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1. Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.
2. Please note that websites are provided for non-publicly funded vaccines in Saskatchewan. All biological product monographs can be found in the Drug Product Database on the Health Canada website at: http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp. **The Ministry of Health does not endorse products or manufacturer websites.**
3. Post-exposure contact immunoprophylaxis management falls under the direction of a Medical Health Officer as per the Saskatchewan Communicable Disease Control Manual, available at: http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx .

1.0 ACTIVE IMMUNIZING AGENTS

- **Cholera – *E. coli* Vaccine (Chol-Ecol-O)**
  - DUKORAL®
- **Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)**
  - INFANRIX™-IPV/Hib
  - PEDIACEL®
- **Diphtheria-Tetanus-acellular Pertussis-Hepatitis B-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-HB-IPV-Hib)**
  - INFANRIX™-hexa
- ***Haemophilus influenzae* type b Conjugate Vaccine (Hib)**
  - Act-HIB ®
  - HIBERIX®
- **Hepatitis A Vaccine (HA) Indications**
- **Hepatitis A Vaccine (HA)**
  - Avaxim™ and Avaxim™ Pediatric
  - Havrix® 1440 and Havrix® 720 Junior
  - Vaqta®
- **Hepatitis A and B Vaccine Combined Vaccine (HAHB)**
  - Twinrix™ and Twinrix Junior™
- **Hepatitis A and Typhoid Vaccine (HA-Typh-I)**
  - ViVAXIM®
- **Hepatitis B (HB) Vaccine Indications**
- **Hepatitis B Vaccine - Immigrant Populations Ineligibility List**
- **Hepatitis B Re-Vaccination Assessment Algorithm**
- **Hepatitis B Vaccine Dosage and Formulation Options for HIV Infected Adults and Children**
- **Hepatitis B Series Completion Recommendations for Children Presenting at 11-15 Years Old**
- **Hepatitis B Completion Scenarios**
- **Hepatitis B Vaccine (HB)**
  - ENGERIX®-B
  - RECOMBIVAX HB®
- **Herpes Zoster Vaccine**
  - Shingrix™ **(RZV)**
  - ZOSTAVAX® II **(LZV)**

- **Human Papillomavirus Vaccine**
  - CERVARIX™ **(HPV-2**)
  - GARDASIL® **(HPV-4)**
  - GARDASIL®9 **(HPV-9)**
- **Immunization Recommendations for Children 4-6 years of Age**
- **Influenza Vaccine**
  - AFLURIA TETRA
  - AGRIFLU™
  - FLUAD™ AND FLUAD PEDIATRIC
  - FLULAVAL TETRA®
  - FLUMIST® QUADRIVALENT
  - FLUVIRAL®
  - FLUZONE® QUADRIVALENT
  - FLUZONE® HIGH DOSE
  - INFLUVAC®
- **Japanese Encephalitis Vaccine (JE)**
  - IXIARO™
- **Measles-Mumps-Rubella Vaccine (MMR)**
  - MMRII™
  - PRIORIX™
- **Measles-Mumps-Rubella-Varicella Vaccine (MMRV)**
  - PRIORIX-Tetra™
  - ProQuad™
- **Meningococcal Conjugate C Vaccine** (**Men-C-C**)
  - MENJUGATE™ and MENJUGATE™ Liquid
  - Neis Vac-C®
- **Meningococcal Conjugate ACYW-135 Vaccine** (**Men-C-ACYW-135**)
  - Menactra®
  - Menveo™
  - NIMENRIX™
- **Multicomponent Meningococcal B Vaccine**
  - BEXSERO® **(MenB)**
  - Trumenba™
- **Pneumococcal Conjugate Vaccine**
  - SYNFLORIX™ **(Pneu-C-10)**
  - Prevnar® 13 **(Pneu-C-13)**
- **Pneumococcal Polysaccharide Vaccine (Pneu-P-23**)
  - PNEUMOVAX® 23
- **Poliomyelitis Vaccine (Inactivated) (IPV)**
  - IMOVAX® Polio
- **Rabies Vaccine (Rab) (Post-exposure prophylaxis)**
  - IMOVAX® Rabies [Human Diploid Cell Vaccine (HDCV)]
  - RabAvert® [Purified Chick Embryo Cell Vaccine (PCECV)]
- **Rotavirus Vaccine**
  - Rotarix™ **(Rot-1**)
  - RotaTeq® **(Rot-5)**

- **Tetanus-Diphtheria Adsorbed Vaccine (Td)**
  - Td Adsorbed™
- **Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)**
  - ADACEL®
  - BOOSTRIX™
- **Tetanus-Diphtheria-Inactivated Poliomyelitis Adsorbed Vaccine(Td-IPV)**
  - Td-Polio Adsorbed™
- **Tetanus-Diphtheria-acellular Pertussis-Inactivated Poliomyelitis Vaccine (Tdap-IPV)**
  - ADACEL®-Polio
  - BOOSTRIX®-Polio™
- **Typhoid Vaccine (Typh-I) (Salmonella Typhi Vi Capsular Polysaccharide)**
  - Typhim Vi®
- **Typhoid Vaccine (Typh-O) (Live Oral Attenuated Ty 21a)**
  - Vivotif®
- **Typhoid Vaccine (Typh-I) (Salmonella Typhi Vi Capsular Polysaccharide)**
  - Typherix®
- **Varicella Vaccine (Var)**
  - VARILRIX®
  - Varivax III™
- **Yellow Fever Vaccine (YF)**
  - YF-Vax™

2.0 DIAGNOSTIC, PASSIVE IMMUNIZING AND ANTITOXIN AGENTS

- **Purified (tuberculosis) Protein Derivative (PPD) (Mantoux)**
  - Tubersol®
- Immune Globulin Preparation Injection Site, Needle Length and Total Site Volume per Age Group
- **Botulism Immune Globulin**
  - BabyBIG
- **Hepatitis B Immune Globulin (HBIg)**
  - HepaGam B ™
  - HyperHEP B™ S/D
- **Immune Globulin (Ig - Intramuscular)**
  - GamaSTAN™ S/D
- **Rabies Immune Globulin (RabIg)**
  - HYPERRAB™ S/D
  - IMOGAM®
- **Tetanus Immune Globulin (TIg)**
  - HYPERTET™ S/D
- **Varicella Zoster Immune Globulin (VarIg)**
  - VariZIG™
- **Botulism Antitoxin (BAT)**
  - Botulism Antitoxin
- **Diphtheria Antitoxin (DAT)**
  - Diphtheria Antitoxin

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

#4: The Types of Immunizing Agents and Their Composition

- Competency: Applies the knowledge of the components and properties of immunizing agents as needed for safe and effective practice.

#8: Administration of Immunizing Agents

- Competency: Prepares and administers immunization agents correctly.

#11: Populations Requiring Special Considerations

- **Competency**: Recognizes and responds to the unique immunization needs of certain population groups

Cholera - E.coli (Chol-Ecol-O) [Non-publicly funded]
DUKORAL® (Valneva Canada. 2015 product monograph available at:
https://www.valneva.ca/download.php?dir=dukoral&file=Dukoral_Product_Monograph.pdf

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

INFANRIX™-IPV/Hib (GlaxoSmithKline 2017 monograph available at: http://ca.gsk.com/media/590970/infanrix-ipv-hib.pdf)

DOSE / PRIMARY SERIES [1, 2]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib-containing vaccine or to any INFANRIX™-IPV/Hib vaccine component. • Children age 5 years and older. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	Sterile suspension for injection/ not less than 25 limit of flocculation (Lf) [30 International Units (IU)] of diphtheria toxoid; 10 Lf (40 IU) of tetanus toxoid; 25 mc of pertussis toxoid; 25 mcg of filamentous haemagglutinin; 8 mcg of pertactin; 40 D-antigen units (DU) of type 1 poliovirus; 8 DU type 2 poliovirus; 32 DU type 3 poliovirus; 10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of *Haemophilus Influenzae* type B covalently bound to 25 mcg of tetanus toxoid per 0.5 mL dose. **Clinically Relevant Nonmedicinal Ingredients:** lactose, sodium chloride, aluminum adjuvant (as aluminum salts), Medium 199 (as stabilizer including amino acids, mineral salts and vitamins) and water for injection, residual formaldehyde, polysorbate 80, potassium chloride, disodium phosphate, monopotassium phosphate, glycine and trace amounts of neomycin sulphate and polymyxin B sulphate. Thimerosal and latex-free. The vial is sealed with a butyl rubber stopper. The syringes are fitted with butyl rubber plunger stoppers and tip caps.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fever, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.
EFFECTIVENESS	Following administration of the 4th dose in the second year of life, more than 99.5% of infants had tetanus and diphtheria antibody titres of > 0.1 IU/mL. Following administration of the 4th dose in the second year of life, a booster response was seen in 98.6%, 97.6% and 97.9% of vaccinated infants against pertussis antigens. Following administration of the 4th dose in the second year of life, 100% of infants were seroprotected for the three polio serotypes. One month after the 4th dose was administered in the second year of life, a Hib titre of ≥ 0.15 mcg/mL was obtained in 99.7% of all infants, and in > 98.3% of infants, a Hib titre of 1 mcg/mL was reached.

[1] Minimum age is 6 weeks.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* and administer DTaP-IPV instead of DTaP-IPV-Hib.

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

Diphtheria-Tetanus-acellular Pertussis-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-IPV-Hib)

PEDIACEL® (Sanofi Pasteur 2012 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=Pediacel_E.pdf). **PENTACEL®** 2012 monograph available from the Ministry of Health upon request.

DOSE / PRIMARY SERIES [1, 2]	**Dose 1**: 0.5 mL IM at 2 months old **Dose 2**: 0.5 mL IM at 4 months old **Dose 3**: 0.5 mL IM at 6 months old **Dose 4**: 0.5 mL IM at 18 months old [3]
REINFORCEMENT [4]	Tdap-IPV at age 4-6 years (school entry)
CONTRAINDICATIONS	• History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component. • Children age 7 years and older. • History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF1), type 3 (Saukett)] and purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein. **Excipients**: aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing process residuals**: bovine serum albumin, neomycin, polymyxin B and trace amounts of streptomycin, formaldehyde and glutaraldehyde. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, and swelling. **Systemic**: Irritability, crying, fevers greater than 38.3°C, drowsiness, decreased activity and decreased appetite, vomiting and diarrhea.
EFFECTIVENESS	One month after the third and fourth doses, no clinically significant differences were observed between the antibody responses to each of the vaccine antigens in children receiving PEDIACEL®. After the third and fourth doses, at least 97.9% of the PEDIACEL® vaccinees achieved seroprotective levels against Hib disease (anti-PRP antibody ≥ 0.15 mcg/mL), diphtheria (diphtheria antitoxin ≥ 0.01 IU/mL), tetanus (tetanus antitoxin ≥ 0.01 EU/mL) and poliomyelitis types 1, 2, and 3 (poliovirus neutralizing antibody titre ≥ 1:8). Seroconversion rates (≥ 4-fold rise) were high for each of the pertussis antibodies after the primary series. A robust booster response was observed after the fourth dose.

[1] Minimum age is 6 weeks. This vaccine is indicated for ages 6 weeks up to and including 5 years of age.

[2] If a child's immunization schedule is delayed, the child may require fewer doses of Hib vaccine. Refer to SIM, Chapter 5, *Immunization Schedules* Section 1.2, *Hib Schedule for Children Delayed by 1 Month or More* and administer DTaP-IPV instead of DTaP-IPV-Hib.

[3] If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give the 4th dose before 12 months of age.

[4] The 5th dose is not necessary if the 4th dose was given after the 4th birthday.

Diphtheria-Tetanus-acellular Pertussis-Hepatitis B-Polio-*Haemophilus influenzae* type b Adsorbed Vaccine (DTaP-HB-IPV-Hib) [Non-publicly funded]

INFANRIX hexa® (GlaxoSmithKline 2018 monograph available at: http://ca.gsk.com/media/590970/infanrix-ipv-hib.pdf)

Haemophilus influenzae type b Conjugate Vaccine (Hib)

Act-HIB® (Sanofi Pasteur 2016 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=act_hib_e.pdf)

INDICATIONS and DOSE / SERIES [1]	
1. As a component of DTaP-IPV-Hib 0.5 mL IM for children at 2, 4, 6, and 18 months of age [2]**.** **2. Children 2-59 months of age who are delayed by 1 month or more** [3] **3. People 5 years and older with the following medical conditions regardless of Hib immunization or Hib disease history:** [4] Anatomic or functional asplenia Including (sickle cell disease) [5, 7]; HIV [7]; immunosuppression related to disease [7] (e.g., congenital immunodeficiency states such as complement, properidin or factor D deficiency; malignant neoplasm including leukemia and lymphoma;) or therapy [7, 7]; candidates or recipients of solid organ or islet cell transplants [7], or cochlear implants [7]. **4. Haematopoietic stem cell transplant (HSCT) recipient** [6]	
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of a Hib-containing vaccine or to any component of Act-HIB®.
VACCINE COMPONENTS	Purified Polyribosylribitol Phosphate Capsular Polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to 18-30 ug of Tetanus Protein 10 ug, Tris (hydroxymethyl) aminomethane, sucrose, sodium chloride. Thimerosal free. The vial stoppers supplied with this product do not contain latex. The stoppers of the vials containing the diluent (0.4% saline) for reconstitution of Act-HIB® contain latex.
EXPECTED REACTIONS	**Local**: redness, tenderness, swelling, pain. **Systemic:** fever more than 38.3°C, fussiness, irritability, lethargy, loss of appetite.
EFFECTIVENESS	After 4 doses, 99% of children maintained high antibody levels at age 4- 5 years.

[1] Minimum age is 6 weeks old.

[2] The 18 months reinforcement dose at may be at as 12 months if there is an 8 week interval following the previous dose.

[3] Refer to SIM, Chapter 5 *Immunization Schedules*, section 1.2 *Hib Schedule for Children Delayed by 1 Month or More*.

[4] Refer to SIM, Chapter 7, *Immunization of Special Populations* for more information on specific conditions.

[5] Give vaccine at least 14 days prior to elective splenectomy, or if impossible, 14 days or more days post-splenectomy. If there is concern that the client may not present later for immunization, give vaccine before discharge.

[6] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant.*

[7] At least 1 year after any previous dose.

Haemophilus influenzae type b Conjugate Vaccine (Hib)

HIBERIX® (GlaxoSmithKline 2018 monograph available at http://ca.gsk.com/media/590783/hiberix.pdf)

INDICATIONS and DOSE / SERIES [1]	
1. As a component of DTaP-IPV-Hib 0.5 mL IM for children at 2, 4, 6, and 18 months of age [2]. **2. Children 2-59 months of age who are delayed by 1 month or more [3]** **3. People 5 years and older with the following medical conditions regardless of Hib immunization or Hib disease history: [4]** Anatomic or functional asplenia Including (sickle cell disease) [5, 7]; HIV [7]; immunosuppression related to disease [7] (e.g., congenital immunodeficiency states such as complement, properidin or factor D deficiency; malignant neoplasm including leukemia and lymphoma;) or therapy [7, 7]; candidates or recipients of solid organ or islet cell transplants [7], or cochlear implants [7]. **4. Haematopoietic stem cell transplant (HSCT) recipient [6]**	
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of a Hib-containing vaccine or to any component of HIBERIX®.
VACCINE COMPONENTS	10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of Hib, covalently bound to approximately 25 mcg tetanus toxoid. It also contains lactose, sodium chloride and water for injection. Diluent is sterile saline.
EXPECTED REACTIONS	**Very Common (≥10%):** pain, redness and swelling at injection site; fever. **Common (≥1-<10%):** loss of appetite, restlessness, vomiting, diarrhea and unusual crying.
EFFECTIVENESS	A titre of 0.15 mcg/mL was obtained in 95-100% of infants one month after the completion of the primary vaccination course. A titre of 0.15 mcg/mL was obtained in 100% of infants one month after the booster dose (94.7% with a titre of 10 mcg/mL).

[1] Minimum age is 6 weeks old.

[2] The 18 months reinforcement dose at may be at as 12 months if there is an 8 week interval following the previous dose.

[3] Refer to SIM, Chapter 5 *Immunization Schedules*, section 1.2 *Hib Schedule for Children Delayed by 1 Month or More*.

[4] Refer to SIM, Chapter 7, *Immunization of Special Populations* for more information on specific conditions.

[5] Give vaccine at least 14 days prior to elective splenectomy, or if impossible, 14 days or more days post-splenectomy. If there is concern that the client may not present later for immunization, give vaccine before discharge.

[6] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant.*

[7] At least 1 year after any previous dose.

Publicly Funded Hepatitis A (HA) Vaccine Indications *

- People born since Jan. 1/82 who live in the Athabasca Health Authority or on reserves in Saskatchewan (excluding Creighton, Air Ronge and La Ronge) regardless of where they access immunization services.
- Men who have sex with men.
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts of individuals who use illicit drugs.
- Case contacts 6 months and older who are identified within 2 weeks of exposure to an infectious HA case [1] (**only 1 dose is publicly funded for these individuals)**
- Non-immune individuals with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals who have liver disease (e.g., alcoholism, hepatitis C, hepatitis B, cirrhosis) who are non-immune to HA.
- Liver transplant candidates or recipients.
- Haematopoietic stem cell transplant (HSCT) recipients.

HA vaccine recommended for but not provided free: [2]

- Travellers to countries with endemic hepatitis A.
- Food handlers.
- Residents in certain institutions, such as correctional facilities and those for developmentally challenged individuals.
- Residents in communities in rural or remote areas lacking adequate sanitation or a secure supply of potable water.

[1] If a client received 1 dose of a HA-containing vaccine more than 6 months previously, provide a 2nd dose of HA vaccine.

[2] These individuals should be referred to a travel clinic, family physician, or nurse practitioner to receive non-publicly funded vaccine.

***** Previously, HIV positive individuals were deemed eligible to receive HA vaccine based on this diagnosis. If such an individual had started a HA series, the series is to be completed.

Hepatitis A Vaccine (HA) (inactivated viral)

AVAXIM® (Sanofi Pasteur 2015 monograph available at:
https://www.vaccineshoppecanada.com/document.cfm?file=avaxim_e.pdf)

AVAXIM® - Pediatric (Sanofi Pasteur 2015 monograph available at:
https://www.vaccineshoppecanada.com/document.cfm?file=Avaxim_Ped_E.pdf)

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE [1] / SERIES NOTE: Either vaccine may be used for persons between 12 to 15 years of age.	**Children 6 months up to and including 15 years of age:** **Dose 1**: AVAXIM® - Pediatric 0.5 mL IM **Dose 2**: AVAXIM® - Pediatric 0.5 mL IM 6-36 months after dose
	Persons 12 years and older: **Dose 1**: AVAXIM® 0.5 mL IM **Dose 2**: AVAXIM® 0.5 mL IM 6-36 months after dose
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine or to any AVAXIM® vaccine components.
VACCINE COMPONENTS	Inactivated hepatitis A virus, (GBM strain) 2-phenoxyethanol, formaldehyde, aluminum hydroxide (expressed as aluminum), Medium 199 Hanks in water for injection, polysorbate 80, traces of neomycin. Latex and thimerosal free.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Pain and redness at injection site. **Systemic:** Weakness, myalgia/arthralgia, headache, gastrointestinal symptoms and mild fever.
EFFECTIVENESS	In clinical studies involving over 1,000 volunteers, specific humoral antibodies against hepatitis A were elicited after the first injection and more than 90% of immunocompetent subjects were protected (titres above 20 mIU/mL) 14 days after vaccination. One month after the first injection, 100% of the subjects were protected. Immunity persisted for at least 36 months and was reinforced after a first booster dose.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A Vaccine (HA) (inactivated viral)

HAVRIX® (for Havrix® 1440 and Havrix® 720 Junior) (GlaxoSmithKline 2017 monograph available at**: http://ca.gsk.com/media/590706/havrix.pdf)**

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1]	**Children 6 months up to and including 18 years of age:** • **USE HAVRIX® pediatric presentation of 720 ELU per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Adults 19 years and older: • **USE HAVRIX® adult presentation of 1440 ELU per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1 [2]
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, or to any HAVRIX® vaccine components.
VACCINE COMPONENTS	HAVRIX® 1440 contains: 1440 ELISA units per 1.0 mL of formaldehyde inactivated hepatitis A virus (HM175 hepatitis A virus strain); HAVRIX® 720 Junior contains: 720 ELISA units per 0.5 mL of formaldehyde inactivated hepatitis A virus (HM175 hepatitis A virus strain); formaldehyde, aluminum hydroxide, amino acids, disodium phosphate, monopotassium phosphate, neomycin sulphate, potassium chloride, polysorbate 20, bovine serum albumin.
EXPECTED REACTIONS	Tend to be mild and transient. **Local:** Soreness and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product**.**

[2] In SK, all eligible adult recipients must receive 1440 ELU for each publicly funded dose, even though studies show that 720 ELISA units may provide an effective 2nd HA dose in adults.

Hepatitis A Vaccine (HA) (purified inactivated viral)

VAQTA® (Merck Frosst 2013 monograph available at: https://www.merck.ca/static/pdf/VAQTA-PM_E.pdf)

INDICATIONS	**Refer to publicly funded HA vaccine indications**
DOSE / SERIES [1]	**Eligible children 6 months up to and including 17 years:** • **USE VAQTA® pediatric presentation of 25U per 0.5 mL** **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 6-12 months after dose 1
	Eligible adults 18 years and older: • **USE VAQTA® adult presentation of 50U per 1 mL** **Dose 1**: 1 mL IM **Dose 2**: 1 mL IM 6-12 months after dose 1
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of an anaphylactic reaction to a previous dose of any HA vaccine, to any VAQTA® vaccine components, or to latex (vials).
VACCINE COMPONENTS	Aluminum hydroxyphosphate sulfate, sodium borate, neomycin, bovine albumin, formaldehyde. Latex in vial stopper.
EXPECTED REACTIONS	**Local:** Soreness and redness at injection site. **Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms.
EFFECTIVENESS	Protective serum antibody levels in 95-100% of people within 4 weeks of immunization.

[1] HA vaccines are interchangeable for any scheduled dose for children and adults, using the age-specific dosage for the particular product.

Hepatitis A and B Vaccine (combined) [Publicly funded for selected populations [2]]

TWINRIX® and TWINRIX® Junior (GlaxoSmithKline 2016 product monograph available at: http://ca.gsk.com/media/592047/twinrix.pdf)

INDICATIONS	Refer to publicly funded HA and HB vaccine indications
DOSE / SERIES [1] ***5 months is required between dose 2 and dose 3.**	**Children 6 months up to and including 18 years:** **USE Twinrix® Junior formulation (360 Elisa units HA/10 mcg HB per 0.5 mL)** • 0.5 mL IM at 0, 1 and 6 months*
	Alternate schedule for children 6 months up to and including 15 years: **USE Twinrix® adult formulation (720 Elisa units HA/20 mcg HB per 1.0 mL)** • 1.0 mL IM at 0 and 6 – 12 months
	Adults 19 years and older: **USE Twinrix® adult formulation (720 Elisa units HA/20 mcg HB per 1.0 mL)** • 1.0 mL IM at 0, 1 and 6 months*
	Rapid dosing for adults 19 years and older: **USE Twinrix® adult formulation (720 Elisa units HA/20 mcg HB per 1.0 mL)** • 1.0 mL IM at 0, day 7, day 21 and 12 months
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B-containing vaccine, to any component of any Twinrix® vaccine formulation, or to latex as the manufacturer cannot guarantee that the product packaging formats do not contain latex.
VACCINE COMPONENTS	Purified, inactivated hepatitis A (HA) virus and purified hepatitis B surface antigen (HBsAg). **Excipients**: aluminum hydroxide, aluminum phosphate, sodium chloride and water for injection. **Residues:** amino acids for injection, formaldehyde, neomycin sulphate and polysorbate 20. May contain traces of yeast. Prefilled syringes have rubber stoppers. Thimerosal and preservative free.
EXPECTED REACTIONS	**Very common (≥ 10%)**: Pain and redness at injection site in children and adults; headache in adults. **Common (≥ 1-<10%)**: Adults report gastrointestinal symptoms and swelling at injection site and malaise. Children report headache, drowsiness, loss of appetite, irritability, gastrointestinal symptoms, fever (≥37.5°C) and fatigue and malaise.
EFFECTIVENESS	**Standard 3-dose schedule:** Anti-HAV in adults and children: 100% 1 mo. after 3rd dose. Anti-HBV in adults and children: ~ 100% 1 mo. after 3rd dose.

[1] If a client is to be given monovalent HA vaccine in place of a dose (or doses) of Twinrix®/Twinrix® Junior, the age-specific doses and dosages of following vaccines may be used: HAVRIX® VAQTA® or AVAXIM®. If a client is to be given monovalent HB vaccine in place of a dose (or doses) of Twinrix®/Twinrix® Junior, the age-specific doses and dosages of following vaccines may be used: Engerix-B® or Recombivax® HB.

[2] HAHB vaccines may be used for the following high risk clients who are HA and HB non-immune and don't require a higher dose of HB vaccine: chronic liver disease; bleeding disorders; some transplant recipients. Check with a MHO for further information if required.

Hepatitis A and Typhoid (HA-Typh-I) (combined purified vi polysaccharide typhoid and inactivated hepatitis A vaccine) [Non-publicly funded]
ViVAXIM® (Sanofi Pasteur 2015 product monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=vivaxim_e.pdf)

Publicly Funded Hepatitis B (HB) Vaccine Indications [1, 4]

- Those born since January 1, 1984.
- Grade 6 students.
- Children of immigrants to Canada from regions of intermediate or high HB prevalence.
  - This includes all children born before the family's arrival in Canada **and** all children born after the family's arrival in Canada.
  - Go to map at: http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/hepatitis-b#4621
- RHA/SCA/FNJ Healthcare workers and healthcare students (refer to SIM chapter 7 for definition).
- Those who started a publicly funded series in another jurisdiction.
- Non-immune individuals with bleeding disorders and others who receive repeated infusions of blood or blood products or plasma-derived replacement clotting factors.
- Individuals who are HIV positive who are non-immune to HB.
- Individuals who have liver disease (e.g., alcoholism, hepatitis C, cirrhosis) who are non-immune to HB.
- Individuals with renal disease (predialysis, hemodialysis & peritoneal dialysis) who are non-immune to HB [3].
- Liver or kidney transplant candidates or recipients who are non-immune to HB [2].
- Haematopoietic stem cell transplant (HSCT) recipients [2].
- Household/sexual/close contacts of individuals who have an acute or chronic HB infection [6].
  - Includes children in a child care setting in which there is an HB infected individual.
- Males and females with multiple sexual partners.
- Men who have sex with men
- Individuals that use or share illicit drug snorting, smoking or injection equipment.
- Sexual partners and household contacts of individuals who use illicit drugs.
- Group home residents
- Provincial correctional facility residents.
- Infant born to a HBsAg+ mother or high-risk mother whose HB status at delivery is unknown and STAT test results cannot be obtained within 12 hours after delivery [5, 7].
- Percutaneous (e.g., needle stick, bite) or mucosal exposure (e.g., sexual assault) [4, 6, 7].

HB vaccine recommended for but not provided free: [8]

- Travellers to countries with endemic hepatitis B.
- Non-healthcare workers who have an occupational risk of exposure.

[1] Most SK residents born since 1984 would have received routine HB vaccine in grade 6. If records are unavailable and the client does not recall receiving HB series, proceed with HB vaccine as per indication.

[2] Refer SIM, Chapter 7, *Immunization of Special Populations* for specific medical conditions.

[3] Individuals with chronic kidney disease require specific HB vaccine dosages and series. Refer SIM, Chapter 7, *Immunization of Special Populations,* Appendix 7.4: *Hepatitis B Immunization Algorithm for Clients with Chronic Kidney Disease*.

[4] Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to SIM, *Chapter 7, Immunization of Special Populations, Section 4.2.1, Hepatitis B Infant Immunoprophylaxis Protocol.*

[6] Must present within 14 days of sexual assault.

[7] Post-vaccination testing should be performed no sooner than 1 month after completion of HB vaccine series.

[8] These individuals should be referred to a travel clinic, family physician, or nurse practitioner to receive non-publicly funded vaccine

Hepatitis B Vaccine - Immigrant Populations Ineligibility List

Immigrants from the countries listed in this table **DO NOT** qualify for publicly funded hepatitis B vaccine because their chronic hepatitis B prevalence is <2%. **Immigrants from all other countries are eligible for publicly funded HB vaccine.**

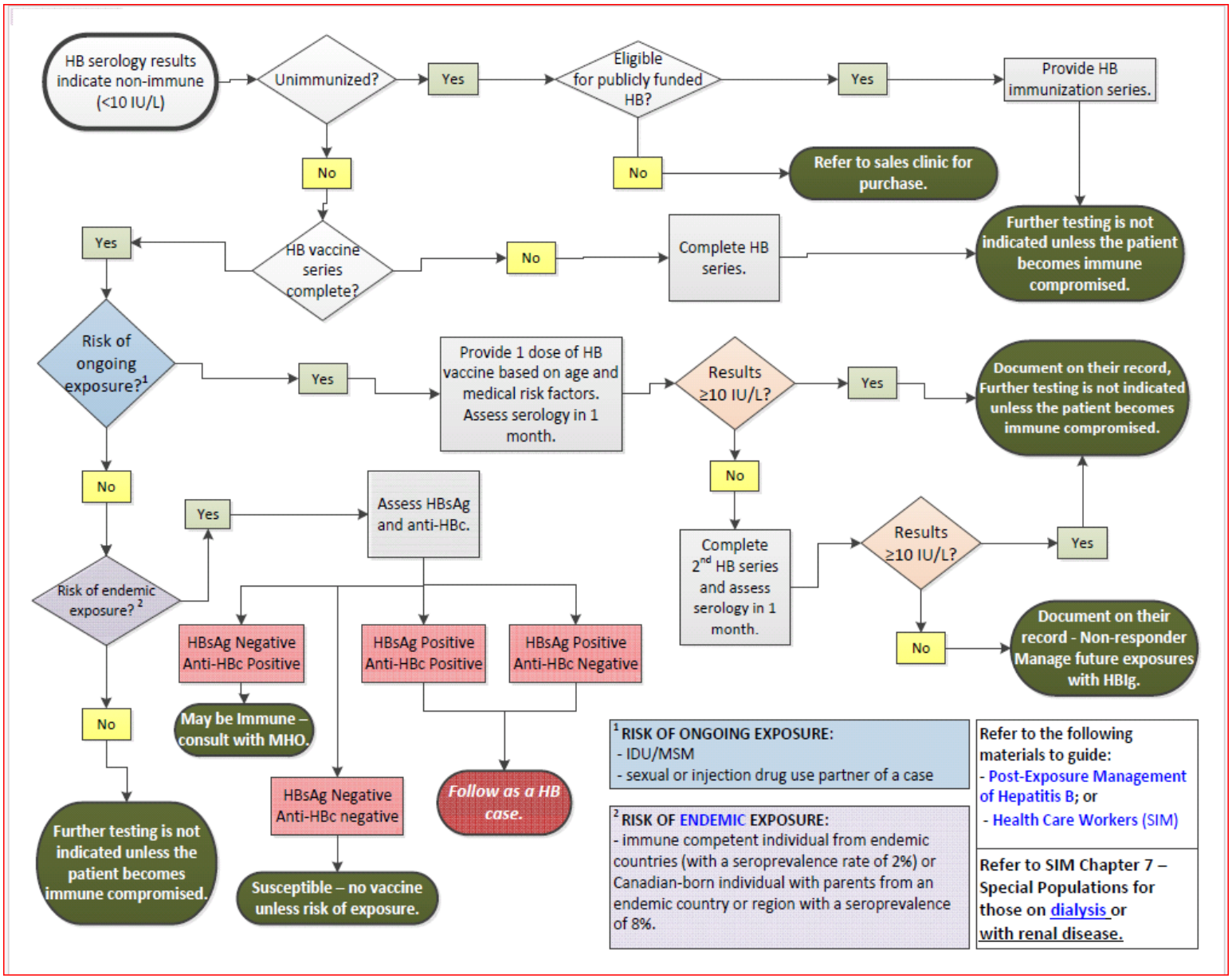
Afghanistan	Dominica	Japan	Poland
Belgium	Egypt	Jordan	Portugal
Andorra	Estonia	Latvia	Puerto Rico
Argentina	Finland	Lithuania	Slovakia
Australia	France	Luxembourg	Slovenia
Austria	French Guiana	Macedonia	Spain
Bahamas	Germany	Malaysia	St. Kitts
Barbados	Greece	Malta	St. Vincent
Belize	Grenada	Mexico	Sweden
Bolivia	Grenadines	Monaco	Switzerland
Bosnia	Guatemala	Montenegro	Trinidad
Brazil	Herzegovina	Morocco	Tobago
British Isles	Hungary	Nepal	Ukraine
Chile	Iceland	Netherlands	United Kingdom
Costa Rica	India	Nevis	Uruguay
Croatia	Indonesia	Nicaragua	USA
Cuba	Iran	Norway	Venezuela
Czech Republic	Iraq	Panama	Poland
Denmark	Ireland	Paraguay	Portugal

Hepatitis B Re-Vaccination Assessment Algorithm

This algorithm provides guidance in determining if vaccination is required in individuals that were tested for Hepatitis B immunity for no specific reason and have been assessed as non-immune for Hepatitis B.
This algorithm should be used in conjunction with the eligibility criteria in Chapter 10.

This algorithm does not supersede Chapter 7 – dialysis patients; Chapter 10 – health care workers; or Post-exposure management of Exposures to Hepatitis B as outlined in the CDC Manual or the Guidelines for Exposures to Blood and Body Fluids or testing for Hepatitis B due to clinical suspicion

Ref: http://www.phac-aspc.gc.ca/publicat/hep/hbv-vhb/index-eng.php.



HEPATITIS B VACCINE DOSAGE AND FORMULATION OPTIONS FOR HIV INFECTED ADULTS AND CHILDREN

Table 1: 40 µg HB Vaccine Options for HB Non-Immune HIV Infected Adults (≥18) [1, 2, 3, 4]

	Recommended Schedule ("0-1 months-2 months-6 months")		
1. Recombivax® HB single-dose 40 µg/mL IM; **OR** 2. 2 IM doses of ENGERIX®-B single-dose 20 µg/mL [5]; **OR** 3. 4 IM doses of Recombivax® HB single-dose 10 µg/mL [5]	Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4
	4 weeks	4 weeks	16 weeks

[1] RecombivaxHB and Engerix-B vaccines are interchangeable.

[2] Adults who are infected with HIV are eligible to receive a 4-dose 40 µg IM HB vaccine series as their primary and/or secondary series.

[3] Adults infected with HIV who have commenced a non-40µg dose HB immunization series should receive their remaining doses as 40 µg/mL doses to complete a 4-dose schedule.

[4] Adults infected with HIV whose HB titres are inadequate after completing a primary 40 µg HB immunization series should receive 1 additional 40 µg dose of HB vaccine and be retested 1 to 6 months later to assess if completion of a second HB series is required.

- If their antibodies are < 10 IU/L, all 40 µg doses in an appropriate second series are to be administered and they should be retested not less than four weeks later to assess if their titres are protective.
- If the individual continues to have titres < 10 IU/L, they must be told that they are non-responders and made aware that they are at risk of HB infection upon exposure. Their immunization record must state that they are non-responders to 2 (40 µg) HB vaccine series.

[5] Given at separate sites or separated by 2.5 cm (1 inch) if given in the same limb

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Table 2: Double Dose HB Vaccine Options for HB Non-Immune HIV Infected Children Aged Birth up to and Including 17 Years [1, 2, 3, 4]

	Recommended Schedule ("0-1 months-6 months")	
1. 2 IM doses of Engerix-B pediatric presentation 10 µg /0.5 mL [5] • **OR** 1 IM dose of adult presentation 20 µg /1 mL 2. 2 IM doses of Recombivax HB pediatric presentation 5 µg /0.5 mL [5] • **OR** 1 IM dose of adult presentation 10 µg /1 mL	Dose 1 to Dose 2	Dose 2 to Dose 3
	4 weeks	20 weeks

[1] RecombivaxHB and Engerix-B vaccines are interchangeable

[2] Children infected with HIV are eligible to receive a 3-dose double dose IM HB series as their primary and/or secondary series.

[3] Children infected with HIV who have commenced a non-double dose HB immunization series should receive their remaining doses as double µg doses to complete the 3-dose series.

[4] Children infected with HIV whose HB titres are inadequate after completing a primary double µg HB immunization series should receive 1 additional double µg dose of HB vaccine and be retested 1 to 6 months later to assess if completion of a second HB series is required.

- If their antibodies are < 10 IU/L, all double µg doses in an appropriate second series are to be administered and they should be retested not less than four weeks later to assess if their titres are protective.
- If the individual continues to have titres < 10 IU/L, they must be told that they are non-responders and made aware that they are at risk of HB infection upon exposure. Their immunization record must state that they are non-responders to 2 (double µg) HB vaccine series.

[5] Given at separate sites or separated by 2.5 cm (1 inch) if given in the same limb.

Hepatitis B Series Completion Recommendations for Children Presenting at 11-15 Years Old (applies to those 10 years who are currently in Grade 6)

If a student has an incomplete HAHB series:

1. The PHN should recommend completion of the original HAHB series [1].
2. If parent wishes to complete HB only, follow the Saskatchewan Committee on Immunization's (SCOI) recommendations for the appropriate scenario [2].

#	Historical (Valid) Dose(s) & Vaccine(s)	Dosing Recommendations / Comments
1	1) HAHB 0.5 ml at ≥ 6 months old	2) HB 0.5 ml min. 4 weeks later; then 3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
2	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
3	1) HAHB 0.5 ml at ≥ 6 months old 2) HAHB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HAHB & 3rd HB.
4	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
5	1) HAHB 0.5 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
6	1) HAHB 1 ml at ≥ 6 months old	2) HB 1.0 ml ≥ 24 weeks (min. 16 weeks) later.
7	1) HAHB 1 ml at ≥ 6 months old 2) HB 0.5 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
8	1) HAHB 1 ml at ≥ 6 months old 2) HB 1 ml min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HAHB **&** 3rd HB.
9	1) HB 0.5 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
10	1) HB 0.5 ml at any age 2) HAHB 1 mL at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HAHB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
11	1) HB 1 ml at any age 2) HAHB 0.5 ml at ≥ 6 months old, min. 4 weeks later	3) HB 0.5 ml min. 8 weeks later from 2nd HB. There must be min. 16 weeks between 1st HB **&** 3rd HB.
12	1) HB 1 ml at any age 2) HAHB 1 mL at ≥ 6 months old, min. 16 weeks later	**Considered complete** (CIG HB Table 3).

[1] If completing with HAHB, document HB refusal. Document in Comments: "Parent intends to complete HAHB to complete series."

[2] Document consent grant. Document in Client Warning: "Parent requests to complete HB series."

Hepatitis B Completion Scenarios (excluding children 11-15 years old)

- If a client was immunized by **Public Health in Saskatchewan**, SIM chapter 1, *Appendix 5.1 School Immunization Programs* **may be** consulted to determine the HB series the client was eligible for.
- If a client's documented immunization record does not show the HB-containing vaccine volumes **and** the client **was not immunized by Public Health in Saskatchewan** for previous doses in which a minimum 3-dose series has not been completed, it is recommended that:
  - 0.5 mL HB doses are administered to clients younger than 20 years of age at appropriate intervals to complete a 3-dose series.
  - 1 mL HB doses are administered to clients 20 years of age and older at appropriate intervals to complete a 3-dose series.
- **PHNs are to consult their regional MHO for case-by-case determination** before contacting the Ministry.

Scenario A: Client originally started on a 2-dose series when 11-15 years (or at 10 years old and in Grade 6):

#1 Q – A client between 16-19 years of age needs to complete the HB series. They received their first dose (1 mL) of a two dose series in grade 6, when they were between 11-15 years of age. How should their series be completed?
#1 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 0.5 mL IM HB vaccine then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#2 Q – A client aged ≥ 20 years needs to complete the HB series. They received their first dose (1 mL) of a two dose series in grade 6, when they were between 11-15 years of age. How should their series be completed?
#2 A – If the minimum interval of 4 weeks has passed since the first dose, and based on their age at this presentation, their schedule is complete when the get:

- A 2nd dose of 1 mL IM HB vaccine then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Scenario B: Client originally started on a 3-dose series of 0.5 mL

#3 Q – A client received their first and/or second dose(s) of 0.5 mL between 0-19 years, and presents between ages 0-19. How should the series be completed?
#3 A – Complete the series with 0.5 mL IM for each outstanding dose.

- A 2nd dose of 0.5 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 0.5 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

#4 Q – If client received first and/or second dose of 0.5 mL dose between 0-19 years and presents ≥ age 20 years or older. How should their series be completed?
#4 A – Complete the series with 1 mL IM for each outstanding dose.

- A 2nd dose of 1 mL IM HB vaccine 4 weeks later (if required) then;
- A 3rd dose of 1 mL IM HB vaccine 8 weeks after the second dose and at least 16 weeks after dose 1.

Hepatitis B Vaccine (recombinant viral)

ENGERIX®-B (GlaxoSmithKline 2015 monograph available at: http://ca.gsk.com/media/590068/engerix-b.pdf)

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4]	**Children from birth up to and including 19 years old:** • **USE ENGERIX-B pediatric formulation 10 mcg per 0.5 mL** 0.5 ml IM (10 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including grade 6 students younger than 11 years old): • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** **Dose 1**: 1 mL (20 mcg) IM **Dose 2**: 1 mL (20 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE ENGERIX-B adult formulation 20 mcg per 1 mL** 1 ml (20 mcg) IM at 0, 1 and 6 months
	• **For HIV infected persons, refer to: Hepatitis B Vaccine Dosage and Formulation Options for HIV Infected Adults and Children**
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of Engerix-B.
VACCINE COMPONENTS	Each 1.0 mL adolescent/adult dose of vaccine contains 20 mcg of hepatitis B surface antigen adsorbed onto 0.5 mg of Al3+ as aluminum hydroxide. Each 0.5 mL pediatric dose contains 10 mcg of hepatitis B surface antigen adsorbed onto 0.25 mg of Al3+ as aluminum hydroxide. Latex free. Rubber stoppers.
EXPECTED REACTIONS	**Local:** Soreness and redness at injection site. **Systemic:** Headache, fatigue, fever, and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RecombivaxHB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Renal disease clients require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Immunization of Special Populations*, Section 2.12, *Renal Disease*.

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol*.

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

Hepatitis B Vaccine (recombinant)

RECOMBIVAX HB® (Merck Frosst 2012 monograph available at: https://www.merck.ca/static/pdf/RECOMBIVAX_HB-PM_E.pdf)

INDICATIONS	Refer to publicly funded HB vaccine indications
DOSE / SERIES [1, 2, 3, 4]	**Eligible children from birth up to and including 19 years:** • **USE RECOMBIVAX® HB pediatric formulation 5 mcg per 0.5 mL** 0.5 ml IM (5 mcg) at 0, 1 and 6 months[5] or refer to minimum intervals in Ch. 5.
	2-dose regimen for adolescents 11 to 15 years of age (including grade 6 students younger than 11 years old): • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** **Dose 1**: 1 mL (10 mcg) IM **Dose 2**: 1 mL (10 mcg) IM 6 months after dose 1
	Eligible adults 20 years and older: • **USE RECOMBIVAX ® HB adult formulation 10 mcg per 1 mL** 1 mL (10 mcg) IM at 0, 1 and 6 months
	• **For HIV infected persons, refer to: Hepatitis B Vaccine Dosage and Formulation Options for HIV Infected Adults and Children**
REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of RECOMBIVAX® HB.
VACCINE COMPONENTS	Hepatitis B surface antigen. **Excipients:** Amorphous aluminum hydroxyphosphate, sodium chloride, sodium borate. May contain trace amounts of formaldehyde, yeast protein. Thimerosal free. Latex in vial stopper.
EXPECTED REACTIONS	**Local:** Soreness and redness at injection site. **Systemic**: Headache, fatigue, fever, and malaise.
EFFECTIVENESS	50-99% response-varies with age and immunocompetence.

[1] Engerix®-B & RECOMBIVAX HB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the particular product.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 2.1, *Minimum Intervals for Specific Vaccine Series* for minimum interval scheduling.

[3] Renal disease clients require a specific HB vaccine dosage and series; refer to SIM, Chapter 7, *Special Populations,* Section 2.12, *Renal Disease.*

[4] High risk infants less than 2000 g require 4 dose series. Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol.*

[5] Infant must be at least 24 weeks of age to receive 3rd dose.

Herpes Zoster Vaccine (Zos) (non-live recombinant, AS01$_B$ adjuvanted) [Non-publicly funded]
Shingrix™ (GSK 2017 monograph available at: http://ca.gsk.com/media/1350788/shingrix_pm-2017-10-13.pdf)

Herpes Zoster Vaccine (Zos) (live attenuated viral) [Non-publicly funded]

ZOSTAVAX ® II (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/ZOSTAVAX_II-PM_E.pdf)

Human Papillomavirus Vaccine (HPV-2) [Non-publicly funded]

CERVARIX® (GlaxoSmithKline 2014 monograph link available at: http://gsk.ca/english/docs-pdf/product-monographs/Cervarix.pdf)

Human Papillomavirus 4-valent Vaccine (HPV-4) (recombinant) [not publicly funded]

GARDASIL® (Merck Frosst 2015 monograph available at:
https://www.merck.ca/static/pdf/GARDASIL-PM_E.pdf

Human Papillomavirus 9-valent Vaccine (HPV-9) (recombinant)

GARDASIL®9 (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf)

INDICATIONS	• Females born since January 1, 1996 who are either currently in grade 6 **or** who did not receive or complete a series when in grade 6 • Males who are currently in Grade 6 OR males born since Jan. 1, 2006 or males who did not receive or complete series when in grade 6 (2017/18 school year start date). • Immunocompromised females and males aged 9 up to and including 26 years of age (ineligible at 27th birthday).
SERIES **----------Note: immune compromised individuals must always receive a 3-dose HPV series.**	• **2-dose schedule**: 0.5 mL IM at 0 and 6 months for those 11 to 14 years of age o A student who received their first HPV dose before their 15th birthday is eligible to complete the 2-dose schedule in the future as long as 6 months has passed since their first dose. • **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months for eligible immune competent persons ≥15 years of age up to and including 26 years of age (ineligible at 27th birthday). ---------- • **3-dose schedule**: 0.5 mL IM at 0, 2, and 6 months for females and males aged 9 up to and including 26 years of age with the following risk factors (ineligible at 27th birthday). **NOTE: Birth cohort eligibility (as described above under Routine Indication) does not apply to these risk factors; age at presentation applies.** o Immunocompromised – Acquired complement deficiency o Immunocompromised – Congenital immunodeficiency o Immunocompromised – HIV o Immunocompromised – Related to Disease o Immunocompromised – Treatment - Specify
REINFORCEMENT	Currently no recommendations.
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of a HPV vaccine, or to any component of GARDASIL®9. 2. Pregnancy [1]. The vaccine should not be given during pregnancy because safety of receipt of HPV vaccine during pregnancy has not been adequately studied. Women who become pregnant before series completion should defer immunization until no longer pregnant. In pregnant women who are inadvertently vaccinated, there is no need to consider any intervention except reassurance, as the vaccine has not been associated with teratogenicity.
VACCINE COMPONENTS	Each 0.5-mL dose contains approximately 30 mcg of HPV Type 6 L1 protein, 40 mcg of HPV Type 11 L1 protein, 60 mcg of HPV Type 16 L1 protein, 40 mcg of HPV Type 18 L1 protein, 20 mcg of HPV Type 31 L1 protein, 20 mcg of HPV Type 33 L1 protein, 20 mcg of HPV Type 45 L1 protein, 20 mcg of HPV Type 52 L1 protein, and 20 mcg of HPV Type 58 L1 protein, approximately 500 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant), 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, 9.56 mg of sodium chloride, and water for injection. Latex and thimerosal free.
EXPECTED REACTIONS	**Local:** Mild to moderate pain, swelling, and redness at injection site. **Systemic:** Headache, tiredness, fever.
SPECIAL CONSIDERATIONS	Sexually active vaccine recipients should be routinely screened for genital cancers as indicated.

Human Papillomavirus 9-valent Vaccine (HPV-9) (recombinant) **GARDASIL®9** (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf)	
EFFECTIVENESS	Girls and Boys 9 through 15 Years of Age An extension study of 614 girls and 565 boys 9 through 15 years of age at enrollment who were randomized to vaccination with GARDASIL actively followed subjects for endpoint cases of HPV 6-, 11-, 16-, or 18-related persistent infection, CIN (any grade), AIS, VIN, VaIN, cervical cancer, vulvar cancer, vaginal cancer, and external genital lesions from the initiation of sexual activity or age 16 onwards. An interim analysis of the per-protocol effectiveness population included 246 girls and 168 boys who completed the GARDASIL vaccination series within one year, were seronegative to the relevant HPV type at initiation of the vaccination series, and had not initiated sexual activity prior to receiving the third dose of GARDASIL. The median follow-up from the first dose of vaccine was 7.2 years with a range of 14 0.5 to 8.5 years. At the time of interim analysis, no cases of persistent infection of at least 12 months' duration and no cases of HPV 6-, 11-, 16-, or 18-related CIN (any grade), AIS, VIN, VaIN, cervical cancer, vulvar cancer, vaginal cancer, or external genital lesions were observed over a total 1,105 person-years at risk. There were 4 cases of HPV 6-, 11-, 16-, or 18-related persistent infection of at least 6 months' duration, including 3 cases related to HPV 16 and 1 case related to HPV 6, none of which persisted to 12 months' duration.

[1] Pregnant women exposed to GARDASIL® are encouraged to report their exposure or suspected adverse reactions by contacting Merck Canada Inc., at 1-800-567-2594 or the Vaccine Safety Section at Public Health Agency of Canada at 1-866-844-0018 or www.phac-aspc.gc.ca/im/vs-sv/index-eng.php.

Immunization Recommendations for Children 4-6 years of Age [1,2,3]

Immunization History Doses received prior to 4th birthday [2, 3]	4 years old[7] (48 to 59 months of age)	5 or 6 years old[7] (60 to 83 months of age)
0 valid DTaP-IPV-Hib	Give 4 DTaP-IPV-Hib at appropriate intervals.	
1 valid DTaP-IPV-Hib	Give 3 DTaP-IPV-Hib at appropriate intervals.	
2 valid DTaP-IPV-Hib or DTaP-IPV [4]	Give 2 DTaP-IPV-Hib at appropriate intervals.	
3 valid DTaP-IPV-Hib or DTaP-IPV [4]	Give 1 DTaP-IPV-Hib at appropriate interval.	
4 valid DTaP-IPV-Hib or DTaP-IPV [4]	Give 1 Tdap-IPV at appropriate interval. [5, 6]	
Medically HR child	Follow above recommendations	Follow above recommendations, administering additional doses of Hib if required.

[1] Panorama Forecaster for 4-6 year olds **may be affected** as it expects this age group to have specific doses of D and aP antigens to be up to date (UTD). **Remember that Panorama is only a scheduling tool and cannot replace clinical assessment of valid doses and appropriate vaccine/antigen administration.**

[2] Additional doses of Hib are not a concern. If an extra safe dose (ESD) of Hib shows as invalid but a valid dose has been received at or after 15 months of age, child is UTD for this antigen.

[3] Addition doses of IPV are not a concern. If an extra safe dose (ESD) of polio shows as invalid but dosing intervals have been respected, do not override.

[4] Historical doses may be DTaP-IPV-Hib or a combination of DTaP-IPV-Hib and DTaP-IPV. Child must have received at least 1 dose of Hib at or after 15 months.

[5] In the event that the Forecaster indicates that this dose is invalid, do not override to valid as future forecasting may be affected. Add a note in the comment section indicating that dose is considered valid.

[6] Tdap-IPV is intended as the 5th dose for these antigens. There must be 4 valid "D" and "aP or wP" antigens in history.

[7] If a child younger than 7 has received a Tdap-IPV for any of the first four doses of the tetanus-containing vaccines, provide another dose of DTaP-IPV Hib at appropriate interval, for optimum protection. (Rationale is the child did not receive sufficient diphtheria or pertussis antigen amount with Tdap-IPV).

Non-Publicly Funded Influenza Vaccines 2018-19

AFLURIA® TETRA Sequiris 2018 product monograph: https://www.seqirus.ca/docs/4/275/1.3.1%20AFLURIA%20TETRA_PM_Canada_approved%2022%20Feb%202018.pdf

AGRIFLU™ Sequiris 2018 product monograph: Not yet available

INFLUVAC® BGP Pharma 2019 product monograph: Not yet available

FLUVIRAL® GSK 2018 product monograph: Not yet available

FLUAD™ and **FLUAD™ Pediatric** Sequiris 2018 product monograph: Not yet available

FLUMIST® QUADRAVALENT AstraZeneca Canada 2018 Product monograph: https://www.astrazeneca.ca/content/dam/az-ca/downloads/productinformation/flumist-qlaiv-product-monograph-en.pdf

Influenza Vaccine (Inf) (inactivated split virion)

FLULAVAL TETRA® GlaxoSmithKline 2017 product monograph available at:
http://ca.gsk.com/media/590283/flulaval-tetra.pdf

INDICATION	**DOSE / SERIES**		
Prevention of seasonal influenza	**Age group**	**Dosage**	**No. of Doses**
	6 months-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine. 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	• Severe oculo-respiratory syndrome (ORS) after a previous dose of influenza vaccine.		
VACCINE COMPONENTS	Each dose of 0.5 mL of FLULAVAL TETRA ® contains 15mcg HA of: A/Michigan/45/2015 X-275 (H1N1)pdm09-like strain, A/Hong Kong/4801/2014 X-263B (H3N2)-like strain, B/Phuket/3073/2013-like strain and B/Brisbane/60/2008-like strain. The vaccine is formulated with phosphate buffered saline composed of: sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate and water for injection. Each 0.5-mL dose contains, α-tocopheryl hydrogen succinate (267 mcg), and polysorbate 80 (683 mcg). Each 0.5-mL dose may also contain residual amounts of egg proteins (ovalbumin $\leq$0.3 mcg), sodium deoxycholate, ethanol, formaldehyde and sucrose from the manufacturing process. Thimerosal, a mercury derivative, is added as a preservative. Each 0.5-mL dose contains 50 mcg thimerosal (<25 mcg mercury). Antibiotics are not used in the manufacture of this vaccine. The vial stopper does not contain latex.		
EXPECTED REACTIONS	**Very common (≥10%)**: pain and redness at the injection site, headache, fatigue, and myalgia. **Common (≥1% to <10%)**: swelling at the injection site, fever, chills, malaise, chest tightness, arthralgia, red eyes, sore throat, and cough.		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Discard multi-dose vials 28 days after first entry. Protect from light.		
EFFECTIVENESS	The humoral immune response was assessed in terms of a serum haemagglutinin-inhibiting (HI) antibody titer against each virus strain included in the Q-QIV vaccine. In adult studies the immune response was assessed 21 days following vaccination. In pediatric studies, the immune response was assessed 28 days following the last vaccination.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Influenza High Dose Vaccine (InfHD) (inactivated trivalent split virion)

FLUZONE® High Dose Sanofi Pasteur 2018 product monograph:
https://www.vaccineshoppecanada.com/document.cfm?file=fluzone_hd_e_2018.pdf

INDICATION	Prevention of seasonal influenza in long-term care residents ≥ 65 years old
DOSE / SERIES	0.5 mL IM annually. Shake the prefilled syringe well to uniformly distribute the suspension before administering the dose.
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Those younger than 65 years old.
PRECAUTIONS	• Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.
VACCINE COMPONENTS	FLUZONE® High Dose contains 60 mcg HA A/Michigan/45/2015 X-275 (H1N1)pdm09-like strain, A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2)-like strain and B/Colorado/6/2017-like strain (B/Maryland/15/2016 BX-69A). Each dose: ≤100 mcg formaldehyde, up to 0.5 mL sodium phosphate buffered, isotonic sodium chloride solution and ≤250 mcg Triton® X-100. Latex, antibiotic, thimerosal and gelatin free.
EXPECTED REACTIONS	Injection site: Pain 35.6%, erythema 14.9% and swelling 8.9% in study recipients. Systemic: Myalgia 21.4%, malaise 18%, headache 16.8 % and fever 3.6% in study recipients.
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.
SPECIAL CONSIDERATIONS	Protect vials from light. A multidose vial of FLUZONE® Quadrivalent which has been entered and stored at 2° to 8° C may be used up to the expiry date indicated on the vial label.
EFFECTIVENESS	Refer to product monograph for various immunogenicity data.

Influenza Vaccine (Inf) (inactivated quadrivalent split virion)

FLUZONE® Quadrivalent Sanofi Pasteur 2018 product monograph available at:
hhttps://www.vaccineshoppecanada.com/document.cfm?file=fluzone_qiv_e_2018.pdf

INDICATION	**DOSE / SERIES (Min. 6 months old)**		
Prevention of seasonal influenza	**Age group**	**Dosage**	**No. of Doses**
	6 months-8 years	**0.5 mL**	**1 or 2** [1]
	9 years and older	**0.5 mL**	**1**
CONTRA-INDICATIONS	1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine 2. History of anaphylactic reaction to any component of any influenza vaccine. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified. 4. Infants less than 6 months of age.		
PRECAUTIONS	• Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine.		
VACCINE COMPONENTS	FLUZONE® Quadrivalent contains 15 mcg HA of A/Michigan/45/2015 X-275 (H1N1)pdm09-like strain, A/Singapore/INFIMH-16-0019/2016 IVR-186 (H3N2)-like strain, B/Phuket/3073/2013-like strain and B/Colorado/6/2017-like strain (B/Maryland/15/2016 BX-69A). Each 0.5 mL dose: ≤100 mcg formaldehyde, up to 0.5 mL sodium phosphate buffered, isotonic sodium chloride solution and ≤250 mcg Triton® X-100. 0.01% w/v thimerosal in multidose presentation only (25 mcg mercury/0.5 mL dose). Latex, antibiotic and gelatin free.		
EXPECTED REACTIONS	**Very common (≥10%)**: pain and redness at the injection site, headache, fatigue, and myalgia. **Common (≥1% to <10%)**: swelling at the injection site, fever, chills, malaise, chest tightness, arthralgia, red eyes, sore throat, and cough.		
ADVERSE EVENTS	Immediate, allergic-type responses, such as hives, allergic asthma, or systemic anaphylaxis occur extremely rarely.		
SPECIAL CONSIDERATIONS	Protect vials from light. A multidose vial of FLUZONE® Quadrivalent which has been entered and stored at 2° to 8° C may be used up to the expiry date indicated on the vial label.		
EFFECTIVENESS	Refer to product monograph as data depends on age and studies design.		

[1] Children under 9 years of age who have not previously received seasonal influenza vaccine require 2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only a single dose is required.

Japanese Encephalitis Vaccine **[Non-publicly funded]**

IXIARO® (Valneva 2016 product monograph available at:
file:///C:/Users/Public/Documents/Ixiaro_Product_Monograph%20(1).pdf)

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

M-M-R® II (Merck Frosst 2017 product monograph available at: https://www.merck.ca/static/pdf/MMR_II-PM_E.pdf)

INDICATIONS [1, 2, 3]	**DOSE / SERIES**
Series for those born since January 1, 1970 who are 12 months and older	**Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later
For adults born before January 1, 1970, refer to SIM Chapter 5, *Appendix 5.2: Adult Eligibility for Publicly Funded MMR Vaccine.* [3]	
Immunocompromised individuals • As determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations*, under specific condition for information.	
REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• Measles/mumps/rubella immunization should be given at the same time as other live vaccines. Otherwise there must be 4 or more weeks between administering live vaccines. • For high risk/immunocompromised clients only: separate the administration of MMR and varicella vaccines by 4 weeks. • Anti-Rho (D) immune globulin may interfere with response to the rubella component of the vaccine. Rubella-susceptible women who receive anti-Rho (D) immune globulin post-partum should either be given MMR vaccine at the same time and tested 3 months later for rubella immunity, or should be immunized with MMR vaccine 3 months post-partum, with follow-up ensured (Ref: CIG Evergreen). • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions.* • Physician-diagnosed thrombocytopenia after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of MMRII. • Immunocompromised individuals unless determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations*, under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. – • Recent administration of an immune globulin preparation or blood product [3]
VACCINE COMPONENTS	Measles virus, Enders' Edmonston strain (live, attenuated); Mumps virus, Jeryl Lynn® (B level) strain (live, attenuated); and Rubella virus, Wistar RA 27/3 strain (live, attenuated). **Excipients**: sorbitol, hydrolyzed gelatin, medium 199 with Hank's salts, sodium phosphate monobasic, sodium phosphate dibasic (anhydrous), sucrose, sodium bicarbonate, minimum essential medium (Eagle), potassium phosphate dibasic (anhydrous), neomycin, monosodium L-glutamate monohydrate, potassium phosphate monobasic, phenol red, water for injection. **Manufacturing process residuals:** Recombinant human albumin, fetal bovine serum, may contain minute quantities of egg protein. Preservative, latex and thimerosal free.

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated) **M-M-R® II** (Merck Frosst 2017 product monograph available at: https://www.merck.ca/static/pdf/MMR_II-PM_E.pdf)	
EXPECTED REACTIONS	**Local:** Tenderness, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** Moderate fever, rash, malaise, headache, nausea, myalgia, and paraesthesia; thrombocytopenia; encephalitis. Acute transient arthritis or arthralgia is uncommon in children, but frequency and severity increases with age.
EXPECTED REACTIONS	**Local:** Tenderness, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** Moderate fever, rash, malaise, headache, nausea, myalgia, and paraesthesia; thrombocytopenia; encephalitis. Acute transient arthritis or arthralgia is uncommon in children, but frequency and severity increases with age.
SPECIAL CONSIDERATION	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form (*Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Travelling infants 6 months to younger than 12 months of age should be offered an early publicly funded dose of MMR vaccine if they are travelling to:

- Countries outside of North Americas; **or**
- Mass gatherings (generally defined of ≥ 25,000 people according to the WHO) of international travellers (e.g. sporting events, pilgrimages, etc.) anywhere in the world.

[2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.51, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[3] Refer to SIM Chapter 5, Appendix 5.2*: Adult Eligibility for Publicly Funded MMR Vaccine.*

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

PRIORIX® (GlaxoSmithKline 2017 monograph available at: http://ca.gsk.com/media/591220/priorix.pdf)

INDICATIONS [1, 2,]	**DOSE / SERIES**
Series for those born since January 1, 1970 who are 12 months and older	**Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC minimum 4 weeks later
For adults born before January 1, 1970, refer to SIM Chapter 5, *Appendix 5.2: Adult Eligibility for Publicly Funded MMR Vaccine*. [3]	
Immunocompromised individuals • As determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations*, under specific condition for information.	
REINFORCEMENT	Not indicated after 2 MMR doses.
PRECAUTIONS	• Measles/mumps/rubella immunization should be given at the same time as other live vaccines. Otherwise there must be 4 weeks between administering live vaccines. • For high risk/immunocompromised clients only: separate the administration of MMR and varicella vaccine by 4 weeks. • Anti-Rho (D) immune globulin may interfere with response to the rubella component of the vaccine. Rubella-susceptible women who receive anti-Rho (D) immune globulin post-partum should either be given MMR vaccine at the same time and tested 3 months later for rubella immunity, or should be immunized with MMR vaccine 3 months post-partum, with follow-up ensured (Ref: CIG evergreen). • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Family history of congenital immunodeficiency. Refer to SIM, Chapter 6, *Contraindication and Precautions*. • Physician-diagnosed thrombocytopenia after first dose of a MMR-containing vaccine.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella-containing vaccine, to any component of Priorix, or to latex when administering Priorix with the pre-filled syringe (latex is present in the pre-filled syringe of diluent for Priorix). • Immunocompromised individuals unless determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations*, under specific condition for information. • Pregnancy. Counsel female recipients to avoid pregnancy for 1 month following immunization. Inadvertent immunization during pregnancy is not considered a medical indication for therapeutic abortion. • Recent administration of an immune globulin preparation or blood product [3]
VACCINE COMPONENTS	Not less than: $10^{3.0}$ $CCID_{50}$ of the Schwarz measles; $10^{3.7}$ $CCID_{50}$ of the RIT 4385 mumps; and $10^{3.0}$ $CCID_{50}$ of the Wistar RA 27/3 rubella virus strains/ per 0.5 mL dose, and amino acids, lactose, mannitol, neomycin sulphate and sorbitol. Vaccine and diluent vial stoppers made of natural rubber. Thimerosal free. The vaccine may contain minute quantities of egg protein
EXPECTED REACTIONS	**Local:** Tenderness, redness, swelling, induration, wheal and flare reaction, urticaria. **Systemic:** Moderate fever, rash, malaise, headache, and nausea, myalgia, and paraesthesia; thrombocytopenia; encephalitis. Acute transient arthritis or arthralgia is uncommon in children, but frequency and severity increases with age.

Measles-Mumps-Rubella Vaccine (MMR) (live, attenuated)

PRIORIX® (GlaxoSmithKline 2017 monograph available at:
http://ca.gsk.com/media/591220/priorix.pdf

SPECIAL CONSIDERATIONS	Re: Immunization of immunocompromised clients - consult the appropriate physician (i.e., either the primary care physician most familiar with the client's current medical status or a medical specialist) and obtain a completed *MMR Immunization Referral Form (*Chapter 7, *Immunization of Special Populations,* Appendix 7.3) before immunization.
EFFECTIVENESS	After 1st dose, 85-95% protection to measles; 95.5% to mumps; 99.3% to rubella. After 2nd dose 100% protection to all antigens.

[1] Travelling infants 6 months to younger than 12 months of age should be offered an early publicly funded dose of MMR vaccine if they are travelling to:

- Countries outside of North America; **or**
- Mass gatherings (generally defined of ≥ 25,000 people according to the WHO) of international travellers (e.g. sporting events, pilgrimages, etc.) anywhere in the world.

[2] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[3] Refer to SIM Chapter 5, Appendix 5.2*: Adult Eligibility for Publicly Funded MMR Vaccine.*

Measles-Mumps-Rubella-Varicella Vaccine (MMRV) (live, attenuated)

PRIORIX-TETRA™ (GlaxoSmithKline 2017 product monograph available at: http://ca.gsk.com/media/591336/priorix-tetra.pdf)

INDICATIONS [1]	DOSE / SERIES [3, 4]
1. Children born since October 1, 2009. 2. Children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases. 3. Grade 6 students	1. Dose 1: 0.5 mL SC (at 12 months) Dose 2: 0.5 mL SC (at 18 months) 2. Dose: 0.5 mL SC (only one dose if born before October 1, 2009). 3. 0.5 mL SC. If second dose is required, given ≥4 weeks after first dose.

PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency* • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, to any component of PRIORIX-TETRA™, or to latex. • Recent administration of an immune globulin preparation or blood product [2]. • Pregnancy. • Immunocompromised individuals unless determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information.
VACCINE COMPONENTS	Live, attenuated measles virus (Schwarz strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated mumps virus (RIT 4385 strain, derived from Jeryl Lynn strain) not less than $10^{4.4}$ $CCID_{50}$; Live, attenuated rubella virus (Wistar RA 27/3 strain) not less than $10^{3.0}$ $CCID_{50}$; Live, attenuated varicella virus (Oka strain) not less than $10^{3.3}$ PFU; amino acids for injection, lactose, mannitol, neomycin sulphate, sorbitol, water for injection. Vaccine and diluent vial stoppers contain rubber. The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Thimerosal free. Latex-free
EXPECTED REACTIONS	**Local:** Pain, redness at injection site (Very Common ≥ 1/10). **Systemic**: Fever (Very Common ≥ 1/10); rash 1 week post-vaccination, irritability (Common ≥ 1/100 to < 1/10).
ADVERSE EVENTS	Following the administration of the first dose of PRIORIX-TETRA®, higher incidences of fever (approximately 1.5 fold) were observed when compared to the concomitant administration of PRIORIX® [*MMR*] and VARILRIX® vaccines at separate injection sites (p.6). Review fever management with client.
EFFECTIVENESS	One year after 2nd MMRV dose, 98.8% of all children were protected measles, rubella and varicella and 90.6% were protected against mumps.

[1] Minimum age for vaccine is 9 months and applies to exceptional circumstances only

[2] There must be 4 weeks minimum spacing between MMRV doses

[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*

[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.

[5] MMRV vaccines are considered interchangeable.

Measles-Mumps-Rubella-Varicella Vaccine (MMRV) (live, attenuated)

ProQuad™ (Merck Frosst 2017 product monograph available at: https://www.merck.ca/static/pdf/PROQUAD-PM_E.pdf)

INDICATIONS [1]	**DOSE / SERIES** [3, 4]
1. Children born since October 1, 2009. **2**. Children 1 year up to and including 12 years of age who require protection against MMR and varicella diseases. **3**. Grade 6 students	**1**. **Dose 1**: 0.5 mL SC (at 12 months) **Dose 2**: 0.5 mL SC (at 18 months) [2] **2**. **Dose**: 0.5 mL SC (only one dose if born before October 1, 2009). **3**. 0.5 mL SC. If second dose is required, given ≥4 weeks after first dose.

PRECAUTIONS	• Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine. • Physician-diagnosed thrombocytopenia after first dose of a MMR-containing vaccine. • Family history of congenital immunodeficiency. Refer to SIM Chapter 7, *Immunization of Special Populations* Section 3.1, Congenital Immunodeficiency • Do TB skin testing on the same day as MMR immunization, or delay TB skin testing for 4 or more weeks. • Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG). • It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a measles/mumps/rubella or varicella-containing vaccine, or to any component of ProQuad™**.** • Recent administration of an immune globulin preparation or blood product [2]. • Pregnancy • Immunocompromised individuals unless determined by their specialist. Refer to SIM, Chapter 7, *Immunization of Special Populations,* under specific condition for information..
VACCINE COMPONENTS	Live, attenuated measles virus derived from Enders' attenuated Edmonston strain; live, attenuated mumps virus (JERYL LYNN® (B level) strain; live, attenuated rubella virus (Wistar RA 27/3 strain); live, attenuated Oka/Merck strain of varicella-zoster virus; sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, residual components of MRC-5 cells including DNA and protein, neomycin, bovine serum albumin and other buffer and media ingredients. The vaccine may contain minute quantities of egg protein. Preservative, latex and thimerosal free.
EXPECTED REACTIONS	**Local:** Pain, tenderness, soreness, bruising, redness at injection site (Very Common ≥ 1/10). **Systemic**: Fever ≥ 38.9°C (Very Common ≥ 1/10); rash 1 week post-vaccination, irritability, diarrhea, vomiting, upper respiratory infections (Common ≥ 1/100 to < 1/10).
ADVERSE EVENTS	Administration of ProQuad™ (dose 1) to children 12 to 23 months old was associated with higher rates of fever and febrile seizures at 5 to 12 days after vaccination when compared to children vaccinated with M-M-R® II and VARIVAX® administered separately. Review fever management with client.
EFFECTIVENESS	The antibody persistence rates 1 year post-vaccination in recipients **of a single dose** of ProQuad™ were 98.9% (1722/1741) for measles, 96.7% (1676/1733) for mumps, 99.6 (1796/1804) for rubella, and 97.5% (1512/1550) for varicella (≥ 5 gp ELISA units/mL)

[1] Minimum age for this vaccine is 12 months. Consult MHO for recommendations regarding exceptional circumstances.
[2] There must be 4 weeks minimum spacing between MMRV doses
[3] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.*
[4] Individuals who are eligible for a 2-dose varicella series who have **documentation of lab confirmed** varicella after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose as they will have developed immunity. Provide a second dose of varicella-containing vaccine to those without this documentation.
[5] MMRV vaccines are considered interchangeable.

Meningococcal Conjugate C Vaccine (Men-C-C)

MENJUGATE® (GSK 2017 monograph available at:
http://ca.gsk.com/media/1213633/menjugate.pdf

MENJUGATE® Liquid (GSK 2017 monograph available at:
http://ca.gsk.com/media/1213630/menjugate-liquid.pdf

INDICATIONS [1]	**DOSE / SERIES**
1. Routine for children at 12 months of age. 2. People born since January 1, 1993 to September 30, 2000 who did not receive in grade 6, up to and including 21 years of age (ineligible at 22nd birthday). 3. Meningococcal serotype C post-exposure immunoprophylaxis.	**1.** One dose: 0.5 mL IM at 12 months or older **2.** One dose: 0.5 mL IM **3.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM

CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of a MENJUGATE brand of Men-C-C vaccine.
VACCINE COMPONENTS	Powdered formulation: *Neisseria meningitidis* group C (strain C11) oligosaccharide conjugated to-*Corynebacterium diphtheriae* protein CRM-197, aluminum hydroxide, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate heptahydrate, mannitol, water for injection. The tip cap of the diluent syringe contains 10% Dry Natural Rubber. Although the risk for developing allergic latex reactions is very small, healthcare professionals are encouraged to consider the benefit risk prior to administering this vaccine to patients with known history of hypersensitivity to latex. Liquid formulation: *Neisseria meningitidis* group C (strain C11) oligosaccharide conjugated to *Corynebacterium diphtheriae* protein CRM-197, aluminum hydroxide, histidine, sodium chloride, water for injection with bromobutyl rubber stopper and tip cap (styrene butadiene Type II rubber). Although no natural rubber latex is detected in the syringe tip cap, the safe use of Menjugate in latex-sensitive individuals has not been established.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: dizziness, fever, headache, nausea, vomiting.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 8 weeks.
[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.
[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.
[4] There must be an interval of at least 24 weeks between the administration of a meningococcal polysaccharide vaccine and the administration of Men-C-C. The minimum interval between Men-C-C doses is 8 weeks.

Meningococcal Conjugate C Vaccine (Men-C-C)

NeisVac-C® (Pfizer Canada 2015 monograph available at: http://www.pfizer.ca/sites/g/files/g10017036/f/201505/NeisVac-C_PM_182023_31Mar2015_EN.pdf)

INDICATIONS [1]	**DOSE / SERIES**
1. Routine for children at 12 months of age. 2. People born since January 1, 1993 to September 30, 2000 who did not receive in grade 6, up to and including 21 years of age (ineligible at 22nd birthday). 3. Meningococcal serotype C post-exposure immunoprophylaxis.	**1.** One dose: 0.5 mL IM at 12 months or older **2.** One dose: 0.5 mL IM **3.** Children 2 - 11 months old: [2, 3] • **Dose 1**: 0.5 mL IM • **Dose 2**: 0.5 mL IM 2 months later Those 12 months and older: [4] • One dose 0.5 mL IM

CONTRAINDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal vaccine or to any component of NeisVac-C®.
VACCINE COMPONENTS	One dose 0.5 mL contains: *Neisseria meningitidis* group C polysaccharide 10 mcg, tetanus toxoid, aluminum hydroxide, sodium chloride. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: redness, swelling and pain at injection site. **Systemic**: dizziness, fever, headache, nausea, vomiting.
EFFECTIVENESS	Effectiveness: more than 90% in all age groups in the short-term.

[1] Minimum age for vaccine is 8 weeks.

[2] Men-C-C vaccines are interchangeable for infants younger than 12 months of age.

[3] If an infant has a history of receiving their last dose before 12 months of age, give an additional dose at 12 months or older.

[4] There must be an interval of at least 24 weeks between the administration of a meningococcal polysaccharide vaccine and the administration of Men-C-C. The minimum interval between Men-C-C doses is 8 weeks.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menactra® (Sanofi Pasteur 2017 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=menactra_e.pdf)

DOSE : 0.5 mL IM

INDICATIONS [1, 5]

1. Grade 6 students – 1 dose [2, 3]
2. Those ≥ 9 months of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program	**Age 9 months through 11 months -** 3-dose series a. 1st dose followed by 2nd dose at least 2 months later. b. Give 3rd at/after 12 months of age, with at least 2 months between doses 2 and 3. [5]
	Age 12 to 23 months [5] **-** 2-dose series with at least 2 months between doses
	2 years and older [5] **-** 2-dose series with at least 1 month between doses
REINFORCE-MENT DOSES	**Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency.** Reinforcement dose scheduling depends on age at first dose received: • If first dose received at ≥7 years → reimmunize every 5 years. • If first dose received at age ≤ 6 years → A booster dose should be given every 3 to 5 years.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of any meningococcal-containing vaccine, or to any component of Menactra.
VACCINE COMPONENTS	Each dose contains 4 mcg each of meningococcal A, C, Y and W-135 polysaccharides conjugated to a total of approximately 48 mcg of a diphtheria toxoid protein carrier, sodium chloride 4.25 mg, sodium phosphate (dibasic, anhydrous), sodium phosphate (monobasic), water for injection. Vial presentations do not contain latex.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling. **Systemic**: Headache, malaise, chills, fever.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28. Duration of protection remains unknown.

Meningococcal Conjugate ACYW-135 Vaccine **(Men-C-ACYW-135)**

Menactra® (Sanofi Pasteur 2017 monograph available at: htthttps://www.vaccineshoppecanada.com/document.cfm?file=menactra_e.pdf)

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).

[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).

[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in Grade 8.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

Menveo™ (GSK 2017 monograph available at: http://ca.gsk.com/media/1213533/menveo.pdf)

DOSE: 0.5 mL IM

INDICATIONS [1, 5]

1. Grade 6 students – 1 dose [2, 3]
2. Those ≥ 8 weeks of age and older with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

4. In meningococcal A, C, Y or W-135 outbreak exposure situations, **Menveo** may be used in children as early as 8 weeks of age. Refer to the Saskatchewan Communicable Disease Control Manual at http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program)	**Age 8 weeks through 6 months**: 4 dose series - 2 months, 4 months and 6 months of age followed by a 4th dose at/after 12 months of age. [5]
	Age 7 months through 11 months: 3 dose series - 1st dose, 2nd dose and 3rd dose with 2 month intervals between these 3 doses. • Give 3rd at/after 12 months of age, with at least 2 months between doses 2 and 3
	Age 12 months through 10 years old: 2-dose series with at least 2 months between doses.
	Age 11 years and older (including adults): 2-dose series with at least 1 month between doses.
REINFORCE-MENT DOSES	**Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency.** Reinforcement dose scheduling depends on age at first dose received: • If first dose received at ≥7 years → reimmunize every 5 years. • If first dose received at age ≤ 6 years → A booster dose should be given every 3 to 5 years.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of Menveo™.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)	
Menveo™ (GSK 2017 monograph available at: http://ca.gsk.com/media/1213533/menveo.pdf)	
VACCINE COMPONENTS	5 ug each of meningococcal C, W-135 and Y oligosaccharides conjugated and 10 ug of meningococcal A oligosaccharide conjugated to a total of approximately 47 ug of Cross Reactive Material (CRM197) from *Corynebacterium diphtheriae*, potassium dihydrogen phosphate, sucrose, sodium chloride, sodium dihydrogen phosphate monohydrate, di-sodium hydrogen phosphate bihydrate.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling at injection site. **Systemic**: Headache, myalgia, malaise, nausea.
EFFECTIVENESS	93-100% of children, adolescents & adults show a ≥4-fold rise in titres at day 28.

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).

[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).

[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in Grade 8.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX® (Pfizer Canada 2018 monograph available at: https://www.pfizer.ca/sites/g/files/g10045006/f/201802/Nimenrix_PM_SNDS_203844_19Feb2018_E.pdf)

DOSE: 0.5 mL IM

INDICATIONS

1. Grade 6 students -1 dose [2, 3]
2. Those ≥ 12 months of age and older (no age limit) with the following medical conditions as noted in Chapter 7 Special Populations:
   - asplenia – congenital, acquired or functional [4]
   - HIV – ONLY for children up to and including 17 years of age
   - CSF disorders
   - Sickle cell disease
   - cochlear implant recipient or candidate
   - congenital immunodeficiency or acquired complement deficiency [6]
   - solid organ or islet transplant recipient or candidate
   - hematopoietic stem cell transplant (HSCT) recipient
3. Individuals who have previously been vaccinated with Men-P-ACYW-135 and for whom there is a need for re-vaccination due to high risk medical status: → administer Men-C-ACYW-135 as follows:

Age at first dose of Men-P-ACYW-135	**Immunize with Men-C-ACYW-135 when 2 years and older, and it has been:**
3-12 months of age	6 months since last dose of Men-P-ACYW-135
13-23 months of age	1 year since last dose of Men-P-ACYW-135
2-5 years of age	2 years since last dose of Men-P-ACYW-135
≥ 6 years of age	5 years since last dose of Men-P-ACYW-135

SERIES BASED ON AGE AT PRESENTATION FOR HIGH RISK CLIENTS (excludes routine Grade 6 program	**6 weeks to <12 months** 3-dose series • 1st dose followed by 2nd dose at least 2 months later. • Give 3rd dose at/after 12 months of age, with at least 2 months between doses 2 and 3. [5]
	12 to 23 months [5] **-** 2-dose series with at least 2 months between doses
	2 years and older [5] **-** 2-dose series with at least 1 month between doses
REINFORCE-MENT DOSES	**Only for asplenia (congenital, acquired or functional), congenital immunodeficiency or acquired complement deficiency.** Reinforcement dose scheduling depends on age at first dose received: • If first dose received at ≥7 years → reimmunize every 5 years. • If first dose received at age ≤ 6 years → A booster dose should be given every 3 to 5 years.
CONTRA-INDICATIONS	History of anaphylactic reaction to a previous dose of a meningococcal containing vaccine, or to any component of NIMENRIX™.
VACCINE COMPONENTS	*Neisseria meningitidis* serogroup A polysaccharide, *Neisseria meningitidis* serogroup C polysaccharide, *Neisseria meningitidis* serogroup W-135 polysaccharide, *Neisseria meningitidis* serogroup Y polysaccharide, sucrose, trometamol, sodium chloride, water for injection.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling, bruising at injection site. **Systemic**: Headache, irritability, fatigue.
EFFECTIVENESS	For all serogroups (A, C, W-135, Y), the persistence of the antibodies elicited by NIMENRIX™ was similar or higher than those induced by the licensed Men-C-ACYW-135 vaccines.

Meningococcal Conjugate ACYW-135 Vaccine (Men-C-ACYW-135)

NIMENRIX® *(Pfizer* Canada 2018 monograph available at https://www.pfizer.ca/sites/g/files/g10045006/f/201802/Nimenrix_PM_SNDS_203844_19Feb2018_E.pdf)

[1] The recommended interval between the administration of Men-C-C vaccine and Men-C-ACYW-135 vaccine is 4 weeks (regardless of which vaccine was given first).

[2] Those born since January 1, 2000 up to and including 21 years of age (ineligible upon 22nd birthday).

[3] If a Grade 6 student has received a previous Men-C-ACYW-135 vaccine in the preceding 3 years, it is acceptable to withhold the Grade 6 dose and give the vaccine when the student is in grade 8.

[4] Give vaccine at least 14 days prior to elective splenectomy, or if not possible, 14 or more days post-splenectomy. When there is concern that the patient may not present later for immunization, give vaccine before discharge.

[5] A high-risk child 12 months of age and older, or an adult who is cohort eligible for a Men-C-C, does not required Men-C-C vaccine when they are eligible to receive Men-C-ACYW-135 vaccine.

[6] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

Multicomponent Meningococcal B vaccine (recombinant, adsorbed) (4CMenB)

BEXSERO® (GSK 2017 product monograph available at: http://ca.gsk.com/media/1212390/bexsero.pdf)

INDICATIONS	• Those ≥ 8 weeks of age with the following medical conditions: as noted in Chapter 7:
	  • asplenia – congenital, acquired or functional
	  • sickle cell disease
	  • congenital immunodeficiency
	  • acquired complement deficiency [1]
	  • Children up to and including 17 years of age who are infected with HIV
	• Those ≥ 8 weeks of age who have been identified as 'close contacts' of persons infected with meningococcal B. Refer to Saskatchewan Communicable Disease Control Manual at http://www.ehealthsask.ca/services/manuals/Pages/CDCManual.aspx

DOSE	0.5 mL IM. Protect from light.
CONTRA-INDICATIONS	BEXSERO should not be administered to individuals who are hypersensitive to this vaccine or to any ingredient in the formulation or components of the container closure.
DOSE/SERIES AND REINFORCE-MENT RECOMMEN-DATIONS BASED ON AGE AT PRESENTATIO N	**Infants aged 2 months through 5 months** • 3-dose primary series: 0.5 mL IM at 2 months, 4 months and 6 months of age followed by a 4th dose after 12 months of age. ○ The primary series can also be given at 2, 3 and 4 months of age (4 week intervals), but the immune response to the NHBA antigen is lower.
	Infants aged 6 months through 11 months • 3-dose primary series: 0.5 mL IM for 1st dose, 2nd dose and 3rd dose with 2 month intervals between the 1st and 2nd doses and the 2nd and 3rd doses. ○ The 3rd dose **is required** in the second year of life with an interval of at least 2 months between the second and third dose.
	Children aged 12 months to 10 years old: • 2-dose series - 0.5 mL IM, with a 2-month (8 week) interval between the 1st and 2nd doses.
	Individuals aged 11 years and older (including adults) • 2-dose series - 0.5 mL IM, with at least a one-month (4 week) interval between the 1st and 2nd doses.
VACCINE COMPONENTS	BEXSERO® contains recombinant *Neisseria meningitidis* serogroup B NHBA fusion protein; recombinant *Neisseria meningitidis* serogroup B NadA protein; recombinant *Neisseria meningitidis* serogroup B fHbp fusion protein; and outer membrane vesicles (OMV) from *Neisseria meningitidis* serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4. Additional excipients: sodium chloride, histidine, sucrose, water for injection. The vaccine does not contain thimerosal. The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, health professional should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex.

Multicomponent Meningococcal B vaccine (recombinant, adsorbed) (4CMenB) **BEXSERO®** (GSK 2017 product monograph available at: http://ca.gsk.com/media/1212390/bexsero.pdf)	
EXPECTED REACTIONS	Common reactions to the vaccine may include: • Soreness, tenderness, redness and swelling at the injection site. • Fever, loss of appetite, sleepiness, irritability, headache, vomiting, diarrhea, headache or skin rash. • These reactions are mild and generally last 1 to 2 days • Injection site reactions like extensive swelling of the vaccinated limb, blisters at or around the injection site and/or a hard lump at the injection site (which may persist for more than one month) have also been reported
EFFECTIVENESS	Immunogenicity information in the product monograph indicates that administration of age-appropriate series provides 75% to 100% immunogenicity among the 4 meningococcal components. Duration of protection is unknown.

NOTE: BEXSERO® is a recombinant adsorbed vaccine that contains 4 serotype B components. According to the manufacturer (verbal communication, May 2014), there are no recommended interval requirements between BEXSERO® and other meningococcal serotype-containing vaccine that are conjugates or polysaccharides. However, case-by case review of an individual's immunization history in consultation with a MHO consultation may result in specific recommendations for administration of BEXSERO® doses.

[1] Patients being treated with SOLIRIS (eculizumab) are at high risk for Invasive Meningococcal Disease despite being immunized with meningococcal vaccines (CDC, 2017, https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_e).

[2] An increased risk of hemolysis or low hemoglobin has been observed when patients already being treated with SOLIRIS (eculizumab) get vaccinated against serogroup B meningococcal infection with Bexsero® (Alexion Pharma Canada, 2017).

Meningococcal group B [Bivalent recombinant lipoprotein (rLP2086) [Non-publicly funded]
Trumenba™ (Pfizer 2018 Product monograph available at:
http://www.pfizer.ca/sites/g/files/g10037206/f/201801/Trumenba_PM_211262_04-Jan-2018_E_0.pdf)

Pneumococcal Conjugate 10-Valent Vaccine (Pneu-C-10) [Non-publicly funded]

SYNFLORIX™ (GlaxoSmithKline 2017 monograph available at: http://ca.gsk.com/media/591956/synflorix.pdf)

Pneumococcal Conjugate 13-Valent Vaccine (Pneu-C-13)

Prevnar® 13 (Pfizer December 2015 monograph available at:
http://www.pfizer.ca/sites/g/files/g10028126/f/201601/Prevnar_13_PM_189931_22Dec2015_E.pdf)

INDICATIONS & AGE-APPROPRIATE DOSE / SERIES [1, 2, 3,4]

- **Minimum age is 6 weeks old.**
- This vaccine is not publicly funded for **healthy** individuals aged 5 years and older.

A. CHILDREN 2 – 59 MONTHS OF AGE:

(A1) Routine schedule for healthy infants:
Dose 1: 2 months of age: 0.5 mL IM
Dose 2: 4 months of age: 0.5 mL IM
Dose 3: 12 months of age: 0.5 mL IM

(A2) Routine schedule for medically high risk infants:
Dose 1: 2 months of age: 0.5 mL IM
Dose 2: 4 months of age: 0.5 mL IM
Dose 3: 6 months of age: 0.5 mL IM
Dose 4: 12 months of age: 0.5 mL IM (min. 8 weeks after 3rd dose).

(A3) Pneumococcal Conjugate Schedule for Healthy Children Delayed by 1 Month or More

Age at Presentation [1]	Pneumococcal conjugate vaccine history	Completion of primary series requirement	Reinforcement
3 to 11 months	0	2 doses (min. 4 weeks apart)	One dose at 12 months of age or older [2]
	1 dose	1 dose (min. 4 weeks since first dose)	
	2 doses	0 doses	
12 to 23 months	0 doses	2 doses [3]	Not required
	1 dose at less than 12 months	2 doses [3]	Not required
	1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months	1 dose [2]	Not required
	1 dose at less than 12 months **and** 1 dose at 12 months or older	1 dose [2]	Not required
24 to 59 months	0	1 dose	Not required
	Any age-appropriate series incomplete by 24 months old	1 dose [3]	Not required

(A4) Pneumococcal Conjugate Schedule for Medically High Risk Children Delayed by 1 Month or More [5]

Age at Presentation [1]	Pneumococcal conjugate vaccine history	Completion of primary series requirement	Reinforcement [4]
3 to 11 months	0 doses	3 doses (min. 4 weeks apart)	One dose at 12 months of age or older [2]
	1 dose	2 doses (min. 4 weeks apart)	
	2 doses	1 dose (min. 4 weeks since first dose)	
12 to 23 months	0 doses	2 doses [3]	Not required
	1 dose at less than 12 months	2 doses [3]	Not required
	1 dose at 12 months or older	1 dose [2]	Not required
	2 or 3 doses at less than 12 months	1 dose [2]	Not required
	1 dose at less than 12 months **and** 1 dose at 12 months or older	1 dose [2]	Not required
24 to 59 months	0 doses	1 dose	Not required
	Any age-appropriate series incomplete by 24 months old	1 dose [3]	Not required

Pneumococcal Conjugate 13-Valent Vaccine (Pneu-C-13)

Prevnar® 13 (Pfizer December 2015 monograph available at:
http://www.pfizer.ca/sites/g/files/g10028126/f/201601/Prevnar_13_PM_189931_22Dec2015_E.pdf)

B. HEMATOPOIETIC STEM CELL TRANSPLANT RECIPIENTS (all ages)

Dose 1: 0.5 mL IM at 6 months post-transplant
Dose 2: 0.5 mL IM at 7 months post-transplant
Dose 3: 0.5 mL IM at 8 months post-transplant
Dose 4: 0.5 mL IM at 18 months post-transplant

C. Medically High-Risk Children Aged 60 Months - 17 Years Who Are at Risk of Invasive Pneumococcal Disease [4]

Medically high-risk children aged 60 months - 17 years who are Pneu-C-13 naïve (e.g., have not completed an age or risk appropriate Pneu-C-13 series prior to 59 months of age) are eligible to receive **one dose of Pneu-C-13 vaccine** given no sooner than 8 weeks after a pneumococcal conjugate 7- or 10-valent vaccine dose or a pneumococcal polysaccharide 23-valent vaccine dose (Canadian Immunization Guide, 2012).

CONTRA-INDICATIONS	History of an anaphylactic reaction to a previous dose of any pneumococcal vaccine, or to any component of Prevnar® 13.
VACCINE COMPONENTS	Each 0.5 mL dose of the vaccine is formulated to contain approximately 2.2 mcg of each saccharide for *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F, 4.4 mcg of saccharide for serotype 6B, 34 mcg CRM_{197} carrier protein, 4.25 mg sodium chloride, 100 mcg polysorbate 80, 295 mcg succinic acid and 125 mcg aluminum as aluminum phosphate adjuvant. Latex free.
EXPECTED REACTIONS	**Local**: redness, swelling, tenderness at injection site **Systemic**: fever, irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea.
EFFECTIVENESS	Completed series induces 97.8-100% protection against all strains in vaccine.

[1] Refer to SIM, Chapter 5, *Immunization Schedules*, Section 1.3A, *Pneumococcal Conjugate Schedule for Children Delayed by 1 Month or More* and Section 1.3B, *Pneumococcal Conjugate Schedule for Medically High Risk Children Delayed by 1 Month or More*.

[2] Minimum 8 weeks after the previous dose received.

[3] Minimum 8 weeks between doses.

[4] High risk children should receive one dose of Pneu-P-23 vaccine at 2 years of age, and at least 8 weeks after the final dose of Pneu-C-13 vaccine.

NOTE: **For those 18 and older,** a 1-year minimum interval is required if Pneu-P-23 is given before Pneu-C-13, and an 8 week interval is required if Pneu-C-13 is given before Pneu-P-23. HSCT recipients may be an exception to this recommendation.

[5] Refer to SIM, Chapter 7, Immunization of *Special Populations* for specific medical condition recommendations **and age restrictions.**

Medical high-risk conditions may include:

- asplenia – congenital, acquired or functional
- renal disease
- liver disease including cirrhosis, hepatitis B, hepatitis C
- CSF disorders
- cardiac or lung disease (except asthma, unless management involves high dose oral corticosteroid therapy)
- cochlear implant recipient or candidate
- congenital immunodeficiency or acquired complement deficiency
- cystic fibrosis
- diabetes mellitus
- immunosuppressive medical treatment (e.g., lymphoma, Hodgkin's, multiple myeloma, high dose steroids, chemotherapy radiation therapy, post-solid organ transplant therapy)
- HIV
- malignancies/cancer
- neurological conditions that impeded the clearance of oral/respiratory secretions
- sickle cell disease and other hemoglobinopathies
- solid organ or islet transplant recipient or candidate
- hematopoietic stem cell transplant (HSCT) recipient
- residents of group homes, LTC facilities

Pneumococcal Polysaccharide 23-Valent Vaccine (Pneu-P-23)

PNEUMOVAX® 23 (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/PNEUMOVAX_23-PM_E.pdf)

INDICATIONS	• **All persons ≥ 65 years of age.** • **All residents of Extended or Intermediate Care Facilities.** • **All persons ≥ 2 years of age with:** o alcoholism o asplenia – congenital, acquired or functional [1] o renal disease o liver disease including cirrhosis, hepatitis B, hepatitis C o CSF disorders o cardiac or lung disease (except asthma, unless management involves high dose oral corticosteroid therapy) o cochlear implant recipient or candidate o congenital immunodeficiency or acquired complement deficiency o cystic fibrosis o diabetes mellitus o immunosuppressive medical treatment [2] (e.g., lymphoma, Hodgkin's, multiple myeloma, high dose steroids, chemotherapy radiation therapy, post-solid organ transplant therapy) o HIV [2] o malignancies/cancer **(individual must currently have)** [2] o neurological conditions that impeded the clearance of oral/respiratory secretions o sickle cell disease and other hemoglobinopathies o solid organ or islet transplant recipient or candidate o hematopoietic stem cell transplant (HSCT) recipient o residents of group homes, LTC facilities o homelessness and/or illicit drug use
DOSE / SERIES [3, 4]	• **Adults and children 2 years and older:** 0.5 mL SC or IM.
REINFORCEMENT **Reinforcement doses are not provided to healthy individuals.**	A **one-time** reinforcement dose should be offered 5 years later to those who have: • asplenia – congenital, acquired or functional • sickle cell disease and other hemoglobinopathies • immunosuppressive medical treatment • congenital immunodeficiency • acquired complement deficiency • renal disease • liver disease including cirrhosis, hepatitis B, hepatitis C • HIV • malignancies/cancer[5] • hematopoietic stem cell transplant (HSCT) recipient (as per agency guidelines)
CONTRA-INDICATIONS	History of an anaphylactic reaction to a previous dose of any pneumococcal vaccine or to any component of PNEUMOVAX® 23 vaccine.
PRECAUTIONS	Adverse reactions may intensify if revaccination occurs within 2 years.
VACCINE COMPONENTS	Purified capsular polysaccharides from the following 23 serotypes of *Streptococcus pneumoniae*: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F. **Excipients:** Sodium chloride**,** phenol**,** water for injection. Latex and thimerosal free.

Pneumococcal Polysaccharide 23-Valent Vaccine (Pneu-P-23) **PNEUMOVAX® 23** (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/PNEUMOVAX_23-PM_E.pdf)	
EXPECTED REACTIONS	**Local:** Soreness and erythema; rarely - severe Arthus reaction. **Systemic:** Low grade fever.
EFFECTIVENESS	Efficacy ranges from 50-80% in immunocompetent persons. Antibody levels decline after 5-10 years.

[1] Give vaccine at least 14 days before splenectomy, or, if not possible 14 days post-splenectomy. If there is concern that the patient may not present later for immunization, give at hospital discharge.

[2] Give vaccine before initiation of immunosuppression therapy, and early in the course of HIV infection.

[3] Pneu-P-23 vaccine may be given to children ≤ 17 years no sooner than 8 weeks after the last dose of Pneu-C-13 vaccine.

[4] **NOTE**: **For those 18 and older,** a 1-year minimum interval is required if Pneu-P-23 is given before Pneu-C-13, and an 8 week interval is required if Pneu-C-13 is given before Pneu-P-23. HSCT recipients may be an exception to this recommendation.

[5] Individuals who are 'cancer-free' do not qualify for additional vaccine doses (i.e., a second dose of Pneu-P-23) as their risk is the same as everyone else.

Poliomyelitis Vaccine (IPV) (trivalent, inactivated, whole virus, Vero cell origin)

IMOVAX® Polio (Sanofi Pasteur 2011 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=IMOVAX_Polio_E.pdf)

INDICATIONS NOTE: IPV is to replace OPV doses (for age requirements) documented as of April 1, 2016	**DOSE / SERIES (0.5 mL)**
1. Infants and children up to and including 3 years of age who do not require diphtheria, pertussis, tetanus, or Hib. **2**. Children 4 years to 17 years of age who do not require diphtheria or tetanus vaccine. **3.** Adults ≥18 years**.** **4**. Previously unimmunized children and adult solid organ transplant (SOT) candidates and recipients. **5**. HSCT recipients: [1] Individuals 7 years and older who are concurrently receiving Tdap.	**1. Infants and children up to and including 3 years of age:** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2 **Dose 4**: 0.5 mL SC at school entry (min. interval 6 months after dose 3) (this dose is not necessary if dose 3 was given on or after the 4th birthday). **2. & 3. Individuals 4 years and older that require a primary series** **Dose 1**: 0.5 mL SC **Dose 2**: 0.5 mL SC given 1 month after dose 1 **Dose 3**: 0.5 mL SC given 6 months after dose 2. **NOTE: At minimum, one dose must be given at or after 4 years of age.** **4.** Use schedule (1) or (2) above as appropriate for age **5. Dose 1**: 0.5 mL SC (1 year after HSCT) **Dose 2**: 0.5 mL SC (2 months after dose 1) **Dose 3**: 0.5 mL SC (1 year after dose 1)
REINFORCEMENT	**Reinforcement doses are not publicly funded**.
CONTRAINDICATIONS	History of anaphylactic reaction to any oral or injectable polio-containing vaccine, or to any IPV vaccine component.
VACCINE COMPONENTS	Each 0.5 mL dose contains: Type 1 (Mahoney) 40 D-antigen units; Type 2 (MEF1) 8 D-antigen units; Type 3 (Saukett) 32 D-antigen units. **Excipients**: 2-phenoxyethanol **Manufacturing Process Residuals**: Formaldehyde, residual calf serum protein. **Trace amounts of:** neomycin, streptomycin and polymyxin B, Medium 199 Hanks (without phenol red). Latex and thimerosal free.
EXPECTED REACTIONS	Minor local reactions, fever.
EFFECTIVENESS	Immunity following injectable poliovirus vaccine series has been shown to persist for 4 or more years after a primary series.

[1] Refer to SIM, Chapter 7, *Immunization of Special Populations,* Section 3.6 *Transplant Recipient - Haematopoietic Stem Cell Transplant. Documentation of a 3-dose primary series given by any route with at least one dose received at 4 years of age or older.*

Rabies Vaccine (Rab) Post-Exposure Indication [Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies (Sanofi Pasteur 2006 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=IMOVAX_E.pdf)

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • **NOTE:** if the exposure occurred and was managed in another country and was not in accordance with current WHO standards (approved vaccine or schedule) the rabies post-exposure prophylaxis series should be restarted as outlined below.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4 dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: **(2A)** For individuals with a history of previous immunization with an approved course of either pre- or post-exposure prophylaxis with either human diploid cell culture vaccine (HDCV) such as IMOVAX Rabies or purified chick embryo cell vaccine (PCECV) such as RabAvert, the procedure is as follows: • Rabies Immune Globulin (RabIg) - not necessary. • Rabies vaccine – 2 doses: on day 0 and day 3. **(2B)** For individuals with a history of previous immunization with an unapproved schedule or with a vaccine other than HDCV or PCECV, but has had an acceptable level of antibodies demonstrated in the past, the procedure is the same as above. **(2C)** For individuals with a history of previous immunization with an unapproved schedule or with a vaccine other than HDCV or PCECV, but who did not have an acceptable level of antibodies demonstrated in the past, the following applies: • A sample for serology may be drawn at the time of exposure (before RabIg or vaccine is administered) to potentially reduce the number of doses of vaccine needed. • RabIg is to be administered. • Rabies vaccine – Refer to **Section 1, *Previously Unimmunized Individuals* above.** • **The MHO may recommend discontinuing additional doses of rabies vaccine provided that 2 doses have been administered if serology indicates adequate immunity (≥ 0.5 IU/mL).**

Rabies Vaccine (Rab) Post-Exposure Indication [Human Diploid Cell Vaccine (HDCV)] (Inactivated whole virus)

IMOVAX® Rabies (Sanofi Pasteur 2006 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=IMOVAX_E.pdf)

RECONSTITUTION	**Package with Two Needles** 1. Attach the plunger and reconstitution needle to the syringe and reconstitute the freeze-dried vaccine by introducing the diluent provided into the vial of powder. 2. Gently swirl the contents until completely dissolved. 3. Withdraw the suspension from the vial into the syringe. 4. Remove the reconstitution needle and replace it with an appropriate needle for intramuscular injection. **Package with Attached Needle** 1. Reconstitute the freeze-dried vaccine in its vial with the diluent supplied in the syringe. 2. Gently swirl the contents until completely dissolved.
CONTRAINDICATIONS	1. There are **NO** contraindications to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product.
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, IMOVAX® Rabies or to any of the components of IMOVAX® Rabies. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Rabies virus (WISTAR Rabies PM/WI 38 1503-3M Strain), human albumin, neomycin, phenol red and may contain traces of beta propiolactone.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, muscle aches, abdominal pain, fatigue, and dizziness.
SPECIAL CONSIDERATION	IMOVAX® Rabies is pink to red in color following reconstitution. Also, it does not contain any preservative and should be used immediately after reconstitution or discarded**.**
EFFECTIVENESS	After 3 pre-exposure doses, all vaccinees reached antibody levels to confer protection. 96% showed seroconversion at 5 years.

Source: Memo to MHOs from SK CMHO *Rabies Post Exposure Prophylaxis Recommendations,* December 20, 2007.

- Wherever possible, an immunization series should be completed with the same product. However, if this is not feasible, PCECV and HDCV are considered interchangeable. People who require a booster dose of rabies vaccine can be given PCECV or HDCV regardless of the vaccine used for the initial vaccination series (CIG, 2012 Rabies : http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-rabi-rage-eng.php

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert® (GSK 2018 monograph available at: http://ca.gsk.com/media/1213530/rabavert.pdf)

INDICATIONS	**ONLY Post-Exposure Prophylaxis is publicly funded:** • As determined by Regional Medical Health Officers. • **NOTE:** if the exposure occurred and was managed in another country and was not in accordance with current WHO standards (approved vaccine or schedule) the rabies post-exposure prophylaxis series should be restarted as outlined below.
SERIES	**1. Previously Unimmunized Individuals:** **(1A) Unimmunized immunocompetent individuals to receive a 4 dose series:** • **1 mL IM on days 0 – 3 – 7 – 14** • **Day 0**: 1 mL IM as soon as possible after exposure **PLUS Rabies Immune globulin (RabIg).** • **Days 3, 7**, and **14**: 1 mL IM. **(1B) Unimmunized immunocompromised individuals* to receive a 5 dose series**: • **1 ml IM on days 0 – 3 – 7 – 14 – 28** • **Day 0:** 1 mL IM as soon as possible after exposure **PLUS RabIg.** • **Days 3, 7, 14** and **28:** 1 mL IM. *includes those taking antimalarials and/or any immunosuppressants (e.g., corticosteroids) that can result in immunosuppression. --- **2. Previously Immunized Individuals**: **(2A)** For individuals with a history of previous immunization with an approved course of either pre- or post-exposure prophylaxis with either human diploid cell culture vaccine (HDCV) such as IMOVAX Rabies or purified chick embryo cell vaccine (PCECV) such as RabAvert, the procedure is as follows: • Rabies Immune Globulin (RabIg) - not necessary. • Rabies vaccine - 2 doses: on day 0 and day 3. **(2B)** For individuals with a history of previous immunization with an unapproved schedule or with a vaccine other than HDCV or PCECV, but has had an acceptable level of antibodies demonstrated in the past, the procedure is the same as above. **(2C)** For individuals with a history of previous immunization with an unapproved schedule or with a vaccine other than HDCV or PCECV, but who did not have an acceptable level of antibodies demonstrated in the past, the following applies: • A sample for serology may be drawn at the time of exposure (before RabIg or vaccine is administered) to potentially reduce the number of doses of vaccine needed. • RabIg is to be administered. • Rabies vaccine - Refer to **Section 1, *Previously Unimmunized Individuals* above.** • **The MHO may recommend discontinuing additional doses of rabies vaccine provided that 2 doses have been administered if serology indicates adequate immunity (≥ 0.5 IU/mL).**

Rabies Vaccine (Rab) Post-Exposure Indication [Purified Chick Embryo Cell Vaccine (PCECV)] (Inactivated)

RabAvert® (GSK 2018 monograph available at: http://ca.gsk.com/media/1213530/rabavert.pdf)

RECONSTITUTION	1. Use the **longer of the 2 needles supplied** (21g x 1.5") to withdraw the entire contents of the sterile diluent into the syringe. 2. Insert the needle at a 45° angle and slowly inject the entire contents of the diluent into the vaccine vial. 3. Mix gently to avoid foaming. Unscrew the syringe from the needle to eliminate negative pressure. 4. Reinsert the syringe into the needle. Withdraw the total amount of reconstituted vaccine into the syringe. 5. **Replace the long needle with the smaller needle (25g x 1") for IM injection.**
CONTRAINDICATIONS	1. There are **NO contraindications** to rabies vaccine given for post-exposure purposes**.** 2. **DO NOT GIVE RABIES VACCINE IN THE GLUTEAL REGION.** 3. Rabies vaccine and RabIg must not be administered in the same anatomical site. 4. Use separate needles and syringes for each product
PRECAUTIONS	• Administer vaccine in an emergency room setting if history of anaphylactic reaction to a previous dose of rabies vaccine, RabAvert®, eggs or egg products, or to any of the components of RabAvert®. • There are insufficient data regarding concurrent use of mefloquine with rabies immunization.
VACCINE COMPONENTS	Freeze-dried rabies antigen, polygeline, human serum albumin, neomycin, chlortetracycline, amphotericin B, ovalbumin, potassium glutamate, sodium EDTA and may contain traces of beta propiolactone.
EXPECTED REACTIONS	**Local**: Pain, redness, swelling and itching at injection site. **Systemic:** Fever, nausea, headache, muscle aches, abdominal pain, fatigue, and dizziness.
SPECIAL CONSIDERATION	RabAvert® does not contain a preservative and should be used immediately after reconstitution or discarded.
EFFECTIVENESS	Antibodies develop 7 days after 2nd dose and persist for at least 5 years after the third dose.

Source: Memo to MHOs from SK CMHO *Rabies Post Exposure Prophylaxis Recommendations,* December 20, 2007.

- Wherever possible, an immunization series should be completed with the same product. However, if this is not feasible, PCECV and HDCV are considered interchangeable. People who require a booster dose of rabies vaccine can be given PCECV or HDCV regardless of the vaccine used for the initial vaccination series (CIG, 2012 Rabies : http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-rabi-rage-eng.php

Rotavirus vaccine (human rotavirus, live, attenuated, oral vaccine) (Rot-1)

ROTARIX™ (GlaxoSmithKline 2018 monograph available at: http://ca.gsk.com/media/1216129/rotarix.pdf)

- **Under no circumstances should Rotarix™ be injected.**
- **Rotarix™ must not be mixed with other nutritive or non-nutritive liquids or medicinal products.**
- **NOTE:** The manufacturer has not addressed if Rotarix™ be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed after Rotarix™ has been administered (http://www.immunize.org/askexperts/experts_rota.asp).[8]

INDICATIONS [1]	**DOSE / PRIMARY SERIES** [2, 3, 4, 5, 6]
SCHEDULE **Minimum age is 6 weeks old.**	**Dose 1:** 1.5 mL PO (entire contents of applicator) at 2 months of age. • **Dose 1 must be received between 6 weeks and 14 weeks 6 days of age.** **Dose 2**: 1.5 mL PO (entire contents of applicator) at 4 months of age. • **Dose 2 must be received by 8 mo. – 1 d.**
REINFORCEMENT	Not indicated at this time.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a rotavirus-containing vaccine or to any ROTARIX™ vaccine component or to latex. • Infants who have a history of intussusception. • Infants with a known or suspected immunocompromising condition should not receive ROTARIX™ without consultation with a specialist or expert in the condition. • Infants diagnosed with Severe Combined Immunodeficiency (SCID) disorder. • Infants with a history of a chronic gastrointestinal tract condition or disease, or any uncorrected congenital malformations (e.g., Meckel's diverticulum). • Infants whose mothers took monoclonal antibody medications during pregnancy. Refer to Chapter Administration of Biological Products *Appendix 8.2 Monoclonal Antibody Medications*.
PRECAUTIONS	1. Preterm infants can receive rotavirus vaccine if: a) they are chronologically aged 6 weeks and; b) are clinically stable. If the infant is in hospital, the vaccine can only administered at the time of discharge or after discharge from the neonatal intensive care unit, nursery, etc. 2. Acute gastroenteritis: 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 at more than 14 weeks 6 days of age. 3. Excretion of the vaccine virus in the stools is known to occur after vaccination and lasts for 10 days on average with peak excretion around the 7th day. Contacts of recent vaccinees should be advised to observe careful hygiene (including washing their hands) when changing children's diapers.
VACCINE COMPONENTS [7]	Each dose contains not less than 106.0 $CCID_{50}$ of human rotavirus RIX4414 strain (live, attenuated), produced on Vero cells. Each dose also contains Dulbecco's Modified Eagle Medium (DMEM), sucrose, di-sodium adipate and sterile water. **Residues:** Porcine Circovirus type 1 (PCV-1). Thimerosal free. The plunger stopper contains butyl rubber.
EXPECTED REACTIONS	Common: ≥ 1% and < 10% may have fever, diarrhea, irritability and loss of appetite. Uncommon: ≥ 0.1% and < 1% may have flatulence, vomiting, abdominal pain, dermatitis.
EFFECTIVENESS	In various studies, the percent of infants with serum anti-rotavirus IgA antibody titres≥ 20 U/mL 1 to 2 months after the second dose ranges from 77.9% (CI 73.8; 81.6) to 94.4% (CI 90.0; 97.3).

Rotavirus vaccine (human rotavirus, live, attenuated, oral vaccine) (Rot-1)

ROTARIX™ (GlaxoSmithKline 2018 monograph available at: http://ca.gsk.com/media/1216129/rotarix.pdf)

- **Rotarix™ must not be mixed with other nutritive or non-nutritive liquids or medicinal products.**
- **Under no circumstances should Rotarix™ be injected.**
- **NOTE:** The manufacturer has not addressed if Rotarix™ be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed after Rotarix™ has been administered (http://www.immunize.org/askexperts/experts_rota.asp).

[1] Age-appropriate infants who have had rotavirus gastroenteritis before starting or completing the full ROTARIX™ series should still initiate or complete the ROTARIX™ series because the initial infection frequently provides only partial immunity.

[2] The minimum interval is 4 weeks between both Rot-1 doses.

[3] If an infant spits out or regurgitates any of the Rot-1 dose, no replacement dose should be administered.

[4] There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after immunization with ROTARIX™ vaccine.

[5] ROTARIX™ vaccine may be administered at any time before, concurrently with, or after administration of any blood product, including antibody-containing products.

[6] There are no data on the interchangeability of RotaTeq® and ROTARIX™ vaccines. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known, complete the series with the available product. If any dose in the series was RotaTeq®, a total of 3 doses of rotavirus vaccine should be administered provided the age limit of 8 months minus 1 day is not exceeded.

[7] Porcine Circovirus type 1 (PCV-1) material has been detected in ROTARIX™ vaccine. PCV-1 is not known to cause disease in animals and is not known to infect or cause disease in humans. There is no evidence that the presence of PCV-1 poses a safety risk.

[8] Additional teaching/supplies/policy should be available to PHNs before administer via this route (i.e., checking NG tube placement and flushing post administration).

Rotavirus Vaccine (Rot-5) (oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Merck Frosst 2018 monograph available at: https://www.merck.ca/static/pdf/ROTATEQ-PM_E.pdf)

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions. Do not reconstitute or dilute.**
- **NOTE:** The manufacturer has not addressed if RotaTeq® be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed after Rotarix™ has been administered (http://www.immunize.org/askexperts/experts_rota.asp).[8]

INDICATIONS [1]	**DOSE / PRIMARY SERIES** [2, 3, 4, 5, 6]
SCHEDULE **Minimum age is 6 weeks old.**	**Dose 1:** 2 mL PO (entire contents of applicator) at 2 months of age. • **Dose 1 must be received between 6 weeks and 14 weeks 6 days of age.** **Dose 2**: 2 mL PO (entire contents of applicator) at 4 months of age. **Dose 3**: 2 mL PO (entire contents of applicator) at 6 months of age. • **Dose 3 must be received by 8 mo – 1 d.**
REINFORCEMENT	Not indicated at this time.
CONTRA-INDICATIONS	• History of anaphylactic reaction to a previous dose of a rotavirus-containing vaccine or to any RotaTeq® vaccine component or to latex. • Infants who have a history of intussusception. • Infants with a known or suspected immunocompromising condition should not receive RotaTeq® without consultation with a specialist or expert in the condition. • Infants diagnosed with Severe Combined Immunodeficiency (SCID) disorder or who have a family history of SCID or recurrent, unexplained early deaths in the family. • Infants with a history of a chronic gastrointestinal tract condition or disease, or any uncorrected congenital malformations (e.g., Meckel's diverticulum). • Infants whose mothers took monoclonal antibody medications during pregnancy. Refer to Chapter Administration of Biological Products *Appendix 8.2 Monoclonal Antibody Medications*.
PRECAUTIONS	1. Preterm infants can receive rotavirus vaccine if: a) they are chronologically aged 6 weeks and; b) are clinically stable. If the infant is in hospital, the vaccine can only administered at the time of discharge or after discharge from the neonatal intensive care unit, nursery, etc. 2. Acute gastroenteritis: 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 at more than 14 weeks 6 days of age. 3. Excretion of the vaccine virus in the stools is known to occur after vaccination and lasts for 10 days on average with peak excretion around the 7th day. Contacts of recent vaccines should be advised to observe careful hygiene (including washing their hands) when changing children's diapers.
VACCINE COMPONENTS [7]	Human-bovine rotavirus reassortants G1, G2, G3, G4, and P1A, sucrose, sodium citrate dihydrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, diluent and Vero cell culture media. Trace amounts of fetal bovine serum may be present. Preservative-free, thimerosal-free and latex-free.
EXPECTED REACTIONS	Fever (20.9%), diarrhea (17.6%) and vomiting (10.1%).
EFFECTIVENESS	In phase III clinical studies, 92.9% to 100% of recipients of RotaTeq® achieved a significant rise in serum anti-rotavirus IgA after a three-dose regimen.

Rotavirus Vaccine (Rot-5) (oral live viral pentavalent human-bovine reassortant)

RotaTeq® (Merck Frosst 2018 monograph available at: https://www.merck.ca/static/pdf/ROTATEQ-PM_E.pdf)

- **Under no circumstances should RotaTeq® be injected.**
- **RotaTeq® is to be administered orally without mixing with any other vaccines or solutions. Do not reconstitute or dilute.**
- **NOTE:** The manufacturer has not addressed RotaTeq® be given via g-tube but the CDC considers administration of rotavirus vaccine via g-tube to be an acceptable practice. Ensure the g-tube is flushed after RotaTeq® has been administered (http://www.immunize.org/askexperts/experts_rota.asp).

[1] Age-appropriate infants who have had rotavirus gastroenteritis before starting or completing the full RotaTeq® series should still initiate or complete the RotaTeq® series because the initial infection frequently provides only partial immunity.

[2] The minimum interval is 4 weeks between all Rot-5 doses.

[3] If an infant spits out or regurgitates any of the Rot-5 dose no replacement dose should be administered.

[4] There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after immunization with RotaTeq® vaccine.

[5] RotaTeq® vaccine may be administered at any time before, concurrently with, or after administration of any blood product, including antibody-containing products.

[6] There are no data on the interchangeability of RotaTeq® and ROTARIX™ vaccines. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known, complete the series with the available product. If any dose in the series was RotaTeq®, a total of 3 doses of rotavirus vaccine should be administered provided the age limit of 8 months minus 1 day is not exceeded.

[7] DNA fragments from porcine circoviruses (PCV) 1 and 2 have been detected in RotaTeq®. The source is porcine-derived material used in the manufacture of the vaccine. PCV-1 and PCV-2 are not known to cause disease in humans.

[8] Additional teaching/supplies/policy should be available to PHNs before administer via this route (i.e., checking NG tube placement and flushing post administration).

Tetanus-Diphtheria Vaccine (Td) (Adsorbed)

Td Adsorbed (Sanofi Pasteur 2012 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=td_adsorbed_e.pdf)

INDICATIONS (≥7 years old)	**DOSE / SERIES**
1. Wound management [1] 2. For those 7 years and older who are up-to-date for polio and pertussis immunization. 2. Adults 18 years and older who have not started or completed a primary series, or whose immunization status in unknown.	1. **Dose:** 0.5 mL IM [2] 2. **First visit [3]: one dose of Tdap followed by two doses of Td.** **Second visit:** Td 0.5 mL IM 1 month after Tdap. **Third visit**: Td 0.5 mL IM 6-12 months after 2nd Td dose.
REINFORCEMENT	Tetanus-containing vaccine is recommended every 10 years for adults [1].
CONTRAINDICATIONS	1. History of anaphylactic reaction to a previous dose of any tetanus or diphtheria-containing vaccine, or to any Td vaccine component. 2. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given • Refer to *Tetanus Immune Globulin* (TIg) in this chapter. • Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.* 3. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	Tetanus toxoid, diphtheria toxoid. Excipients: Aluminum phosphate (adjuvant), 2-phenoxyethanol, isotonic solution of sodium chloride in water for injection. Manufacturing process residuals: formaldehyde is present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local:** Discomfort, pain, swelling, redness at injection site. **Systemic**: Fever, chills, sore or swollen joints.
SPECIAL CONSIDERATION	For wound prophylaxis, Td and TIg should be administered using separate syringes and different sites.
EFFECTIVENESS	May not protect 100% of susceptible individuals.

[1] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management.
[2] Tetanus toxoid should not be given routinely to clients who have received a tetanus-containing vaccine in the previous 5 years. Refer to Chapter 5, Section 2.1, *Minimum Intervals for Specific Vaccine Series.*
[3] Refer to Chapter 5, Section 1.6, *Adults 18 Years and Older When Starting Immunization.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

ADACEL® (Sanofi Pasteur 2012 monograph available at:
https://www.vaccineshoppecanada.com/document.cfm?file=ADACEL_E.pdf)

INDICATIONS, DOSES and SERIES [*, 1, 2] (0.5 mL IM) (Min. age 4 years old)

1. Wound Management. [1]
2. Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements.
3. Reinforcement dose for Grade 8 students. [2]
4. One dose for adults 18 years and older to replace routine Td reinforcement dose
5. Adult caregivers of infants <6 months old who have not received Tdap as an adult. [3]
6. Pregnant women: in every pregnancy, ideally between 27-32 weeks gestation. [4]
7. Special Populations - Refer to Chapter 7, *Immunization of Special Populations* for specific medical condition.
8. Children and Adolescents 7-17 years of age (inclusive):
   - **A.** Booster dose for those who missed receiving the school entry booster dose.
   - **B.** Incompletely immunized children and adolescents [3]:
     - If the first dose of DTaP-containing vaccine was administered **after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as:
       - Dose 1 was administered after the 1st birthday
       - Dose 2: 1 month after 1st dose
       - Dose 3: 6 months after 2nd dose
     - If the first dose of DTaP-containing vaccine was administered **before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as:
       - Dose 1 was administered before the 1st birthday
       - Dose 2: 1 month after 1st dose
       - Dose 3: 1 month after 2nd dose
       - Dose 4: 6 months after 3rd dose
     - Unimmunized children and adolescents completing a 3-dose primary series given as:
       - Dose 1
       - Dose 2: 1 months after 1st dose
       - Dose 3: 6 months after 2nd dose
8. Adults 18 years of age and older:
   - **A.** Unimmunized or incompletely immunized adults completing a 3-dose primary series given as:
     - Tdap-IPV as Dose 1
     - Td and IPV for Doses 2: 1 months after 1st dose
     - Td and IPV for Doses 3: 6 months after 2nd dose

REINFORCEMENT	None
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	Each 0.5 mL is formulated to contain: tetanus toxoid, diphtheria toxoid, acellular pertussis [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol. **Manufacturing residuals**: Formaldehyde and glutaraldehyde are present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Redness, tenderness, swelling, induration, pain. **Systemic:** Headache, decreased energy, generalized body-ache, nausea, diarrhea, fever, sore or swollen joints.
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*. Tdap is recommended for those 7-17 years [who are not up to date with pertussis vaccine] (CIG).

[2] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8.

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection years.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-acellular Pertussis Vaccine (Tdap)

BOOSTRIX® (GlaxoSmithKline 2018 monograph available at: http://ca.gsk.com/media/589361/boostrix.pdf)

INDICATIONS, DOSES and SERIES [*, 1, 2] (0.5 mL IM) (Min. age 4 years old)
1. Wound Management [1] **2.** Booster (5th) dose at age 4-6 years (school entry) who have met polio vaccine requirements. **3.** Reinforcement dose for Grade 8 students. [2] **4.** One dose for adults 18 years and older to replace routine Td reinforcement dose. **5.** Adult caregivers of infants <6 months old who have not received Tdap as an adult. [3] **6.** Pregnant women: Tdap in every pregnancy, ideally between 27-32 weeks gestation. [4] **7.** Special Populations - Refer to Chapter 7, *Immunization of Special Populations* for specific medical condition. **8.** Children and Adolescents 7-17 years of age (inclusive): **A.** Booster dose for those who missed receiving the school entry booster dose. **B.** Incompletely immunized children and adolescents [3]: • If the first dose of DTaP-containing vaccine was administered **after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as: • Dose 1 was administered after the 1st birthday • Dose 2: 1 month after 1st dose • Dose 3: 6 months after 2nd dose • If the first dose of DTaP-containing vaccine was administered **before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as: • Dose 1 was administered before the 1st birthday • Dose 2: 1 month after 1st dose • Dose 3:1 month after 2nd dose • Dose 4: 6 months after 3rd dose • Unimmunized children and adolescents completing a 3-dose primary series given as: • Dose 1 • Dose 2: 1 month after 1st dose • Dose 3: 6 months after 2nd dose **8.** Adults 18 years of age and older: **A.** Unimmunized or incompletely immunized adults completing a 3-dose primary series given as: • Tdap-IPV as Dose 1 • Td and IPV for Doses 2: 1 month after 1st dose • Td and IPV for Doses 3: 6 months after 2nd dose

REINFORCEMENT	None
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria or pertussis-containing vaccine, or to any Tdap vaccine component. 3. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given. Refer to *Tetanus Immune Globulin* (TIg) in this chapter. [1] 4. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	Diphtheria toxoid, tetanus toxoid, three purified pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (69 kDalton outer membrane protein)] adsorbed onto aluminum salts. Thimerosal free. Latex-free.
EXPECTED REACTIONS	**Local**: redness, tenderness, swelling, induration, pain. **Systemic**: headache, decreased energy, generalized body-ache, nausea, diarrhea, fever sore or swollen joints
EFFECTIVENESS	93-100% show protective levels for at least 5 years

***** According to the National Advisory Committee on Immunization (NACI), there is no upper age limit for the administration of Tdap. This differs from the information in the Tdap product monographs.

[1] Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*. Tdap is recommended for those 7-17 years [who are not up to date with pertussis vaccine] (CIG).

[2] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8.

[3] There is no minimum interval between a dose of Td and Tdap when Tdap is being given for pertussis protection years.

[4] Refer to Chapter 7 *Appendix 7.7: Tdap Immunization Decision Chart for Pregnant Women.*

Tetanus-Diphtheria-Inactivated Poliomyelitis Adsorbed Vaccine (Td-IPV)

Td-Polio Adsorbed (Sanofi Pasteur 2010 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=td_polio_adsorbed_e.pdf)

INDICATIONS	**DOSE / SERIES**
1. Primary immunization of those 7 years and older when only tetanus, diphtheria and polio are indicated. 2. Solid organ transplant candidates or recipients 7 years and older when only tetanus, diphtheria and polio are indicated 3. HSCT recipients 7 years and older when only tetanus, diphtheria and polio are indicated	1. **Dose 1**: 0.5 mL IM **Dose 2**: 0.5 mL IM 4 weeks after 1st dose. **Dose 3**: 0.5 mL IM 6-12 months after 2nd dose 2. & 3. • Refer to Chapter 7, *Immunization of Special Populations* for specific medical condition.
REINFORCEMENT	• Reinforcement (booster) doses of IPV vaccine are not publicly funded. • Tetanus-containing vaccine is recommended every 10 years for adults [1]
CONTRAINDICATIONS 1. History of anaphylactic reaction to a previous dose of any tetanus, diphtheria, or polio-containing vaccines or to any Td-IPV vaccine component. 2. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given: ○ Refer to *Tetanus Immune Globulin* (TIg) in this chapter. ○ Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.* 3. History of Guillain-Barré syndrome (GBS) occurring within 6 weeks of receipt of a tetanus-containing vaccine.	
VACCINE COMPONENTS	Each dose (0.5 mL) is formulated to contain: tetanus toxoid 5 Lf, diphtheria toxoid 2 Lf purified inactivated poliomyelitis vaccine, Type 1 (Mahoney) 40 D-antigen units, Type 2 (MEF1) 8 D-antigen units, Type 3 (Saukett) 32 D-antigen units. Other ingredients per dose include 0.5% v/v of 2-phenoxyethanol (not as a preservative), 1.5 mg of aluminum phosphate equivalent to 0.33 mg of aluminum as the adjuvant, and 27 ppm of formaldehyde. The vaccine also contains approximately 10 ppm polysorbate 80 and ≤50 ng of bovine serum albumin (by calculation). Trace amounts of neomycin and polymyxin B may be present from the cell growth medium. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Discomfort, tenderness, pain, swelling, redness at injection site. **Systemic**: Headache, malaise, dizziness, muscle aches.
EFFECTIVENESS	After completing primary series, protective antibodies persist for up to 10 years.

[1] Tetanus toxoid should not be given routinely to clients who have received a tetanus-containing vaccine in the previous 5 years. Refer to Chapter 5, Section 2.1, *Minimum Intervals for Specific Vaccine Series*.

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

ADACEL®-POLIO (Sanofi Pasteur 2013 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=adacel-polio_e.pdf)

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old)

1. Wound Management [5]

2. Booster (5th) dose at age 4-6 years (school entry) [1, 2]

3. Children and Adolescents 7-17 years of age (inclusive):

- **A.** Booster dose for those who missed receiving the school entry booster dose.
- **B.** Incompletely immunized children and adolescents [3]:
  - If the first dose of DTaP-containing vaccine was administered **after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as:
    - Dose 1 was administered after the 1st birthday
    - Dose 2: 1 month after 1st dose
    - Dose 3: 6 months after 2nd dose
  - If the first dose of DTaP-containing vaccine was administered **before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as [4]:
    - Dose 1 was administered before the 1st birthday
    - Dose 2: 1 month after 1st dose
    - Dose 3: 1 month after 2nd dose
    - Dose 4: 6 months after 3rd dose
  - Unimmunized children and adolescents completing a 3-dose primary series given as:
    - Dose 1
    - Dose 2: 1 month after 1st dose
    - Dose 3: 6 months after 2nd dose

4. Adults 18 years of age and older:

- **A.** Unimmunized or incompletely immunized adults completing a 3-dose primary series given as:
  - Tdap-IPV as Dose 1
  - Td and IPV for Doses 2: 1 month after 1st dose
  - Td and IPV for Doses 3: 6 months after 2nd dose

REINFORCEMENT	None
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of DPT, DTaP, Tdap or IPV-containing vaccine or to any ADACEL®-POLIO vaccine component. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of tetanus – containing vaccine. 4. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given: ▪ Refer to *Tetanus Immune Globulin* (TIg) in this chapter. ▪ Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management.*
VACCINE COMPONENTS	Tetanus toxoid, reduced diphtheria toxoid, acellular pertussis antigens [pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), fimbriae types 2 and 3 (FIM)], and inactivated poliomyelitis vaccine [type 1 (Mahoney), type 2 (MEF-1) and type 3 (Saukett)]. **Excipients**: Aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80. **Manufacturing residuals**: Bovine serum albumin, formaldehyde, glutaraldehyde, streptomycin, neomycin and polymyxin B are present in trace amounts. Latex and thimerosal free.
EXPECTED REACTIONS	**Local**: Pain, swelling, redness. **Systemic**: Tiredness, fever, headache, nausea, body aches, sore or swollen joints, and chills.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib, DTaP-IPV or Tdap was given after the 4th birthday.

[2] Refer to SIM, Chapter 10 *Immunization Recommendations for Children 4-6 years of Age.*

[3] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8.

[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.

[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management. Tdap-IPV is recommended for those 7-17 years [who are not up to date with polio and pertussis vaccines] (CIG).

Tetanus-Diphtheria-Acellular Pertussis-Inactivated Poliomyelitis Adsorbed Vaccine (Tdap-IPV)

BOOSTRIX®-POLIO (GlaxoSmithKline 2017 monograph available at: http://ca.gsk.com/media/589683/boostrix-polio.pdf)

INDICATIONS, DOSES and SERIES (0.5 mL IM) (Min. age 4 years old)

1. Wound Management (if client assessed as needing pertussis and polio antigens). [5]

2. Booster (5th) dose at age 4-6 years (school entry). [1, 2]

3. Children and Adolescents 7-17 years of age (inclusive):

A. Booster dose for those who missed receiving the school entry booster dose.

B. Incompletely immunized children and adolescents: [3]

- If the first dose of DTaP-containing vaccine was administered **after the 1st birthday**, administer remaining dose(s) in order to complete a 3-dose primary series given as:
  - Dose 1 was administered after the 1st birthday)
  - Dose 2: 1 month after 1st dose
  - Dose 3: 6 months after 2nd dose
- If the first dose of DTaP-containing vaccine was administered **before the 1st birthday**, administer remaining dose(s) in order to complete a 4-dose primary series given as [4]:
  - Dose 1 was administered before the 1st birthday
  - Dose 2: 1 month after 1st dose
  - Dose 3: 1 month after 2nd dose
  - Dose 4: 6 months after 3rd dose
- Unimmunized children and adolescents completing a 3-dose primary series given as:
  - Dose 1
  - Dose 2: 1 month after 1st dose
  - Dose 3: 6 months after 2nd dose

4. Adults 18 years of age and older:

A. Unimmunized or incompletely immunized adults completing a 3-dose primary series given as:

- Tdap-IPV as Dose 1
- Td and IPV for Doses 2: 1 month after 1st dose
- Td and IPV for Doses 3: 6 months after 2nd dose

REINFORCEMENT	None
CONTRA-INDICATIONS	1. Children younger than 4 years old. 2. History of anaphylactic reaction to a previous dose of DPT, DTaP, Tdap or IPV-containing vaccine or to any ADACEL®-POLIO vaccine component. 3. History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of tetanus – containing vaccine. 4. When a contraindication exists to tetanus toxoid and a client sustains a major or unclean wound, TIg should be given ▪ Refer to *Tetanus Immune Globulin* (TIg) in this chapter. ▪ Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*.
VACCINE COMPONENTS	Not less than 2.5 limit of flocculation ('Lf'), or 2 IU ('International Units') of diphtheria toxoid; not less than 5 Lf (20 IU) of tetanus toxoid; 8 mcg of pertussis toxoid, 8 mcg of filamentous haemagglutinin, 2.5 mcg of pertactin (69 kDa outer membrane protein), 40 D-antigen units (DU) of Type 1 poliovirus, 8 DU Type 2 polio virus and 32 DU Type 3 polio virus. Aluminum adjuvant (as aluminum salts), sodium chloride, water for injection and medium 199. Formaldehyde, neomycin and polymyxin are present as traces. Thimerosal free. Latex –free.
EXPECTED REACTIONS	**Local**: pain, redness and swelling reported by 33.5 - 66.9% of recipients. **Systemic**: Fatigue, headache, fever, various gastrointestinal symptoms, drowsiness, irritability.
EFFECTIVENESS	Tetanus, diphtheria and polio antibodies are robust and pertussis antibodies in fully immunized children persist after 3 years of receiving Tdap-IPV as a replacement for DTaP-IPV.

[1] Not required if the 4th dose of DTaP-IPV-Hib, DTaP-IPV or Tdap was given after the 4th birthday.

[2] Refer to SIM, Chapter 10 *Immunization Recommendations for Children 4-6 years of Age.*

[3] Children who complete their primary series, or receive a booster dose of Tdap after their 11th birthday, do not require an additional dose of Tdap in Grade 8.

[4] As only 3 doses of polio are required, Tdap may be used as one of the doses in this series, ensuring the recommended intervals for polio are maintained.

[5] Refer to Chapter 5, Section 3.7, Tetanus Prophylaxis in Wound Management. Tdap-IPV is recommended for those 7-17 years who are not up to date with polio and pertussis vaccines.

Typhoid Vaccine (Typh-I) (*Salmonella typhi* Vi Capsular Polysaccharide) (Inactivated)

[Non-publicly funded]

TYPHIM Vi® (Sanofi Pasteur 2013 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=Typhim_Vi_E.pdf)

Typhoid Vaccine (Typh-O) (Live Oral Attenuated Ty 21a) [Non-publicly funded]

VIVOTIF® (Valneva 2015 monograph available at:
https://www.valneva.ca/download.php?dir=vivotif&file=2015-01-23_Canadian_Product_Monograph_for_Vivotif_en.pdf

Typhoid Vaccine (Typh-I) (*Salmonella typhi* Vi Capsular Polysaccharide) [Non-publicly funded]

TYPHERIX® (GlaxoSmithKline 2014 monograph available at: http://gsk.ca/english/docs-pdf/product-monographs/Typherix.pdf)

Varicella Vaccine (Var) (live, attenuated)

VARILRIX® (GlaxoSmithKline 2017 monograph available at: http://ca.gsk.com/media/592366/varilrix.pdf)

INDICATIONS [1]	**DOSE 0.5 mL SC** [3]
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. Refer to Chapter 5 Appendix 5.4 *Publicly Funded Varicella Immunization Eligibility and Panorama Directives* for details. 2. Non-immune HCW/post-secondary healthcare students as specified in chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in chapter 7. [2] 4. Susceptible immunocompromised individuals as determined by their specialist. [4]	• 1 year up to and including 12 years old: ▪ ≥ 3 month interval required between doses 1 and 2 but ≥ 4 week is considered valid • 13 years and older: ▪ ≥ 4 week interval required between doses 1 and 2

CONTRAINDICATIONS

- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARILRIX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- Recent administration of an immune globulin preparation or blood product. [2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* .

PRECAUTIONS

- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization for immunocompetent clients should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine other than the second dose of varicella, which should be delayed for 4 weeks to 3 months.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Live, attenuated varicella virus vaccine (Oka-strain), amino acids, lactose, mannitol, sorbitol and water for injection. Neomycin sulphate is present as traces. Thimerosal free.

EXPECTED REACTIONS: Local: Pain, redness, swelling at injection site. **Systemic**: Rash, fever.

SPECIAL CONSIDERATION: Administer vaccine immediately after reconstitution.

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

*****Varicella footnotes are continued on next page.

Varicella Vaccine (Var) (live, attenuated)

VARILRIX® (GlaxoSmithKline 2017 monograph available at http://ca.gsk.com/media/592366/varilrix.pdf)

[2] According to the Canadian Immunization Guide, (2012 Evergreen Ed., accessible at http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php#meas) the first varicella vaccine dose should be given in the immediate post-partum period, before discharge from hospital unless they have received Rh immune globulin [RhIg].
To optimize response to vaccine, varicella-susceptible women who receive RhIg in the post-partum period should generally wait 3 months before being vaccinated with varicella vaccine. The risk of lowered vaccine efficacy needs to be weighed against the need for protection. However, if there is a risk of exposure to varicella, a risk of recurrent pregnancy in the 3-month post-partum period, or a risk that vaccines may not be given later, monovalent varicella vaccines may be given prior to discharge. In that context, serologic testing for varicella should be done 3 months later and non-immune women should be revaccinated with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total). In the event that a post-partum woman receives varicella vaccine prior to receiving RhIg within 72 hours post-delivery, serologic testing for varicella should be done 3 months later and the woman revaccinated if non-immune with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total).

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

[4] Refer to Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*.

Varicella Vaccine (Var) (live, attenuated)

VARIVAX® III (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/VARIVAX_III-PM_E.pdf)

INDICATIONS [1]	**DOSE 0.5 mL SC** [3]
1. Those born since 1993-01-01 are eligible to receive an age or cohort appropriate series. Refer to Chapter 5 Appendix 5.4 *Publicly Funded Varicella Immunization Eligibility and Panorama Directives* for details. 2. Non-immune HCW/post-secondary healthcare students as specified in chapter 7. 3. Non-immune non-pregnant women of child-bearing age as specified in chapter 7. [2] 4. Susceptible immunocompromised individuals as determined by their specialist. [4]	• 1 year up to and including 12 years old: ▪ ≥ 3 month interval required between doses 1 and 2 but ≥ 4 week is considered valid • 13 years and older: ▪ ≥ 4 week interval required between doses 1 and 2

CONTRAINDICATIONS

- History of an anaphylactic reaction to a previous dose of any varicella –containing vaccine, or to any component of VARILRIX®.
- Pregnancy. Women of childbearing age should avoid pregnancy for at least 28 days (1 month) post-vaccination.
- Active untreated TB.
- Recent administration of an immune globulin preparation or blood product. [2] Refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* .

PRECAUTIONS

- Those 18 years and younger should avoid taking salicylates for 6 weeks after receiving a varicella-containing vaccine. Specialist consultation is required prior to immunization of these children with a varicella-containing vaccine.
- Family history of congenital immunodeficiency. Refer to SIM, Chapter 7, *Immunization of Special Populations* Section 3.1, *Congenital Immunodeficiency*
- Do TB skin testing on the same day as varicella immunization or delay TB skin testing for ≥ 4 weeks.
- Varicella immunization for immunocompetent clients should be given on the same day as other live vaccines or delayed until 4 weeks after administration of any other live vaccine other than the second dose of varicella, which should be delayed for 4 weeks to 3 months.
- Systemic antiviral therapy (e.g., acyclovir, valacyclovir, famciclovir) should be avoided for 24 hours after the last dose as it may affect the reproduction of the vaccine virus and may reduce the efficacy of varicella-containing vaccine (CIG).
- It is recommended that people taking long-term antiviral therapy should discontinue these drugs, if possible, from at least 24 hours before administration of varicella-containing vaccine and should not restart antiviral therapy until 14 days after vaccine administration (CIG).

VACCINE COMPONENTS: Oka/Merck varicella strain (live, attenuated) ≥1350 PFU. **Excipients**: Sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, water for injection. Preservative (thimerosal) free. Latex-free.

EXPECTED REACTIONS: Local: Pain, redness, swelling at injection site. **Systemic**: Rash, fever.

SPECIAL CONSIDERATION: Minimum potency remaining at expiry 90 minutes after reconstitution and storage at room temperature. Administer vaccine immediately after reconstitution.

[1] Varicella susceptible is defined as:

- Lack of documented evidence of serological of VZV IgG antibodies; or
- Lack of documented evidence of immunization with 2 doses of a varicella-containing vaccine.
- **NOTE**: verbal history of disease is unacceptable evidence of immunity for those born since Jan. 1, 2003.

*****Varicella footnotes are continued on next page**.

Varicella Vaccine (Var) (live, attenuated)

VARIVAX® III (Merck Frosst 2016 monograph available at: https://www.merck.ca/static/pdf/VARIVAX_III-PM_E.pdf)

[2] According to the Canadian Immunization Guide, (2012 Evergreen Ed., accessible at http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-10-eng.php#meas) the first varicella vaccine dose should be given in the immediate post-partum period, before discharge from hospital unless they have received Rh immune globulin [RhIg].
To optimize response to vaccine, varicella-susceptible women who receive RhIg in the post-partum period should generally wait 3 months before being vaccinated with varicella vaccine. The risk of lowered vaccine efficacy needs to be weighed against the need for protection. However, if there is a risk of exposure to varicella, a risk of recurrent pregnancy in the 3-month post-partum period, or a risk that vaccines may not be given later, monovalent varicella vaccines may be given prior to discharge. In that context, serologic testing for varicella should be done 3 months later and non-immune women should be revaccinated with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total). In the event that a post-partum woman receives varicella vaccine prior to receiving RhIg within 72 hours post-delivery, serologic testing for varicella should be done 3 months later and the woman revaccinated if non-immune with two Var doses given at appropriate intervals from the initial post-partum dose (NOTE: they may receive 3 vaccine doses in total).

[3] Individuals who are eligible for a 2-dose varicella series who have documented evidence of **viral culture confirmed** (breakthrough) varicella disease 42 days or more after their first varicella-containing vaccine dose do not require a second varicella-containing vaccine dose. Provide a second dose of varicella-containing vaccine to those without this documentation as verbal history and/or healthcare practitioner diagnosis of breakthrough disease is unreliable.

[4] Refer to Chapter 7, *Immunization of Special Populations.* Appendix 7.2: *Varicella Immunization Referral Form*

Yellow Fever Vaccine (YF) [Non-publicly funded]

YF-VAX® (Sanofi Pasteur 2016 monograph available at:
hhttps://www.vaccineshoppecanada.com/document.cfm?file=YF_VAX_E.pdf)

Tuberculin Purified Protein Derivative (PPD) (Mantoux)

TUBERSOL® (Sanofi Pasteur 2016 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=tubersol_e.pdf)

INDICATIONS	Screening for latent tuberculosis infection (LTBI). • Refer to TB Prevention and Control Saskatchewan: Clinical Policies and Procedures 30-001: TUBERCULIN SKIN TESTING at: https://www.saskatoonhealthregion.ca/locations_services/Services/TB-Prevention/Documents/PolicyandProcedures/Tuberculin%20skin%20testing%20%28policy%20and%20procedure%29.pdf
DOSE/SERIES	PPD 5 TU 0.1 mL ID in anterior forearm (flexor or dorsal surface) between the wrist and the elbow: • For contact tracing, if the initial skin test is negative, a second test should be given 6 – 12 weeks after the last date of contact. • A second test, done 7 - 21 days after the first test, may be required in certain situations and would be on the advice of TB Control. • A small percentage of persons will only react after a second test or will react to a greater degree (so called "boosting" effect).
EXPECTED REACTIONS	• **Read result in 48 – 72 hours.** • Possible redness, induration and blistering. • Measure only induration (raised) diameter in millimetres and record this measurement.
CONTRA-INDICATIONS	• Pregnancy is not a contraindication to tuberculin testing. • A previous Bacille Calmette-Guerin (BCG) vaccine is not a contraindication to tuberculin testing**.** • History of anaphylactic reaction to a previous dose of Tubersol or any of its components. • **Tubersol should not be administered to:** o known tuberculin positive reactors; o persons with severe blistering tuberculin reactions in the past; o persons with documented active tuberculosis or a clear history of treatment for TB infection or disease; or o persons with extensive burns or eczema.
PRECAUTION	Do TB skin testing on the same day as live vaccines are administered, or delay TB skin testing for ≥4 weeks after a live vaccine if possible.
EXPECTED REACTIONS	Pain, pruritis and bruising at the test site may occur.
0 to 4 mm induration	• HIV infection **with** immune suppression **and** high expectation of TB infection (e.g., client is from a population with a high prevalence of TB, is a close contact of an infectious active TB case, or has an abnormal chest x-ray (as per TB Prevention and Control Saskatchewan, 2013). • Children suspected of having active TB.
≥ 5 mm induration	• HIV infection. • Contact with infectious TB case within the past 2 years. • Presence of fibronodular disease on chest x-ray. • Other immune suppression related to medical therapy or disease: (e.g., organ transplantation, TNF alpha inhibitors, prolonged use of high dose corticosteroids, cancer chemotherapy, or end-stage renal disease).
≥ 10 mm induration	All others - refer to *Canadian Tuberculosis Standards* (7th Ed.) Available at: http://www.respiratoryguidelines.ca/tb-standards-2013.
COMPONENTS	Purified protein derivative of *M. tuberculosis*, phenol, polysorbate 80.

Immune Globulin Preparation Injection Site, Needle Length and Total Site Volume per Age Group

CLIENT AGE	SITE▲ (90° IM)	NEEDLE LENGTH	SIZE (Gauge)	MAX. VOLUME
Children				
• Birth to less than 12 months old	Vastus lateralis	1”	23	1 mL
• 12 months up to and including 4 years	Deltoid * Vastus lateralis	1” 1”	22-23 22-23	1 mL 2 mL
• 5 years up to and including 17 years	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1” – 1½” 1” – 1½” 1” – 1½” 1” – 1½”	20-23 22-23 20-23 20-23	1 mL 3 mL 3 mL 3 mL
Adults				
• 18 years and older	Deltoid [1] Vastus lateralis Ventrogluteal Dorsogluteal [2]	1” – 1½” 1” – 1½” 1” – 1½” 1” – 1½”	20-22 20-22 20-22 20-22	2 mL 5 mL 4 mL 5 mL

(Adapted from BCCDC Immunization Manual, 2009)

* When the deltoid muscle is considered for use in young children 12 months of age or over, assesses the adequacy of the muscle size prior to administration.

▲ Different immune globulin preparations **must be** separated by minimum 2.5 cm if given in the same limb (e.g., TIg and RabIg in adult deltoid). **It is recommended to administer in different sites if possible.**

[1] One deltoid should be reserved for the administration of rabies vaccine **on day 0** of rabies post-exposure immunoprophylaxis.

[2] Use of the dorsogluteal site is **only recommended in adolescents and adults** when the deltoid, vastus lateralis and ventrogluteal sites have had maximum volumes of an immune globulin preparation injected and an additional volume still needs to be administered. This is due to the possibility of sciatic nerve injuries when the injection is done in the dorsogluteal site.

Botulism Immune Globulin (BIg-IV)

BabyBIG (Cangene USA)

This product is not manufactured in Canada and is only available through the *Special Access Program* (SAP). An information binder is shipped with every request for professional reference.

INDICATIONS	To treat patients younger than 12 months of age diagnosed with infant botulism.
INITIAL SERIES	Refer to binder.
REINFORCEMENT	Refer to binder.
CONTRAINDICATIONS	Refer to binder.
COMPONENTS	Refer to binder.
EXPECTED REACTIONS	Refer to binder.
SPECIAL CONSIDERATION	Refer to binder.

Hepatitis B Immune Globulin (HBIg) (Human)

HepaGam B® (Aptevo BioTherapeutics 2017monograph available at: https://hepagamb.ca/_uploads/documents/hepagam/hepagam-b-english-pristine-pm.pdf)

INDICATIONS	**DOSE / SERIES** [1]
1. Infant born to known HBsAg positive woman. 2. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work)) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. 3. Percutaneous or mucosal exposure to HBsAg positive source. 4. Sexual contact with a person who has acute or chronic hepatitis B infection. 5. An at-risk known non-responder to two series of HB vaccine.	1. & 2. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series [2, 3] 3. Give HBIg 0.06 mL/kg of body weight and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization [4, 5] 4. Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] 5. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.

REINFORCEMENT	Currently no recommendations
CONTRA-INDICATIONS	**None**
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Clients with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given HBIg unless the benefits outweigh the risks. • HBIg must be given at a separate anatomic site from hepatitis B vaccine. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

Hepatitis B Immune Globulin (HBIg) (Human) **HepaGam B®** (Aptevo BioTherapeutics 2017 monograph available at: https://hepagamb.ca/_uploads/documents/hepagam/hepagam-b-english-pristine-pm.pdf)	
COMPONENTS	Human plasma protein (≥96% Human IgG), maltose, polysorbate 80. May contain trace amounts of tri-n-butyl phosphate and Triton X-100®
EXPECTED REACTIONS	Local pain and tenderness at injection site, urticaria and angioedema may occur.

[1] There is no upper limit to the volume of HBIg that can be administered.

[2] Refer to SIM, Chapter 7, *Immunization of Special Populations*, Section 4.2.1, *Hepatitis B Infant Immunoprophylaxis Protocol* for more information.

[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.

[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Hepatitis B Immune Globulin (HBIg) (Human)

HyperHEP B® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperHEP-B-SD-en.pdf)

INDICATIONS	DOSE / SERIES [1]
1. Infant born to known HBsAg positive woman. **2**. Infant born to woman at high risk for hepatitis B infection (i.e., intravenous drug use, sex trade work)) whose infectious status is unknown or negative (possible window period) and cannot be determined within 12 hours of birth. **3.** Percutaneous or mucosal exposure to HBsAg positive source. **4**. Sexual contact with a person who has acute or chronic hepatitis B infection. **5**. An at-risk known non-responder to two series of HB vaccine**.**	**1. & 2**. Give HBIg 0.5 mL IM within 12 hours of birth, along with first dose of hepatitis B vaccine series. [2, 3] **3.** Give HBIg 0.06 mL/kg of body weight and hepatitis B vaccine IM as required, considering the client's immune status and history of hepatitis B immunization. [4, 5] **4.** Give HBIg 0.06 mL/kg of body weight IM as soon as possible following the last sexual exposure, along with hepatitis B vaccine series [4, 5] **5**. **Dose 1**: HBIg 0.06 mL/kg of body weight IM. **Dose 2**: HBIg 0.06 mL/kg of body weight IM 4 weeks later.

CONTRAINDICATIONS	**None**
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding HBIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give HBIg with caution (i.e., in a setting capable of managing anaphylaxis) if the person has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Clients with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given HBIg unless the benefits outweigh the risks. • HBIg must be given at a separate anatomic site from hepatitis B vaccine. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

Hepatitis B Immune Globulin (HBIg) (Human)

HyperHEP B® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperHEP-B-SD-en.pdf)

COMPONENTS	Contains human hepatitis B hyperimmune immune globulin≥ 220 IU/mL, glycine, and sodium carbonate. Preservative free. Prefilled syringes contain rubber needle shield and stopper.
EXPECTED REACTIONS	Local pain and tenderness at injection site, urticaria and angioedema may occur.

[1] There is no upper limit to the volume of HBIg that can be administered.

[2] Refer to Chapter 7, Section 4.2.1, *Hepatitis B Infants Immunoprophylaxis Protocol* for more information.

[3] There is no outer time limit for administering HBIg in infants less than 12 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 ml HBIg.

[4] HBIg dose for all clients ≥ 8.3 kg is 0.06 ml/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous or permucosal exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous or permucosal exposure, give Hepatitis B vaccine only. For sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a sexual exposure, give HB vaccine only. Refer to *Saskatchewan Post-Exposure Prophylaxis* recommendations available at: http://www.ehealthsask.ca/services/manuals/Pages/hiv-guidelines.aspx

[5] Refer to *Immune Globulin Preparation Maximum Site Volumes*

Immune Globulin (Ig) (Human) – Contact Canadian Blood Services to order: Tel: 1-888-236-6283.
GamaSTAN® S/D (Grifols Therapeutics 2018 monograph available at: http://www.grifols.ca/documents/17006/133313/GamaSTAN-SD-en.pdf/8166db44-8ec4-44a2-8fa5-f37bcafbf8e6)

INDICATIONS	
1. Recommended and provided free for post-exposure prophylaxis of hepatitis A contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1] **2**. Recommended and provided free for post-exposure prophylaxis of measles contacts as outlined in the *Saskatchewan Communicable Disease Control Manual*. [1]	
CONTRA-INDICATIONS	**Do not give GamaSTAN® S/D product intravenously.**
PRECAUTIONS	• Health Canada has advised that the GamaSTAN® S/D product monograph has been updated to strengthen warnings on the rare but serious risk of blood clots. Blood clots have been reported in patients with and without risk factors, and can occur regardless of immunoglobulin dose or route of administration (injection into a muscle, vein or under the skin). [2] • Human Ig products are amongst the safest blood-derived products available. As the method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV, the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Persons with severe thrombocytopenia or coagulation disorders that contraindicate IM injections should not be give IM Ig unless the benefits outweigh the risks. • Give Ig with caution (e.g., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or history of anaphylactic reaction to glycine or to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, Ig should only be given to such persons if the expected benefits outweigh the risks. • Divide large volumes of Ig into two or more sites. Refer to *Immune Globulin Preparation Maximum Site Volumes* chart in this chapter. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older). • If administration of Ig is necessary less than 14 days after MMR or varicella vaccine, repeat vaccine as per recommended intervals. Refer to SIM, Chapter 5, *Immunization Schedules*, Section 3.5 *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*.
COMPONENTS	GamaSTAN® S/D contains 15-18% immune globulin (human) as active ingredient. It also contains 0.21-0.32 M glycine, USP. Preservative free.
EXPECTED REACTIONS	Local pain and injection site tenderness.

[1] Immune globulin should be given as soon as possible after a known exposure and no later than 2 weeks after the exposure.

[2] Health Canada (Oct. 9, 2014). *Safety information on the risk of blood clots with immunoglobulin products*. Available at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/41783a-eng.php

Rabies Immune Globulin (RabIg) (Human)

HYPERRAB® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperRAB-SD-en.pdf)

INDICATIONS [1, 2]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites. **NOTE:** if the exposure occurred and was managed in another country and was not in accordance with current WHO standards (approved vaccine or schedule) the rabies post-exposure prophylaxis series should be restarted. **NOTE:** Do not give RabIg if clients were previously immunized in accordance with the WHO standards or have documented seroconversion (i.e. level ≥ 0.5 IU/ml) within the past 2 years
DOSE/ INITIAL SERIES [3, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS:** • The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose. • The dose of RabIg is calculated as: $\frac{[20\ IU/kg \times weight\ in\ kg]}{150\ IU/ml} = \_\_\_\_\_ mL$ • RabIg is supplied in 2 ml vials, each 1 mL = 150 IU. • Infiltrate as much RabIg as possible deep into and around the wound(s) in order to neutralize the virus. When more than one wound site exists, each site should be infiltrated with a portion of the RabIg. If there are extensive wounds, where the calculated dose of RabIg (by weight) is not adequate in volume to infiltrate all wounds, dilute the RabIg 2-3 fold in normal saline to create an adequate volume to infiltrate all wounds. • When there is no wound site, the preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older). • **This product monograph states**, "If anatomically feasible, up to one-half the dose of HYPERRAB® S/D should be thoroughly infiltrated in the area around the wound and the rest should be administered intramuscularly in the gluteal area or lateral thigh muscle using a separate syringe and needle. Because of risk of injury to the sciatic nerve, the central region of the gluteal area MUST be avoided; only the upper, outer quadrant should be used" (pp. 10-11).
REINFORCEMENT	Currently no recommendations.
CONTRA-INDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product or to any of the components of a RabIg product, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or

Rabies Immune Globulin (RabIg) (Human)

HYPERRAB® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperRAB-SD-en.pdf)

	inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products. • Regarding RabIg and the administration of live vaccines, refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.* • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.
COMPONENTS	Human rabies hyperimmune globulin, glycine, sodium carbonate. Preservative free.
EXPECTED REACTIONS	Soreness at the site of injection and mild temperature elevations may be observed at times. Sensitization to repeated injections has occurred occasionally in immunoglobulin-deficient patients. Angioneurotic edema, skin rash, nephrotic syndrome, and anaphylactic shock have rarely been reported after intramuscular injection, so that a causal relationship between immunoglobulin and these reactions is not clear.

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

[2] Provide a written record to a client who receives any immune globulin product.

[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.

[4] RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine on day 0.

Rabies Immune Globulin (RabIg) (Human)

IMOGAM® Rabies Pasteurized (Sanofi Pasteur 2015 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=imogam_rabies_e.pdf)

INDICATIONS [1, 2]	**RABIES POST-EXPOSURE PROPHYLAXIS (RPEP):** • As determined by Regional Medical Health Officers. • Rabies vaccine is given in conjunction with RabIg. Rabies vaccine and RabIg must be administered with separate needles and syringes at separate anatomical sites • **NOTE:** if the exposure occurred and was managed in another country and was not in accordance with current WHO standards (approved vaccine or schedule) the rabies post-exposure prophylaxis series should be restarted. **NOTE:** Do not give RabIg if clients were previously immunized in accordance with the WHO standards or have documented seroconversion (i.e. level ≥ 0.5 IU/ml) within the past 2 years.

INITIAL SERIES [3, 4]	**RABIES POST-EXPOSURE PROPHYLAXIS:**
	• The recommended dosage for children and adults is the same: 20 IU/kg of body weight. Because of interference with active antibody production, do not exceed recommended dose.
	  • The dose of RabIg is calculated as:
	  $\frac{[20\ IU/kg \times weight\ in\ kg]}{150\ IU/ml} = \_\_\_\_\_ mL$
	  • RabIg is supplied in 2 ml vials, each 1 mL = 150 IU.
	  • Infiltrate as much RabIg as possible deep into and around the wound(s) in order to neutralize the virus. When more than one wound site exists, each site should be infiltrated with a portion of the RabIg. If there are extensive wounds, where the calculated dose of RabIg (by weight) is not adequate in volume to infiltrate all wounds, dilute the RabIg 2-3 fold in normal saline to create an adequate volume to infiltrate all wounds.
	  • When there is no wound site, the preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

REINFORCEMENT	Currently no recommendations.
CONTRAINDICATIONS	**There are no contraindications to RabIg given for post-exposure purposes.**
PRECAUTIONS	• If client has a history of anaphylactic reaction following receipt of any human Ig product, to any of the components of RabIg (glycine) or to latex, administer RabIg in an emergency room setting. • Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible, that unknown infectious agents may be present in such products. • Regarding RabIg and the administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent blood products that contain IgA. Administer RabIg in an emergency room setting.

Rabies Immune Globulin (RabIg) (Human) **IMOGAM® Rabies Pasteurized** (Sanofi Pasteur 2015 monograph available at: https://www.vaccineshoppecanada.com/document.cfm?file=imogam_rabies_e.pdf)	
COMPONENTS	Antirabies immunoglobulin (10-18% protein) for intramuscular administration. It is prepared by cold alcohol fractionation from pooled venous plasma of individuals immunized with Rabies Vaccine prepared from human diploid cells (HDCV). The product is stabilized with 0.3 M glycine. The globulin solution has a pH of 6.8 ±0.4 adjusted with sodium hydroxide or hydrochloric acid. No preservatives are added. Latex free.
EXPECTED REACTIONS	Local or mild systemic adverse reactions to the globulin are infrequent and may be treated symptomatically. Local tenderness, soreness or stiffness of the muscles may occur at the injection site and may persist for several hours after injection. Urticaria and angioedema may occur. Anaphylactic reactions although rare, have been reported following injection of human immune globulin preparations. Fever, skin reactions or chills have been reported following human rabies immunoglobulins. Rare cases of nausea, vomiting, hypotension, tachycardia and allergic-type reactions have been reported. In very rare cases, anaphylactic shock has been observed.

[1] If RabIg is not administered on day 0, it can be administered up to and including day 7 of the RPEP series. Since vaccine induced antibodies begin to appear within one week, there is no value in administering RabIg more than 8 days after initiation of vaccine.

[2] Provide a written record to a client who receives any immune globulin product.

[3] When notification of an exposure is delayed, RPEP may be started as late as 6 or more months after an exposure.

[4] RabIg should never be administered in the same syringe or needle or in the same anatomical site as vaccine on day 0.

Tetanus Immune Globulin (TIg) (Human)

HYPERTET® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperTET-SD-en.pdf)

INDICATIONS	**DOSE / SERIES**
NOTE: **TIg must be given at separate anatomic sites from a tetanus toxoid-containing vaccine.** 1. TIg is indicated for prophylaxis against tetanus following a major or unclean wound in individuals whose immunization history is incomplete or uncertain. Refer to Chapter 5, Section 3.7, *Tetanus Prophylaxis in Wound Management*. 2. TIg is indicated when a contraindication to a tetanus toxoid-containing vaccine exists and an individual sustains a major or unclean wound. 3. TIg is indicated in individuals known to have a significant immune deficiency state (e.g., HIV) regardless of their immunization history, following any major or unclean wound. 4. TIg is also indicated, although evidence of effectiveness is limited, in the regimen of treatment of active cases of tetanus.	• Give 250 units IM (entire single dose pre-filled disposable syringe) to adults and children who require TIg. • If a contraindication to tetanus toxoid-containing vaccine exists or a client refuses a tetanus toxoid-containing vaccine, and a client sustains a major or unclean wound, consider offering a 2nd dose of TIg approximately 28 days post the 1st dose of TIg (ImmunoFacts, 2013). **NOTE:** The syringe fill volume for each lot is adjusted to ensure a potency of not less than 250 IU/syringe. The actual fill volume for HYPERTET syringes typically ranges between 0.75 ml and 1.3 ml. The needle on the pre-filled syringe is fixed and cannot be changed.

REINFORCEMENT	None if Td/Tdap/Td-IPV/Tdap-IPV vaccine is given concurrently with TIg.
CONTRA-INDICATIONS	TIg should not be given intravenously.
PRECAUTIONS	• Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Regarding TIg and administration of live vaccines refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Give TIg with caution (i.e., in a setting capable of managing anaphylaxis) if the client has a history of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to latex (assess risks versus benefits). • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, TIg should only be given to such persons if the expected benefits outweigh the risks. • In clients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, TIg should be given only if the expected benefits outweigh the risks. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older).

Tetanus Immune Globulin (TIg) (Human)

HYPERTET® S/D (Grifols Therapeutics 2012 monograph available at: http://www.grifols.com/polymitaImages/public/grifols_canada/pdf/product/bioscience/2012/en/HyperTET-SD-en.pdf)

COMPONENTS	15%-18% Human tetanus hyperimmune globulin, glycine, sodium carbonate. Preservative free. Prefilled syringe has rubber needle shield and stopper.
EXPECTED REACTIONS	Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare. In the course of routine injections of large numbers of persons with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection.

Varicella Zoster Immune Globulin (VarIg) (Human)

VariZIG™ Sterile Liquid 125 IU/vial (Aptevo BioTherapeutics 2017 monograph available at: https://varizig.com/capage/_uploads/documents/varizig-pristine-pm-english.pdf)

INDICATIONS [1, 2]	For post-exposure prevention of varicella in the following high-risk clients who cannot receive varicella vaccine and who are at increased risk of severe varicella disease: **Infants and children:** • Immunocompromised clients (congenital or acquired) due to treatment or disease, including some clients receiving high doses of corticosteroids. Clients receiving monthly IGIV may not require VariZIG. • Newborn infants whose mothers develop varicella disease 5 days before to 48 hours after delivery. • Hematopoietic stem cell transplant (HSCT) recipients. • Infants and children in neonatal or pediatric intensive care settings, as determined by infectious disease/infection control specialist. **Adults:** • Susceptible pregnant women. • Immunocompromised adults (congenital or acquired) due to disease or treatment, including clients receiving corticosteroid treatment. Clients receiving regular monthly infusions of IGIV may not require VariZIG™. • Hematopoietic stem cell transplant recipients.
DOSE / SERIES	• Give VariZIG IM or IV as soon as possible, and within 96 hours of the first exposure to varicella or zoster. Clinicians may opt to provide VarIg up to 10 days following exposure to attenuated illness. • 125 IU is given for each 10 kg of body weight and is the minimum dose. • The maximum dose is 625 IU. • The preferred sites for immune globulin administration are the vastus lateralis (all ages) or the deltoid (those 12 months and older). • If VariZIG™ is administered by an intramuscular route, it should be given as an injection into the deltoid muscle or the anterolateral aspects of the upper thigh. Due to the risk of sciatic nerve injury, the gluteal region should not be used as a routine injection site. If the gluteal region is used, use only the upper, outer quadrant.
REINFORCEMENT	If a 2nd varicella exposure occurs more than 3 weeks after a dose of VariZIG™, another dose of VariZIG™ should be given.
SPECIAL HANDLING INSTRUCTIONS	The product should be brought to room or body temperature immediately prior to use. The product should be clear or slightly opalescent. Do not use product that appears cloudy or contains deposits.
CONTRA-INDICATIONS	History of anaphylactic reaction following receipt of any human Ig product, or a history of anaphylactic reaction to any component of VariZIG.

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PRECAUTIONS	• Regarding VariZIG and administration of live vaccines (MMR & Varicella) refer to SIM, Chapter 5, *Immunization Schedules,* Section 3.5, *Spacing of Live Vaccines, Blood Products and Immune Globulin Preparations* and Section 3.5.1, *Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus*. • Human Ig products are amongst the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C or HIV; therefore the risk of transmission of these viruses is considered to be extremely low. However, it is possible that unknown infectious agents may be present in such products. • Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. VariZIG should only be given to such persons if the expected benefits outweigh the risks.
COMPONENTS	**VariZIG™ Powder for Injection:** VariZIG™ is a sterile freeze-dried gamma globulin (IgG) fraction of human plasma containing antibodies to varicella zoster virus. Non-medicinal ingredients include 0.04 M sodium chloride, 0.1 M glycine, and 0.01% polysorbate 80. Each 125 IU vial contains 60-200 mg human immunoglobulin G. It contains no preservative. Rubber stoppers Sterile Diluent (0.8% Sodium Chloride, 10mM Sodium Phosphate) for reconstitution of VariZIG™. **VariZIG Sterile Solution**. It is a gamma globulin (IgG) fraction of human plasma containing antibodies to varicella zoster virus. Non-medicinal ingredients include 10% maltose and 0.03% (w/w) polysorbate 80. Each 125 IU vial contains less than 156 mg human IgG. It contains no preservative and is intended for single use only. VariZIG does not contain mercury and the stopper is latex free.
EXPECTED REACTIONS	The most frequent treatment related adverse events were pain at the injection site (17%), headache (7%), and rash (5%). Other less frequent adverse reactions were myalgia, rigors, fatigue, nausea and flushing. The adverse event profile of VariZIG™ is expected to be comparable to other commercially available varicella zoster immune globulin (human) and intravenous immune globulin (human) products. The most common expected adverse drug reactions are chills, fever, headaches, vomiting, allergic reactions, nausea, arthralgia and moderate low back pain

[1] A dose of ≥ 2 mg/kg/day of prednisone or equivalent, or more than 20 mg/per day, particularly when given for more than 2 weeks.

[2] Patients receiving monthly infusions of ≥ 400 mg/kg of IVIG and whose most recent infusion was within 3 weeks of exposure do not require VariZIG™.

Botulism Antitoxin (BAT)

BAT™ [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]

American product monograph: https://emergentbiosolutions.com/sites/default/files/inline-files/2015-09-08_bat_uspi_approved.pdf [Canadian PM not posted yet]

INDICATIONS	Treatment of botulism
INITIAL SERIES	Refer to product monograph
REINFORCEMENT	Refer to product monograph
CONTRAINDICATIONS	Refer to product monograph
COMPONENTS	Refer to product monograph
EXPECTED REACTIONS	Refer to product monograph
SPECIAL CONSIDERATION	Refer to product monograph

Diphtheria Antitoxin (DAT)

Diphtheria Antitoxin

This product is not manufactured in North America and is only available through the *Special Access Program* (SAP). A product monograph is included with every vial.

INDICATIONS	For passive transient protection against or treatment of diphtheria infections.
INITIAL SERIES	
REINFORCEMENT	
CONTRAINDICATIONS	
COMPONENTS	
EXPECTED REACTIONS	
SPECIAL CONSIDERATION	