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THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

#8: Administration of Immunizing Agents

♦ Competency: Prepares and administers immunization agents correctly.



1.0 ASSESSMENT FOR CONTRAINDICATIONS AND PRECAUTIONS

1.1 Contraindications to Immunization

A contraindication is a condition in a client that increases their risk for a serious adverse event, including anaphylaxis. In general, a vaccine should not be administered when a contraindication is present. Always consult a Medical Health Officer (MHO) for recommendations.

- In Canada, the only contraindication applicable to all vaccines except rabies is a history of an
 anaphylactic reaction to a previous dose of a specific vaccine (or antigen) or to the vaccine
 component.
- In general, severe immunosuppression and pregnancy are contraindications to live vaccines only.
- Refer to <u>Appendix 6.1: Contraindications and Precautions for Inactivated or Live Vaccine Administration</u> for further information.

1.2 Precautions to Immunization

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or might compromise the ability of the vaccine to produce immunity. When a precaution is present, further assessment and a risk-benefit analysis may be necessary. **Always consult a Medical Health Officer (MHO) for recommendations.**

1.3 Client Assessment

Assess every client for the presence of contraindications and precautions prior to any immunization. Consult a Medical Health Officer (MHO) for recommendations as appropriate.

Assess the following factors before administering any vaccine:

- History of anaphylactic reaction to any antigens or components contained in the vaccine.
- Adverse events previously experienced following receipt of the same vaccine or antigens.
- Past and current state of health, specifically any condition that may affect the immune system.
- Assess for history of Guillain-Barré syndrome (GBS). GBS that occurs within 6 weeks of receiving an influenza vaccine and/or a tetanus-containing vaccine and for which no other cause is identified, is a contraindication to further doses of the associated vaccine and antigens.
- Assess infants and young children for past episodes of febrile seizure related or not to immunizations. If a caregiver identifies a positive history for the child, review fever management with the caregiver

Include the following factors if administering a live vaccine:

- History of receipt of immune globulin, blood transfusion or blood product in the past year.
- Receipt of a live vaccine in the previous 4 weeks.
- Pregnancy or planning a pregnancy in the next month.
- ASA for varicella or live influenza vaccine.
- Antivirals.
- History of idiopathic thrombocytopenia within 6 weeks of a previous MMR/MMRV dose.
- If administering a live vaccine to an infant less than 12 months of age, assess for a family history of congenital immunodeficiency which may be manifested as overwhelming infection following natural infection or receipt of a live vaccine with or without death.



2.0 SEVERE ALLERGY TO VACCINE COMPONENTS

2.1 Vaccine Components that may Cause Hypersensitivity

An allergic reaction may be caused by:

- Vaccine antigens (diphtheria, measles, etc.);
- Adjuvants (e.g., aluminum hydroxide, aluminum phosphate);
- Latex in vials and syringes (refer to <u>Appendix 6.2: Selected Publicly Funded Biological Products That Contain Latex</u>);
- Trace amounts of residual animal protein (e.g., bovine albumin, egg protein (ovalbumin));
- Trace amounts of antimicrobial agents (e.g., phenol, neomycin, streptomycin, or polymyxin B);
- Trace amounts of preservatives (e.g., thimerosal, 2-phenoxyethanol);
- Trace amounts of stabilizers (e.g., gelatine, glycine, and sucrose); or
- Other vaccine components such a pH adjusters (e.g., phosphate buffers, hydrochloric acid).

No Canadian licensed vaccines contain penicillin or penicillin derivatives. Certain vaccines contain trace amounts of antibiotics or preservatives (e.g. neomycin or thimerosal) to which clients might be severely allergic. Most often neomycin and thimerosal allergies exhibit as contact dermatitis, a topical manifestation of a delayed type (cell-mediated) immune response, rather than anaphylaxis and this is not a contraindication for administration of these vaccines. Refer to SIM, Chapter 10, Biological Products or individual product monographs/inserts for a complete list of biological product components and stated precautions.

A vaccine is contraindicated in a person with a history of anaphylaxis after previous administration of the same vaccine; and/or in a person with proven immediate or anaphylactic hypersensitivity to any component of the vaccine (with the exception of egg allergy – see below) or its container (e.g., latex). In situations of suspected hypersensitivity or non-anaphylactic allergy to a vaccine or its components, investigation is indicated which may involve immunization in a controlled setting. Consultation with an allergist may be advised as specific administration and client monitoring protocols (e.g., observe for 45 minutes post-vaccination) may be recommended by the MHO.

2.2 Anaphylactic Reaction to Eggs

In Canada, there are several vaccines manufactured by processes involving hens' eggs or their derivatives, such as chick cell cultures (such as the RabAvert® brand of rabies vaccine; and yellow fever, MMRV, MMR and influenza vaccines). These manufacturing processes may result in some vaccines containing trace amounts of residual egg (ovalbumin) and chicken proteins. Hypersensitivity reactions occurring following receipt of these vaccines varies considerably in relation to the amount of residual egg and chicken protein in the vaccine (BCCDC). Ordinarily, a person who can eat eggs or egg products can receive vaccines prepared with egg protein.

Influenza Vaccines:

Egg-allergic individuals including those reported to have had past anaphylaxis, without other contraindications to the vaccine, may receive a full dose of an influenza vaccine without prior influenza vaccine skin testing and in any setting where vaccines are routinely administered.

Rabies Vaccines:

RabAvert® rabies vaccine is grown in chick embryo cell culture and individuals with a history of an anaphylactic reaction to eggs or a positive skin test to ovalbumin should generally not receive RabAvert®.



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Imovax® rabies vaccine is 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 (CIG).

MMR and MMRV

Although the measles and mumps components of MMR and MMRV vaccines are produced in chick embryo cell culture and may contain traces of residual egg and chicken protein, the trace amount of egg or chicken protein in the vaccine 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. Prior egg ingestion is not a prerequisite for immunization with egg protein-containing vaccine (CIG).



3.0 LATEX ALLERGY

Natural rubber latex and dry, natural rubber are products made out of the latex sap from rubber trees. Dry, natural rubber is used in the tips of syringe plungers, the tips of prefilled syringes, and the vial stoppers of some biological products. Natural latex or dry, rubber used in vaccine packaging is generally noted in the manufacturer's product inserts (e.g., monographs). Synthetic rubber and synthetic latex are not linked to allergic reactions.

The Advisory Committee on Immunization Practices (ACIP, 2011) General Recommendations on Immunization states, "if a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber latex should not be administered, unless the benefit of vaccination clearly outweighs the risk for a potential allergic reaction. In these cases, providers should be prepared to treat patients who are having allergic reactions. For latex allergies other than anaphylactic allergies (e.g., a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex may be administered" (MMWR on General Recommendations on Immunization, January 28, 2011, p. 25).

It should be noted that most vaccine vials contain synthetic rubber, and this is not associated with clinical reactivity. Assess clients for a previous anaphylactic reaction to latex when the biological product vial stopper or needle shield contains latex. It is possible the allergenic proteins could be introduced into the product being administered during immunization and cause an anaphylactic reaction. If a person reports an anaphylactic allergy to latex, do not administer vaccines supplied in vials or syringes that contain natural rubber.

Refer to <u>Appendix 6.2</u>: <u>Selected Publicly Funded Biological Products That Contain Latex</u> to determine which current publicly funded biological products contain latex.



4.0 CONDITIONS THAT ARE NOT CONTRAINDICATIONS TO IMMUNIZATIONS

4.1 Antibiotics and Antivirals

Antibiotics and antivirals have no effect on the immune response to most inactivated or live vaccines used in Canada. Exceptions include:

- Live oral typhoid vaccine should be delayed 72 or more hours after antibiotics were taken to treat *Salmonella typhi* infection.
- Live attenuated varicella vaccine may have reduced effectiveness if given concurrently with antivirals effective against herpes viruses.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours as it
 may affect the reproduction of and reduce the efficacy of a live varicella-containing vaccine or a live
 zoster vaccine (CIG)
- On the basis of expert opinion, it is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of a live varicellacontaining vaccine or a live zoster vaccine, and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
- 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.

4.2 Convalescence From or Exposure to an Infection

There is no interference with vaccine immunogenic response or increased risk of adverse events following immunization.

E.g., a child who has been exposed to varicella may be safely immunized with varicella vaccine. A child
who has had varicella disease less than 12 months of age may be safely immunized with all vaccines,
including varicella or MMRV.

4.3 Illness With or Without Fever

- Influenza vaccination should not be delayed because of minor or moderate acute illness, with or
 without fever (NACI, 2020). During the COVID-19 pandemic, individuals with any symptoms of acute
 respiratory infection, including minor symptoms such as sore throat or runny nose, should defer
 influenza vaccination until they have recovered if being immunized in a community setting (NACI,
 2020). Patients in acute care can be immunized regardless.
- Minor illnesses such as teething, stomach upsets, and the common cold, frequently occur in young children and are not a contraindication to immunization. These do not increase the risk of adverse events following immunization and do not interfere with immune responses to vaccines. While there is a theoretical risk that the occurrence of systemic adverse events may complicate the medical management of the other acute illness or that events associated with the acute illness may mistakenly be thought to be vaccine-related adverse events, the potential risk is much less important than the risk associated with missing an opportunity to give a recommended vaccine.

4.4 Breastfeeding

• Generally, there are no contraindications or precautions to immunizing breastfeeding women with inactivated vaccines or live attenuated vaccines like varicella or MMR. After immunization, there is: no reduction in antibody response to vaccines or increased risk of adverse events for the woman (or her infant). Breastfeeding (and pregnancy) are precautions to the administration of yellow fever vaccine in women, as cases of viral transfer to the newborn through vertical transmission or breastfeeding have been documented. Consult a travel centre for further information.



4.5 Neonatal Abstinence Syndrome

(Post-natal) neonatal abstinence syndrome is caused by discontinuation of drugs (e.g., opioids, selective serotonin reuptake inhibitors (SSRIs), benzodiazepines) or alcohol directly to the infant (after birth). The treatment aims to slowly wean the neonate off the substance(s) that he/she was exposed to in utero. There are no contraindications or precautions for immunization of infants with neonatal abstinence syndrome.

4.6 History of Allergy that does not Involve Vaccines or Vaccine Components

Allergy desensitization is not a contraindication to immunization.

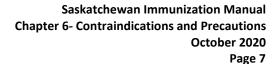
It is safe to immunize people with any of the following:

- Non-specific allergies;
- Environmental allergies;
- Family history of allergies;
- Administration of allergy shots (desensitization therapy for allergy); or
- Allergies to commonly used antibiotics.
 - Exception: vaccines containing neomycin, streptomycin or polymyxin B are contraindicated in individuals with IgE-mediated allergies to these antibiotics. Always consult a Medical Health Officer (MHO) for recommendations.

4.7 Family History of Adverse Reactions to Vaccines

Vaccine adverse reactions that are severe, unusual or unexpected are not known to be inherited.

- **Exception**: A family history of congenital immunodeficiency. This may not be evident in infants less than 12 months of age but may be documented as an overwhelming infection following natural infection or receipt of a live vaccine with or without death (including alive or dead older siblings).
- Note: Assess family history of these types of events prior to administering a live vaccine to an
 infant less than 12 months of age (i.e., MMR vaccine for an infant travelling to a measles
 endemic region). If such a history is present, live vaccines are contraindicated until child is
 assessed for immunodeficiency. Always consult a Medical Health Officer (MHO) for
 recommendations.





5.0 REFERENCES

BCCDC. *Communicable Disease Control Manual, Immunization Program*. Available at: http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm

Centers for Disease Control and Prevention (2012). Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed., second printing. Washington DC: Public Health Foundation. Available from: http://www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters

Centres for Disease Control and Prevention. (2011). *General Recommendation on Immunization*. MMWR, 2011, 60(2). Available from:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s cid=rr6002a1 w

Centres for Disease Control and Prevention (2011) *CDC Health Information for International Travel 2012*. (G. W. Burnette, Ed.). Available from: http://wwwnc.cdc.gov/travel/page/yellowbook-2012-home.htm.

Public Health Agency of Canada (2012) *Canadian Immunization Guide* (Evergreen Ed.). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Public Health Agency of Canada (2008). *Immunization Competencies for Health Professionals*. Available at: http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

Public Health Agency of Canada (2020). *Guidance on the use of influenza vaccine in the presence of COVID-19*. Available at: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-use-influenza-vaccine-covid-19.html

Public Health Agency of Canada (2020). Statement on Seasonal Influenza Vaccine for 2020–2021. Available at: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization-guide-statement-seasonal-influenza-vaccine-2020-2021.html

Wikipedia (n.d.) *Neonatal withdrawal*. Accessed April 13, 2012 from: http://en.wikipedia.org/wiki/Neonatal_abstinence_syndrome.



6.0 APPENDICES

Appendix 6.1: Contraindications and Precautions for Inactivated or Live Vaccine Administration

Issue of concern	Inactivated ¹	Live ¹
History of intussusception and/or uncorrected	None	Contraindication to
congenital gastrointestinal malformation (e.g.		rotavirus vaccines
(Meckel's diverticulum)		
History of anaphylactic reaction to a previous dose	Contraindication	Contraindication
of the vaccine or any of its antigens.		
History of anaphylactic reaction to a vaccine	Contraindication if	Contraindication if the
component.	the specific vaccine	specific vaccine
	contains that	contains that particular
	particular	component
	component	
Severely immunocompromised ² (including severe	Precaution	Contraindication
immunodeficiency disorder [SCID]).		
Pregnancy ² .	None	Contraindication
Severe bleeding disorder ² .	Precaution	Precaution
Recent administration of blood product containing	None	Precaution
antibodies ³ .		
Recent administration of live virus vaccine 4.	None	Precaution
History of Guillain-Barré syndrome (GBS) that	Contraindication;	N/A
occurred within 6 weeks of receipt of influenza	check with MHO	
vaccine or a tetanus-containing vaccine and for		
which no other cause is identified.		
Infant's mother took monoclonal antibodies	None	Contraindication to
during pregnancy.		rotavirus vaccines

(Adapted from BCCDC, 2009)

¹Refer to SIM, Chapter 10, Biological Products for contraindications and precautions specific to each biological product.

² Further information regarding medical condition and associated precaution or contraindication can be found in SIM, Chapter 7, *Immunization of Special Populations*.

³ Specific information regarding the recent administration of blood product containing antibodies is available in SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines*, *Blood Products and Immune Globulin* <u>Preparations</u> and <u>Section 3.5.1</u>, <u>Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live</u> <u>Measles</u>, <u>Mumps</u>, <u>Rubella</u>, or <u>Varicella Virus</u>.

⁴ Injectable live viral vaccines must be administered on the same day or separated by intervals as per <u>Chapter 5</u>, <u>Section 3.3.1 Minimum Spacing between MMRV</u>, <u>MMR and Varicella Vaccines Doses.</u> There is no minimum interval between administration of an oral or intranasal live virus vaccine and an injectable live virus vaccine.



Appendix 6.2: Selected Publicly Funded Biological Products That Contain Latex (Natural)

Most manufacturers identify if their products contain latex in the product monographs; however some
manufacturers have stated to the Ministry of Health that they cannot guarantee that their products do
not contain latex. The following link to SIM <u>Chapter 10</u>, <u>Biological Products</u> is provided so that the most
current product monographs can be accessed for information about latex in specific biological products.