Yukon Immunization Program Manual

Section 8 - Biological Products

Diphtheria & Tetanus-containing Vaccines

SECTION 8 – BIOLOGICAL PRODUCTS

Contents

August 2019

Diphtheria - Tetanus- Acellular Pertussis - Hepatitis B- Polio- Haemophilus Influenza Type b Adsorbed (DTaP- HB- IPV- Hib) (INFANRIX hexa®)

Supplier: GlaxoSmithKline Inc

INDICATIONS	INITIAL SERIES
(1) Primary series for infants starting at 8 weeks of age **(2)** Primary series for high risk infants who have received a birth dose of HBIg and/or Hepatitis B vaccine **(3)** Primary series for previously unimmunized infants and children who are late starting immunization and can complete a primary INFANRIX hexa® series before 7 years of age	**(1) & (2) Dose 1:** 0.5ml **IM** **Dose 2:** 0.5ml **IM** **Dose 3:** 0.5ml **IM** **Give each dose 8 weeks apart** **(3)** See Section 3, 1.2 SCHEDULE B

REINFORCEMENTS

(1) & (2) Booster dose at 18 months of age: 0.5 ml **IM** of DTaP-IPV-Hib (PEDIACEL®)

(3) Booster dose 24 weeks - 12 months after dose 3:

- 0.5ml **IM** of DTaP-IPV-Hib ((PEDIACEL®) if child is ≤ 6 years of age and **no** Hib dose has been given at ≥15 months of age, **or**
- 0.5 ml **IM** of DTaP-IPV (QUADRACEL®) if child is ≤ 6 years of age and a Hib dose has been given at ≥ 15 months of age, **or**
- 0.5 ml **IM** of Tdap-IPV (ADACEL-POLIO®) if child is ≥ 4 years of age and a Hib dose has been given at ≥ 15 months of age, **or**
- 0.5ml **IM** of Tdap (BOOSTRIX®) if the child is ≥ 7 years of age at time of booster dose and received their 3rd dose of an IPV-containing vaccine after their 4th birthday.

CONTRAINDICATIONS

1. History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV, Hib or HB - containing vaccine or to any INFANRIX hexa® vaccine component, or to latex.
2. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a tetanus-containing vaccine.
3. INFANRIX hexa® is not indicated for children ≥ 7 years of age.

VACCINE COMPONENTS

Potential allergens: polymyxin B sulphate, neomycin sulphate, polysorbate 80.
Other components: lactose, aluminum hydroxide, aluminum phosphate sulfate, L-histidine, formaldehyde, polysorbate 20, M199, potassium chloride, disodium phosphate, monopotassium phosphate, glycine, yeast protein.

ADVERSE EVENTS

Local: soreness, redness, swelling.
Systemic: fever, anorexia, restlessness, irritability, persistent or unusual crying, vomiting, diarrhea

SPECIAL CONSIDERATIONS

- INFANRIX hexa® contains only a single dose of HB vaccine (as Engerix®-B) and is **not** indicated for infants and children requiring a Hepatitis B Vaccine Higher Dose Schedule
- **INFANRIX hexa® and PEDIACEL® are NOT interchangeable in a primary series. Clients started on PEDIACEL® should finish primary series with PEDIACEL®**
- Hypotonic-hyporesponsive episodes are not a contraindication to diphtheria, tetanus or acellular pertussis-containing vaccines, and continued immunization with **all** antigens is recommended.
- While the number of Hib doses varies with age of presentation, give INFANRIX hexa® as indicated above, even when doing so provides "extra" Hib doses for age.

August 2019	
Diphtheria - Tetanus - Acellular Pertussis – Polio - Haemophilus Influenzae Type b Adsorbed (DTaP-IPV-Hib) (PEDIACEL®) **Supplier: Sanofi Pasteur**	
INDICATIONS	**(1)** Primary series and booster for infants and children 8 weeks-59 months of age who have had one or more doses of PEDIACEL® **(2)** Primary series for high risk infants who have had doses of hepatitis B vaccine at birth and 4 weeks of age **(3)** Booster dose at 18 months of age for infants who have received a primary Infanrix hexa® series or a primary PEDIACEL® series
INITIAL SERIES ❶	**Dose 1:** 0.5ml **IM** **Dose 2:** 0.5ml **IM** **Dose 3:** 0.5ml **IM** **Give doses 1, 2 and 3 at 8 weeks apart +** **Dose 4:** 0.5ml **IM** **Give dose 4, 12 months after 3rd dose** ❷
REINFORCEMENTS	**School-entry booster is:** 0.5 ml **IM** of DTaP-IPV (QUADRACEL®)❸❹ **or** 0.5 ml **IM** of Tdap-IPV (ADACEL-POLIO®)❸❹
CONTRAINDICATIONS	1. History of anaphylactic reaction to a previous dose of DPT, DTaP, IPV or Hib--containing vaccine or to any PEDIACEL® vaccine component 2. Children ≥ 7 years of age. 3. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a tetanus-containing vaccine.
VACCINE COMPONENTS	**Potential allergens:** neomycin, streptomycin, polymyxin B, polysorbate 80, bovine serum albumin **Other components:**, aluminum phosphate, 2-phenoxyethanol, formaldehyde, glutaraldehyde.
ADVERSE EVENTS	**Local:** redness, pain, swelling. **Systemic:** irritability, crying, fever, drowsiness, decreased activity and appetite, vomiting and diarrhea.
SPECIAL CONSIDERATIONS	Hypotonic-hyporesponsive episodes are not a contraindication to diphtheria, tetanus or acellular pertussis-containing vaccines, and continued immunization with all antigens is recommended

❶ If the child's immunization schedule is delayed, so that the child requires fewer doses of Hib vaccine, administer DTaP-IPV or Tdap-IPV as appropriate rather than PEDIACEL®.

❷ If required, this dose can be given as early as 24 weeks following dose number 3. For protection against Hib, do not give this dose before 15 months of age.

❸ Dose number 5 should be given 30 to 54 months after dose number 4 and no sooner than age 4 (the minimum interval between dose 4 and 5 is 24 weeks). A 5th dose is not necessary if the 4th dose was given after the 4th birthday.

❹ May be given as DTaP-IPV (QUADRACEL®) **or** Tdap-IPV(ADACEL-POLIO®) in 2012.

2019 August	
Diphtheria-Tetanus- Acellular Pertussis - Polio Adsorbed (Tdap-IPV) (Adacel-Polio) **Supplier: Sanofi Pasteur**	
INDICATIONS	**DOSE**
Recommended and provided publically funded to: **(1)** School Entry Booster age 4 – 6 years ❶ **(2)** Adults who have not received a dose of acellular pertussis after 14 years and are eligible for IPV❸ **(3)** Children and adolescents aged 7-17 (inclusive) who missed school entry booster	**One dose:** • 0.5 mL **IM**
(4) Children and adolescents aged 7-17 (inclusive) who have not started or completed their primary series, and Hib is not indicated❷ • Unimmunized children and adolescents • Incompletely immunized clients that started the DTaP containing series **after their 1st birthday** **(5)** Adults aged 18 years and older who are not immunized or incompletely immunized with a primary series❷	**3 doses:** • 0.5mL IM • 0.5mL IM 4-8 weeks after 1st dose • 0.5mL IM 6-12 months after 2nd dose
(6) Children and adolescents aged 7-17 (inclusive) who have not started or completed their primary series, and Hib is not indicated❷❹: • Incompletely immunized clients that started the DTaP containing series **before their 1st birthday**	**4 doses:** • 0.5mL IM • 0.5mL IM 4-8 weeks after 1st dose • 0.5mL IM 4-8 weeks after 2nd dose • 0.5mL IM 6-12 months after 3nd dose

CONTRAINDICATIONS	1. History of anaphylactic reaction to a previous dose of DPT, DTaP, Tdap or IPV-containing vaccine or to any vaccine component 2. Children less than 4 years of age. 3. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a tetanus – containing vaccine.
VACCINE COMPONENTS	aluminium phosphate, phenoxyethanol, polymyxin B sulphate, neomycin, streptomycin, formaldehyde, glutaraldehyde, polysorbate80
ADVERSE EVENTS	**Minor local**: redness, swelling, pain **Minor systemic**: fever, headache, nausea, diarrhea, body aches, tiredness

	2019 August
Diphtheria-Tetanus- Acellular Pertussis - Polio Adsorbed (Tdap-IPV) (Adacel-Polio) **Supplier: Sanofi Pasteur**	
SPECIAL CONSIDERATIONS	Hypotonic-hyporesponsive episodes are not a contraindication to diphtheria, tetanus or acellular pertussis-containing vaccines, and continued immunization with all antigens is recommended.

❶ Routinely, this is the 5th dose in a tetanus containing series. It is not necessary if the 4th dose of PEDIACEL® or QUADRACEL® was given after the 4th birthday.

❷ See Section 3 Schedules and Minimum Interval Table for doses required and which tetanus containing series to use. 3 and 4 dose series above encompass a complete series. No minimum interval between a dose of Td and Tdap-IPV when Tdap-IPV is being used for pertussis and polio protection.

❸ Tdap-IPV will be provided publically funded for those who are eligible for publically funded Tdap and publically funded polio. As well as those who are eligible for publically funded Tdap and non-publically funded polio (e.g. travelers) See Section 8, Biological Products, Polio Vaccine (Inactivated) (Imovax ®Polio) for full indications.

❹ 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.

2019 August	
Tetanus-Diphtheria-acellular Pertussis (Tdap); BOOSTRIX® **Supplier: GlaxoSmithKline Inc., BOOSTRIX®**	
INDICATIONS ❶ ❷	**INITIAL SERIES**
(1) **Reinforcing** dose for all grade 9 students ❶❸❺	**(1)** One dose: 0.5 ml **IM**
(2) Children and adolescents from ≥ 7 years to 17 years of age (inclusive) who have not received any doses of tetanus or diphtheria **(3)** Children and adolescents from ≥ 7 years to 17 years of age (inclusive) who have not received any doses of pertussis vaccine **(4)** Immigrants from ≥ 7 years to 17 years of age (inclusive) with unknown immunization status	**(2) (3) & (4)** Dose 1: 0.5 ml **IM** Dose 2: 0.5 ml **IM** 4 weeks later Dose 3: 0.5 ml **IM** 24 weeks to 12 months after dose 2
(5) Children and adolescents from ≥ 7 years to 17 years of age (inclusive) whose 3 dose primary series of tetanus or diphtheria or pertussis vaccine is incomplete❹	**(5)** One to two doses of Tdap (0.5 ml **IM**) at time of presentation to complete the primary series of 3 doses, followed by another dose of 0.5 ml **IM** in grade 9
(6) Children and adolescents from ≥ 7 years to 17 years of age (inclusive) who have received 3 – 4 doses of tetanus/diphtheria/pertussis-containing vaccine at < 7 years of age, but have not received the school entry booster	**(6)** One dose of Tdap (0.5 ml IM) at time of presentation, followed by another dose of 0.5 ml IM in grade 9
(7) Adults ≥ 18 years of age who have not been immunized, including immigrants with unknown immunization status	**(7)** One dose of Tdap (0.5ml **IM**) followed by two doses of Td
(8) HSCT recipients ≥ 7 to <18 years of age	**(8)** Three doses of Tdap (0.5ml **IM**) at 0, 4 weeks, and 12 months.
(9) HSCT recipients ≥ 18 years of age **(10)** Solid organ transplant candidates or recipients ≥ 7 years of age who have not been previously immunized.	**(9)& (10)** One dose of Tdap (0.5ml **IM**) followed by two doses of Td/IPV
(11) All adults who have not received a dose of acellular pertussis ≥ 19 years of age of age. ❺	**(11)** One dose of Tdap (0.5ml **IM**)
(12) All Pregnant women (≥ 27 weeks gestation) regardless of a pertussis containing immunization history. ❻	**(12)** One dose of Tdap (0.5ml **IM**)
(13) All new mothers who have not received a pertussis containing immunization with this recent pregnancy.	**(13)** One dose of Tdap (0.5ml **IM**)

	2019 August
Tetanus-Diphtheria-acellular Pertussis (Tdap); BOOSTRIX® **Supplier: GlaxoSmithKline Inc., BOOSTRIX®**	
REINFORCEMENTS	Publicly funded as per indication **(11) (12) & (13).**
CONTRAINDICATIONS	1. History of an anaphylactic reaction to a previous dose of any tetanus, diphtheria, or pertussis-containing vaccine or to any component of BOOSTRIX® vaccine. 2. History of Guillain-Barré syndrome (GBS) occurring within 8 weeks of receipt of a tetanus – containing vaccine. 3. < 4 years of age.
VACCINE COMPONENTS	**BOOSTRIX®:** **Potential allergens:** none **Other components:** aluminium hydroxide, aluminium phosphate.
ADVERSE EVENT	**Minor local:** redness, tenderness, swelling, induration, pain **Minor systemic:** headache, decreased energy, generalized body-ache, nausea, diarrhea, fever, sore or swollen joints

❶ There is no minimum interval between a previous ***booster*** dose of a ***tetanus/diphtheria*** –containing vaccine (e.g: Td) and Tdap when Tdap is being given for pertussis protection. Children who have had a tetanus, diphtheria, and pertussis combined vaccine (Tdap) at 10 years of age or older do not require an additional dose of Tdap in grade 9.

❷ Approved for use in those ≥4 years of age with no upper age limit.

❸ Give Tdap to high school students who missed their grade 9 booster.

❹ For example, if the student had received one dose of a tetanus/diphtheria/pertussis – containing vaccine, give two doses of Tdap separated by a period of 24 weeks - 12 months. If the student had received two doses of a tetanus/diphtheria/pertussis – containing vaccine, give one dose of Tdap.

❺ The high school Tdap booster given at age 14-16 years is **not** considered a dose of acellular pertussis in adulthood. At this time, an additional dose of acellular pertussis is recommended 5 years after the Grade 9 (14-16 years of age) dose.

❻ NACI recommends immunization with Tdap vaccine should be offered in every pregnancy, irrespective of previous Tdap immunization history. Immunization with Tdap vaccine should ideally be provided between 27 and 32 weeks of gestation. Immunization between 13 and 26 weeks of gestation may also be considered in some situations (e.g. pregnancies with an increased risk of preterm delivery) to allow for longer placental exposure to higher antibody levels and maximization of antibody transfer. While it is preferable that immunization is administered in sufficient time before birth (i.e. 4 weeks) to allow optimal transfer of antibodies and direct protection of the infant against pertussis, it should be considered until the end of pregnancy, as it has the potential to provide partial protection. If immunization was provided early in pregnancy (e.g. prior to recognition of pregnancy), it is not necessary to re-immunize after 13 weeks of gestation.

	2019 August
Tetanus Diphtheria (Td) Adsorbed **Supplier: Sanofi Pasteur Limited**	
INDICATIONS	**DOSE**
1) Booster dose for persons ≥7 years of age if both diphtheria and tetanus are required, but Pertussis is not required. **2)** Adults ≥ 18 years of age who have not been immunized, including immigrants with unknown immunization status	**(1)** 0.5 ml **IM** every 10 years ❶ **(2)** Administer one dose of Tdap followed by two doses of Td: 1st Td: 0.5 ml **IM** 4 weeks after Tdap 2nd Td: 0.5 ml **IM** 24 weeks – 12 months after 1st Td dose
REINFORCEMENTS	Every 10 years❶ • Adults who have not received one dose of acellular pertussis (Tdap) should receive a single dose of Tdap instead of Td (see Tetanus-Diphtheria-acellular Pertussis)
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 (see Tetanus Immune Globulin (TIg) (HYPERTET ™S/D). History of Guillain-Barré syndrome (GBS) occurring within 8 weeks of receipt of a tetanus – containing vaccine.
VACCINE COMPONENTS	Aluminum phosphate and formaldehyde.
PRECAUTIONS	• Persons who experience a major local reaction or high fever following a dose of Td should not be given another dose for at least 10 years. • When travel to a developing country is planned >5 years after the last Td dose, it may be prudent to offer an early booster, since some developing countries may not be able to guarantee the safe administration of a booster dose if required.
ADVERSE EVENTS	Discomfort, pain, swelling, redness at injection site.
SPECIAL CONSIDERATIONS	For wound prophylaxis, Td and Tetanus Immune Globulin should be administered using separate syringes and different sites.
❶ Tetanus toxoid **should not be given routinely** to clients who have received a booster dose in the previous 5 years.	

2019 August

Tetanus Prophylaxis in Wound Management

History of Tetanus Immunization	Clean, minor wounds		All other wounds ❶	
	Tetanus Toxoid-Containing Vaccine ❷	Tlg	Tetanus Toxoid-Containing Vaccine ❷	Tlg
Uncertain or < 3 doses	Yes	No	Yes	Yes
Primary immunization complete ❸❹	No ❺	No	No ❻	No ❼

❶ Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; tearing away of body parts or structures; and wounds resulting from missiles, crushing, burns and frostbite.

❷ May have been given as Td, Tdap, or Td/IPV. Monovalent tetanus toxoid is not available in Canada.

❸ For additional information on the primary immunization schedule, refer to the Td, Tdap, or Td/IPV vaccine pages.

❹ Wound management for children < 7 years of age would be based on specific spacing and doses required as per INFANRIX hexa®, PEDIACEL® and QUADRACEL™ vaccine pages.

❺ Yes, if > 10 years since last tetanus containing booster.

❻ Yes, if > 5 years since last tetanus containing booster.

❼ No, unless individuals are known to have a significant humoral immune deficiency state (e.g., HIV, agammaglobulinemia), since immune response to tetanus toxoid may be sub-optimal.

In adults, if a tetanus toxoid containing vaccine is required it may be administered as Tdap (if not previously administered ≥ 14 years of age) or as Td. See individual product information in this section.

Note: Tetanus-diphtheria (Td) / Tetanus-diphtheria- acellular pertussis (Tdap) vaccine and Tetanus Immune Globulin (Tlg) should be administered using separate syringes and different sites. If a contraindication exists for a tetanus toxoid-containing vaccine, Tlg would be given where tetanus immunization is required.