of risk to fetus or pregnancy
Rabies	Use if indicated for post-exposure prophylaxis Delay pre-exposure immunization unless substantial risk of exposure	Use if indicated	
Tetanus-reduced diphtheria (Td)	Use if indicated	Use if indicated	• Lack of evidence of risk to fetus or pregnancy
Tetanus-reduced diphtheria reduced acellular pertussis (Tdap)	Consider use in second half of pregnancy if pertussis is circulating locally and Tdap vaccine not previously received in adulthood	Recommended - administer as early as possible post-partum if Tdap vaccine not previously received in adulthood	• Lack of evidence of risk to fetus or pregnancy • Use Tdap vaccine during pregnancy is currently under review by NACI
Typhoid (inactivated)	Use if indicated in high risk situations[1]	Use if indicated	• No data on use during pregnancy or breastfeeding

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VACCINE	USE IN PREGNANCY	USE IN BREASTFEEDING	COMMENTS
		LIVE VACCINES	
Bacille Calmette-Guérin (BCG)	**Contraindicated**	Generally should not be used May be considered in high risk situations	• Lack of evidence of risk to fetus • No data on use in pregnancy or breastfeeding
Influenza (intranasal)	**Should not be used**	Use if indicated	• Live attenuated influenza vaccine has a similar or lower efficacy than inactivated influenza vaccine in adults; inactivated influenza vaccine is preferred if chronic health condition. • No data on use during pregnancy
Measles-mumps-rubella	**Generally contraindicated** Immunize rubella-susceptible women immediately post-partum	Recommended if not immune	• No known fetal effects; theoretical risk • Inadvertent immunization is not a reason for pregnancy termination
Smallpox	**Generally contraindicated** Consider use in high risk situations (e.g., post-exposure, outbreak)[1]	**Generally should not be used** **May be considered in high risk situations** (e.g., post-exposure, outbreak)[1]	• May cause fetal infection • Suspend breastfeeding until scab falls off • Close contacts who are vaccinated should be isolated from pregnant women as well as lactating women and their newborn until scab falls off
Typhoid (oral)	**Contraindicated**	Use inactivated vaccine if indicated	• Although there are no data, it is reasonable to assume that either Typh-I vaccine could be used safely in lactating mothers.
Varicella	**Contraindicated** Immunize varicella-susceptible women immediately post-partum	Recommended if not immune	• No known fetal effects; theoretical risk • Inadvertent immunization is not reason for pregnancy termination