

Program Review for Hepatitis B Schedules and PARIS Immunization Rules: Infants to Clients 19 Years of Age Inclusive

Background	<p>Hepatitis B is a component of the hexavalent product INFANRIX <i>hexa</i>[™] and is available as a monovalent vaccine under the brand names RecombivaxHB and Engerix-B. Hepatitis B is a complex antigen to plan for in PARIS as considerations need to be made for multiple products, antigen combinations (DPTPOHIBHB), and schedule parameters.</p> <p>PARIS immunization rules have been designed to ensure the recommended provincial schedules are met for the majority of VCH clients. These clients are healthy clients born in VCH. Some clients are considered “unique” clients (e.g. some immunization history from another country/jurisdiction, parents who choose alternate schedules/antigen groups, high risk clients). These unique clients may need a client-specific schedule plan by clinicians that is outside of the PARIS planning to ensure best protection.</p>																																																												
Purpose	<p>This is an educational resource to enhance users’ learning. This resource will assist in client planning and provides further information that bridges current BCCDC Immunization Manual recommendations with VCH Hepatitis B program implementation and PARIS planning.</p> <p>This document covers the following:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">#</th> <th style="text-align: left;">Topic</th> <th style="text-align: center;">Page #</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td><u>Bridging Current Hepatitis B Schedules with PARIS Rules for C clients ≤ 19Years</u></td> <td style="text-align: center;">3</td> </tr> <tr> <td></td> <td> <u>1A. Provincial hepatitis B schedules</u></td> <td style="text-align: center;">3</td> </tr> <tr> <td></td> <td> <u>1B. Summary of PARIS Rules e n g i n e f r o m b i r t h t o ≤ 19 y e a r s</u></td> <td style="text-align: center;">4</td> </tr> <tr> <td></td> <td> <u>1Ba. Actions when doses violate PARIS Rules and grace period allowance</u></td> <td style="text-align: center;">5</td> </tr> <tr> <td style="text-align: center;">2</td> <td><u>Managing Hepatitis B 16 Week Interval Criterion (dose 1–3)</u></td> <td style="text-align: center;">5</td> </tr> <tr> <td></td> <td> <u>2A. Routine clients dose 1 received at 2 months of age inclusive</u></td> <td style="text-align: center;">5</td> </tr> <tr> <td></td> <td> <u>2B . All o t h e r c l i e n t s d o s e 1 r e c e i v e d ≥ 3 m o n t h s o f a g e t o 6 y e a r s i n c l u s i v e</u></td> <td style="text-align: center;">6</td> </tr> <tr> <td style="text-align: center;">3</td> <td><u>Clients who Received a Birth Dose of Hepatitis B Vaccine</u></td> <td style="text-align: center;">7</td> </tr> <tr> <td style="text-align: center;">4</td> <td><u>Grade 6 Program and 2–Dose Series</u></td> <td style="text-align: center;">8</td> </tr> <tr> <td style="text-align: center;">5</td> <td><u>Clients Who Present ≥ 7 Years to 19 Years and Who Move Between 3–Dose Series</u></td> <td style="text-align: center;">8</td> </tr> <tr> <td style="text-align: center;">6</td> <td><u>High Risk Neonatal and Infant Hepatitis B Program</u></td> <td style="text-align: center;">9</td> </tr> <tr> <td style="text-align: center;">7</td> <td><u>Managing Special Populations: No Rules Planning</u></td> <td style="text-align: center;">10</td> </tr> <tr> <td style="text-align: center;">8</td> <td><u>Client Histories in PARIS that do not Meet Current Recommended Intervals</u></td> <td style="text-align: center;">10</td> </tr> <tr> <td style="text-align: center;">9</td> <td><u>Product Choices – Hepatitis B</u></td> <td style="text-align: center;">11</td> </tr> <tr> <td style="text-align: center;">10</td> <td><u>Client Scenarios: Applying the PARIS Hepatitis B Immunization Rules</u></td> <td style="text-align: center;">13</td> </tr> <tr> <td></td> <td> <u>Infant to kindergarten</u></td> <td style="text-align: center;">13</td> </tr> <tr> <td></td> <td> <u>School–age children</u></td> <td style="text-align: center;">17</td> </tr> <tr> <td style="text-align: center;">App. A</td> <td><u>Historical Timeline of Hepatitis B 3–Dose Minimum Schedule Recommendations</u></td> <td style="text-align: center;">20</td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	#	Topic	Page #	1	<u>Bridging Current Hepatitis B Schedules with PARIS Rules for C clients ≤ 19Years</u>	3		<u>1A. Provincial hepatitis B schedules</u>	3		<u>1B. Summary of PARIS Rules e n g i n e f r o m b i r t h t o ≤ 19 y e a r s</u>	4		<u>1Ba. Actions when doses violate PARIS Rules and grace period allowance</u>	5	2	<u>Managing Hepatitis B 16 Week Interval Criterion (dose 1–3)</u>	5		<u>2A. Routine clients dose 1 received at 2 months of age inclusive</u>	5		<u>2B . All o t h e r c l i e n t s d o s e 1 r e c e i v e d ≥ 3 m o n t h s o f a g e t o 6 y e a r s i n c l u s i v e</u>	6	3	<u>Clients who Received a Birth Dose of Hepatitis B Vaccine</u>	7	4	<u>Grade 6 Program and 2–Dose Series</u>	8	5	<u>Clients Who Present ≥ 7 Years to 19 Years and Who Move Between 3–Dose Series</u>	8	6	<u>High Risk Neonatal and Infant Hepatitis B Program</u>	9	7	<u>Managing Special Populations: No Rules Planning</u>	10	8	<u>Client Histories in PARIS that do not Meet Current Recommended Intervals</u>	10	9	<u>Product Choices – Hepatitis B</u>	11	10	<u>Client Scenarios: Applying the PARIS Hepatitis B Immunization Rules</u>	13		<u>Infant to kindergarten</u>	13		<u>School–age children</u>	17	App. A	<u>Historical Timeline of Hepatitis B 3–Dose Minimum Schedule Recommendations</u>	20			
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<p>Associated Guidelines, Literature, and Resources</p>	<p>Immunization information changes frequently. The information in this bulletin serves as a quick reference and is current as of April 7th, 2017.</p> <p>Always refer to the on-line version of the BCCDC Immunization Manual for the most up-to-date provincial schedules, products, and dosing guidelines. Other program resources can be found on the VCH intranet and should be used to support learning and clinical judgment.</p> <p>References BCCDC Immunization Manual Banatala, J. E. et al. (2003). Hepatitis B vaccine – Do we need boosters? <i>J Viral Hepat</i>, 10(1): 1-6. Canadian Evergreen Immunization Guide Cassidy, W. M. et al. (2001). Immunologic memory vaccination regimens in adolescents: antibody responses, safety, and a randomized trial of alternative two- and three-dose Hepatitis B. <i>Pediatrics</i>, 107: 626-631. doi: 10.1542/peds.107.4.626</p>
<p>Contributors to Review</p>	<p>Reviewers: Tamsin Morgana, Dr. Meena Dawar, Emily Malnis, Donna Coates, Amanda Liddell, Olga Khrestenko, and Margot Smythe</p>

	Dose 1	Dose 2	Dose 3
Infant program	2 months of age	4 months of age	24 weeks of age (MOA)
All others to 19 years (except grade 6)	Now	1 month	6 months (5 months from dose 2)
Grade 6	Grade 6	6 months	N/A
Minimum age/intervals 3-dose series <i>Note: in this resource</i> <i>“prov min intervals”</i> <i>refers to this row.→</i>	Min age – birth	4 week interval	Min age – 24 weeks of age (MOA) Dose 2 to 3 interval = ≥ 8 wks Dose 1 to 3 interval = ≥ 16 wks

[Refer to Sections III and VII for special populations schedules](#)

History of VCH Variances

PARIS will accept any 3 doses as valid regardless of interval or age if received prior to July 8, 2008. Beginning summer 2011 to March 9, 2014, VCH clinicians were recommended to manually plan for clients to ensure dose 1–3 had a 16 week interval. A PHSU analysis of VCH clients in age range 0–10 years for years 2002 to 2013 who met all criteria was 91.6% (analysis excluded 6MOA minimum age for dose 3 as it was not a criteria for this period).

Meeting the above provincial criteria will be managed through several mechanisms in PARIS and clinically as outlined in this document. It is important to read this document in detail to understand how the planning will work and look like in PARIS as there are 5 different categories for planning based on what age a client receives dose 1 of their Hep B series. The planning in some categories looks different than the above but ultimately all clients’ histories will be valid if the provincial min age and min interval criteria have been met either through PARIS planning and/or manual clinical decisions.

		PARIS Rules Due and Min Planning <small>Due=calendar months (mo)/age; Min=weeks</small>				Final Validation	
Planning categories Client's age at presentation for dose 1 ↓		Planning Interval	Birth Dose	Dose 1-2	Dose 2-3	Dose 3	Dose 1-3
1	Routine Schedule 2 months of age (inclusive) <small>Inclusive = 2 mo+3wks+6days of age</small>	Due	Validation Only	2 mo	2 mo	Min age 24 weeks of age	To ensure "Prov min intervals" have been met an auto check is done for the following: PARIS auto checks Dose 2-3 ≥ 8 wks Dose 1-3 ≥ 16 wks
		Min		4 wk	8 wk		
2	Off Schedule ≥ 3 months – 6 years (inclusive)	Due	4 wk min interval to next dose	1 mo	3 mo		
		Min		4 wk	12 wk		
3	7 Y – 10 Y 6 MOA	Due		1 mo	5 mo		
		Min		4 wk	12 wk		
4	10 Y 7 MOA – 15 Y (Grade 6 program)	Due		6 mo	N/A		
		Min		24 wks (16 wks if Recombivax)	N/A		
5	16 Y – 19 Y	Due		1 mo	5 mo		
		Min		4 wk	12 wk		

Category 1:

Routine Schedule for 2 months of age (inclusive)
2MOA-2mo-2mo [24 weeks of age]

Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
DTPoHibHepB	0y 2m	28/01/2014
DTPoHibHepB	0y 4m	28/03/2014
DTPoHibHepB	0y 6m	28/05/2014
DTPoHIB	1y 6m	21/05/2015
DTPo	4y 0m	21/11/2017
TdP	13y 7m	21/06/2027
Td	23y 7m	21/06/2037

Category 2:

Off Schedule ≥ 3 months – 6 years (inclusive)
NOW-1mo-3mo [24 weeks of age]

Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
DTPoHibHepB	0y 3m	28/01/2014
DTPoHibHepB	0y 4m	28/02/2014
DTPoHibHepB	0y 7m	28/05/2014
DTPoHIB	1y 6m	28/04/2015
DTPo	4y 0m	28/10/2017
TdP	13y 7m	28/05/2027
Td	23y 7m	28/05/2037

1Ba. Actions when doses violate PARIS Rules and grace period allowance

Violations of PARIS Rules

Any doses deemed "INVALID" according to [PARIS rules](#) will be re-planned by PARIS.

Example Category 1: 2 months of age (inclusive)

History: 2 month old received the following:

Dose 1 at 2 MOA; dose 2, at 4wk interval; dose 3 at 8wk interval, but dose 3 was received < 6MOA

Validation: Dose 3 violates PARIS rules. Thus, dose 3 will be 'INVALID' (Status reason: Min age) and re-planned 2 months after last valid dose and not before 24 weeks of age.

Clinical Action: See [clinical action](#) for when to repeat doses.

Grace Period Allowance ≤ 4 days – VCH variance to BCCDC Immunization Manual

If any doses violate the [prov min intervals and age criteria](#) but are ≤ 4 days of the criteria, send the record to your COC immunization lead for a manual validation of the dose. No repeat dose will be required.

2. Managing Hepatitis B 16 Week Interval Criterion (dose 1–3)

2A. Routine clients dose 1 received at 2 months of age inclusive: 3–dose series

Clinicians should be booking clients based on the PARIS DUE intervals (2 calendar months between doses). If the DUE intervals are adhered to then clients will be immunized according to best practice.

On SAVE after dose 3 entry, PARIS will check history to ensure provincial minimum intervals have been met. If not, PARIS will automatically apply an **Alert to read: Dose 1–3<16WK; PROVIDE DOSE 4**. Dose 4 will not be on the plan and needs to be managed clinically.

Clinical Action:

Timing and product choice is based on clinical judgment. There are 3 options for providing dose 4:

1st choice: Provide dose 4 at 18 month booster visit using INFANRIX *hexa*TM

2nd choice: Provide monovalent Hep B, 2 months after dose 3

3rd choice: If the above 2 opportunities pass and client presents for their kindergarten booster, provide dose 4 Hep B as part of client's kindergarten booster using INFANRIX *hexa*TM. The consent will read DPTPO so clinician will need to manually write on consent Hib and Hep B to ensure parent is informed and consents to additional antigens.

The screenshot shows a software window titled "Alerts" with a close button. The alert details are as follows:

- Antigen:** Hepatitis B
- Alert Type:** IMMUNIZATION SCHEDULE
- Alert:** DOSE 1-3<16WK;PROVIDE DOSE 4
- From:** 16/02/2014
- To:** (blank)
- Authoriser Type:** INTERNAL TEAM-OTHER
- Authoriser:** TRAINING02IM
- Notes:** (empty text area)

End-date alert when dose 4 received. Dose 4 will have a status of "VALID" once entered.

Notes:

Based on PARIS analysis, this Alert will only apply to a small minority of clients who started their series 2 months of age inclusive and broke the minimum interval between dose 1–3.

The PARIS auto checks will not apply to clients with 3–dose valid PARIS histories prior to March 10, 2014 or any histories received prior to July 8, 2008.

Book clients using DUE intervals: Clinicians should be booking clients based on PARIS DUE intervals (0–1–3 calendar months between doses). If the DUE intervals are adhered to then clients will meet Hepatitis B planning criteria.

Manual planning is required when provincial minimum intervals need to be applied:

Example: Client actually received dose 2 - 8 weeks after dose 1 and clinician wants to give dose 3 in 8 weeks for risk reasons, but PARIS is planning a 3 month interval from dose 2.

Clinical Action: If a clinician chooses to immunize a client sooner than PARIS DUE or Min intervals (e.g. travel reasons, risk for return etc.), manual planning is required to ensure the minimum Hep B criteria are met. Following dose 1 or 2, the manual plan needs to be communicated in the chart using an immunization alert and immunization casenote.

Antigen: HEPB

Alert type: Immunization Schedule

Alert: IMSCHEDCN (description: Imm schedule – refer to case note)

Clients who have received 3 doses of hepatitis B:

On save, after dose 3 entry, PARIS will calculate the interval between all doses and will validate < 12 WK interval between dose 2–3 if:

- 1) There is an interval of ≥ 8 WK between dose 2–3 AND
- 2) There is an interval of ≥ 16 WK between dose 1–3 AND
- 3) Dose 3 was received ≥ 24 weeks of age

If any criteria are not met a 4th dose is required and will be planned by PARIS for 3 months after dose 2 AND ≥ 6 MOA.

Clinical Action for Dose 4:

Timing and product choice is based on clinical judgment. There are 3 options for providing dose 4:

1st choice: Provide at 18 month booster visit using INFANRIX *hexa*TM

2nd choice: Provide monovalent Hep B, as per PARIS plan

3rd choice: If the above 2 opportunities pass and client presents for their kindergarten booster, provide dose 4 Hep B as part of client's kindergarten booster using INFANRIX *hexa*TM. Check the consent. Any additional antigens being provided (e.g. Hib, Polio) by giving INFANRIX *hexa*TM that are not on the consent will need to be manually written in to ensure parent is informed and consents to additional antigens.

Dose 4 will have a status of "VALID" once entered.

Note: The PARIS auto checks will not apply to clients with 3–dose valid PARIS histories prior to March 10, 2014 or any histories received prior to July 8, 2008.

Clinically, these clients should be on a 0–1–6 month series plan. However, for program implementation reasons to accommodate the use of INFANRIX *hexa*[™], all clients (regardless of risk) who present with a history of a birth dose of Hep B will continue to be planned for 3 doses of DPTPOHIBHB on a DUE and Min interval plan based on when they present for their next dose.

Example A- category 1 PARIS planning: if dose 2 of Hep B is received as DPTPoHibHB at 2 months of age inclusive then *category 1* of DUE/Min planning applies until series is complete. For validation, the min interval plan will be 4 weeks from birth to dose 2.

**Routine Schedule for 2 months of age (inclusive) who received a birth dose of Hep B
2MOA–2mo–2mo [6MOA]**

Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
DPTPoHibHepB	0y 2m	28/01/2014
DPTPoHibHepB	0y 4m	28/03/2014
DPTPoHibHepB	0y 6m	28/05/2014
DPTPoHIB	1y 6m	28/05/2015
DTPPo	4y 0m	28/11/2017
TdP	13y 7m	28/06/2027
Td	23y 7m	28/06/2037

Note: Plan will look like this and group antigens, regardless of product choice. See [product choice](#) section for further information.

Immunization History (Antigen Group View)

Antigen	Date	Age Given	Status
Hepatitis B	28/11/2013	0y 0m	VALID

Example B - category 2 PARIS planning: If dose 2 is received at ≥ 3 months – 6 years (inclusive), then DUE/Min planning from this category applies. For validation, The min interval plan will be 4 weeks from birth to dose 2.

Example C – client receives monovalent Hep B and DPTPOHIB-containing product (e.g. Pediacel®)

Initially, a 4th dose of hepatitis B will be planned for these clients. Following data entry of histories, PARIS will automatically look for clients who received a group “other than” DPTPOHIBHB for their primary series. When this scenario presents in PARIS, the 4th planned dose of Hep B will automatically be removed from the client’s chart after the third dose of Hep B is entered and saved.

Clinical Action: No further action required of clinicians. Many jurisdictions have incorporated a birth dose of hepatitis B into the routine immunization schedule. Thus, a clinical assessment of risk for hepatitis B disease with clients who present from other jurisdictions with complete 3–dose series is not required.

[See section 6 for the management of high risk infants.](#)

Hepatitis B, 2–dose grade 6 program PARIS planning			
Category 4	Dose 1 DUE	Dose 2 DUE	MIN Interval
	10 years & 7 months of age (July before grade 6)	6 months later	24 weeks* Engerix®-B = 24 weeks RecombivaxHB® = 16 weeks

*Be sure to document trade name. PARIS will validate ≥ 16 week interval on SAVE if both doses have a trade name of RecombivaxHB®.

Hepatitis B, 3–dose planning intervals when clients present late					
Category 3+5	Age at presentation	PLAN	Dose 1	Dose 2	Dose 3
	7 Y – 10 Y 6 MOA and 16 Y – 19 Y	DUE	NOW	1 mo	5 mo
		MIN	NOW	4 wk	12 wk
		PARIS Validation	NOW	4 wk	Dose 2–3: ≥ 8 WK AND Dose 1–3: ≥ 16 WK

PARIS planning engine will accommodate a client’s transition between 2 and 3 dose plans.

Planned Immunizations (Antigen Group View)

Antigen	Age Due
Hepatitis B	16y 0m
Hepatitis B	16y 5m

Immunization History (Antigen Group View)

Antigen	Date	Age Given
Hepatitis B	28/01/2009	11y 0m

Client started on a 2–dose series (10 years & 7 months–15 years) but does not complete before the age of 16. PARIS has moved client back to a 3–dose series plan.

Dosage at school-based clinics: Clients on a 3-dose series ≤ 19 years of age inclusive require 3 x 0.5mL doses. For school-based grade 6 clinics, clients on a 3 x 0.5mL dose series can be given a 1.0mL dose in the school setting. Rationale is to reduce the complexity of clinic planning, management, risk for error, and risk of less antigen concentration if withdrawing a 0.5mL dose from a 1mL vial.

6. High Risk Neonatal and Infant Hepatitis B Program Complete program protocols available on VCH Intranet at VCH CD Control:

http://vchconnect/programs_services/cdc/communicable_disease_manual/hepatitis_b/page_113684.htm

<p>Risk category: "other than mother"</p>	<p>Protocols apply to newborns living in a household where someone other than their mother has hepatitis B infection (e.g. father, caregiver, grandparent). This information may have been learned by a PHN or PA from the liaison records, routine client contact such as phone conversation, child health clinic, or post-partum visit etc.</p>
	<p>Local level documentation and clinical action</p> <p>If a family presents to public health, PHN immunizes infant according to PARIS plan and recommends that family/infant visit their primary healthcare provider for post-vaccination serology which should occur 1 month following last dose of Hep B.</p> <p>Alert and immunization casenote: A high risk alert should be applied to the client's chart.</p> <ul style="list-style-type: none"> ○ Antigen: HEPB ○ Alert type: Immunization Schedule ○ Alert: 0,2,4,6 month schedule ○ Write a casenote alert and document in an immunization casenote that the family has been informed to seek follow-up serology following completion of series. <p>Note: For specifics on schedules for unique client scenarios and product choices refer to the BCCDC Immunization Manual section VII, page 19 and 20.</p>
<p>Risk category: "mother"</p>	<p>Protocols apply to an infant whose mother is Hepatitis B positive or infant received HBIG at birth. This information is learned by PHN or PA at local public health office through liaison records, routine client contact such as phone conversation, child health clinic, or post-partum visit.</p>
	<p>Local level documentation and clinical action</p> <p>Document in PARIS any known immunizations administered (e.g. in hospital or by midwife) Set the immunization alert type titled "0,2,4,6 month schedule" as per above. Local public health office sends notification of infant via PARIS to CD team inbox If infant presents to public health to be immunized, immunize according to PARIS Plan.</p> <p>CD central team</p> <p>CD central team will follow-up with family to ensure client receives follow-up serology one month after last planned dose is received and will document test results in client's chart.</p> <p>Note: For specifics on schedules for unique client scenarios and product choices refer to the BCCDC Immunization Manual section VII, page 19 and 20.</p>

At this time, PARIS is unable to plan for some special populations (high-risk, post exposure, immunocompromised) and other clients. Manage these clients by using an immunization alert when they require a different hepatitis B schedule/dosage as determined by their medical condition, exposure, or previous history. Refer to the [BCCDC Immunization Manual, Section III](#) for client-specific recommendations.

Do not use minimum intervals for immunizing high-risk clients as clients will receive best protection with due intervals.

The following HEPB PARIS immunization alerts are available:

Post exposure

Alert type: Immunization schedule

Alert: HEPB016 (0,1,6 MONTH HEP B SCHEDULE)

Product choice for Immune-suppressing conditions that require double doses

Double doses are required for some immune-suppressing conditions. For infants and children under 7 years of age who present with an immune-suppressing condition that requires double doses, **do not offer INFANRIX hexa™ as the hepatitis B dosage is not a double dose.** These children will require a double-dose of a monovalent hepatitis B product (check package instructions) and a DPTPOHIB-containing product (e.g. Pediacel®). See also [product choices](#).

Alert type: Immunization schedule

Alert: DD (DOUBLE DOSE HEPB: NO HEXA) for clients under 7 years of age or;

Alert: HEPBDD (HEPB HIGH RISK DBLE DOSE SCHED) for clients over 7 years of age

There are a variety of hepatitis B histories that PHNs will encounter. For example, a client from China received a 3-dose series in 1999 that does not match the current BC recommended schedule.

Managing histories that were completed prior to July 8, 2008

Within VCH, those clients who received any 3 doses regardless of interval or age are considered complete for series if the series was completed prior to July 8, 2008. When these histories are entered into PARIS, on SAVE they will be validated.

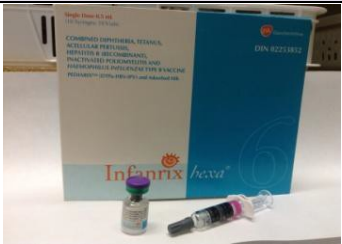



Managing histories received after July 8, 2008 to March 9, 2014

Histories entered into PARIS were validated based on the rules at that time (Due interval: 2–4–6 months of age; min interval 0–4 wks–8 wks). Beginning summer 2011 to March 9, 2014, VCH clinicians were recommended to manually plan for clients to ensure dose 1–3 had a 16 week interval. The major rules rewrite effective March 10, 2014 protected all previous VALID histories as VALID. For a historical timeline of acceptable minimum intervals and PARIS planning please [see appendix A](#).

Will there be a booster program for clients with hepatitis B histories entered and validated prior to March 9, 2014 that do not match the current recommended provincial schedule?

There is no recommendation at this time to retrospectively review clients with older hepatitis B histories and provide a booster dose. Further study to determine duration of protection from immunizations administered in infancy is required. If new information emerges and recommendations change, a strategy will be implemented at that time.

9. Product Choices - Hepatitis B

Infants to 6 years inclusive	Birth – 10 years & 6 months; 16–19 years	Grade 6 (10 years 7 months –15 years); Adults ≥ 20 years of age
 <p>The Hep B component of INFANRIX hexa™ is Engerix®-B.</p> <p>A 0.5mL dose of INFANRIX hexa™ contains the equivalent of 10 µg HBsAg</p> <p>*Not for clients who require a double dose</p>	 <p>Engerix®-B Pediatric 10 mcg/0.5mL Note: This represents a single dose</p> <p><i>No Photo available</i></p> <p>Recombivax HB® Pediatric 5mcg/0.5mL Note: This also represents a double dose from Birth to 11 years of age (This is why you may see some jurisdictions providing a 0.25mL dose of Recombivax HB® Pediatric).</p>	 <p>Engerix®-B Adult 20 mcg/1.0mL</p>  <p>Recombivax HB® Adult 10mcg/1.0mL</p>

Reminder: Document trade names of all products when known

Special Populations

For all special population recommendations refer to section III of the [BCCDC Immunization Manual](#).

- Double mcg required for: Chronic liver disease, HSCT, HIV, solid organ transplant
- Chronic kidney disease clients – product choice and dose based on age of presentation.

Product Interchangeability

Despite differences in mcg concentration, monovalent hepatitis B products are interchangeable. Follow package and dosing instructions by manufacturer for age, health status, and intervals.

Product choice for clients to 6 years of age inclusive when DTPPOHIBHB grouping is involved

Example: Routine antigen grouping in PARIS, product choice is a clinical decision.

Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
DTPoHibHepB	0y 2m	28/01/2014
DTPoHibHepB	0y 4m	28/03/2014
DTPoHibHepB	0y 6m	28/05/2014
DTPoHIB	1y 6m	21/05/2015
DTPo	4y 0m	21/11/2017
TdP	13y 7m	21/06/2027
Td	23y 7m	21/06/2037

Screen Shot example:

For the majority of clients, when PARIS groups antigens together the grouping will match product choice. For the hepatitis B infant program, PARIS planning most often involves antigen grouping DTPPOHIBHB which aligns with the choice to provide INFANRIX hexa™.

When the grouping does not match product choice

Clinical judgment is required to choose the right product for each client as DPTPO-containing products cannot be interchanged for the 3–dose primary series. For some clients, the grouping of antigens in PARIS may not match the correct product choice for a client and clinical judgment is required. This generally occurs when clients are from another jurisdiction, immunized outside of public health, late and off-schedule, or choosing their own schedule and timing.

Product choice decisions are determined by the following:

- Client’s history: previous doses received and product(s) received
- Age of client at presentation for next doses
- Antigens needed (primary vs booster)

Determining the right product: Clinical action for Primary Series of DPTPOHIBHB

Planned Immunizations (Antigen Group View)

Antigen	Age Due	Due Date
DPTPoHibHepB	0y 4m	10/03/2014
DPTPoHibHepB	0y 6m	10/05/2014
DPTPoHIB	1y 6m	10/05/2015
DTPPo	4y 0m	10/11/2017
TdP	13y 7m	10/06/2027
Td	23y 7m	10/06/2037

Review client’s chart: Assess which product client received for dose 1 of their primary series and keep them on the same product for dose 2 and 3.

For example, if a client received monovalent hepatitis B and DPTPOHIB (Pediace^l) for dose 1 of their primary series, these two products must be provided separately to complete their primary series even though PARIS will plan DPTPoHibHB in one row and it means more injections.

Immunization History (Antigen Group View)

Antigen	Date	Age Given	Status
DPTPoHIB	10/01/2014	0y 2m	VALID
Hepatitis B	10/01/2014	0y 2m	VALID

Client histories where products have already been interchanged during the primary series

There are no clinical studies to support interchanging INFANRIX *hexa*TM with Pediace^l for a primary series. However, if a client presents with a history of receiving a different product for dose 1 and dose 2 then any product can be chosen for dose 3. If the original vaccine is not known or not available, an alternative combination product can be used to complete the primary immunization series.

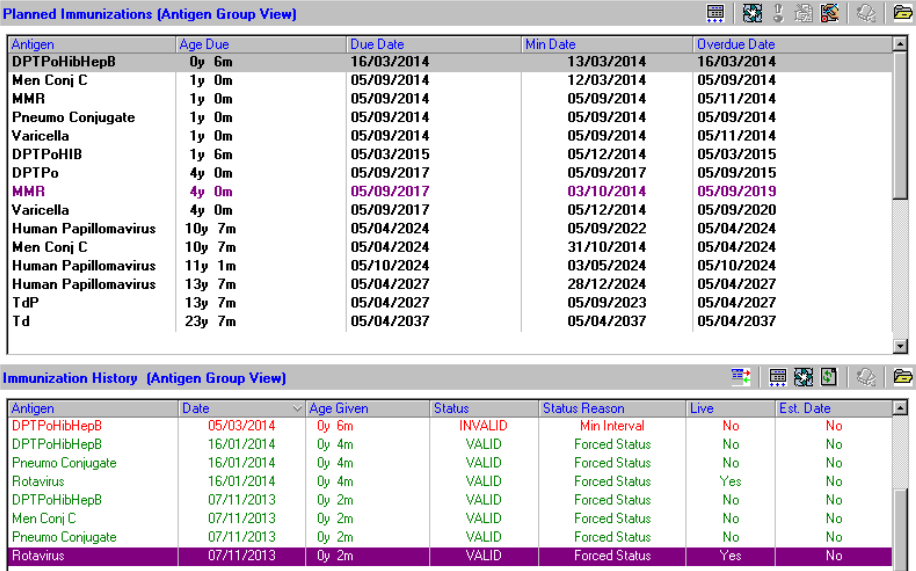
Clinical action for booster doses of DPTPO[HIB] and need for HB:

Interchanging products is acceptable for booster doses: For booster doses following completion of a 3–dose primary series, it is acceptable to interchange combination products and give extra HIB or polio to reduce the number of injections. This is especially helpful to reduce the number of injections when a client is late starting their hepatitis B series and also requires a booster of DPTPO[HIB]. Reminder to check the PARIS consent and if all antigens are not on the consent they will need to be manually added.

10. Client Scenarios: Applying the PARIS Hepatitis B Immunization Rules

Refer to 1B. Summary of PARIS Rules engine from birth to ≤ 19 years when reviewing these scenarios

Scenario		Clinical practice
Infant to Kindergarten age		
10.1	<p>A client started her Hep B series at 2 months of age. Client received dose 2, 12 weeks later and dose 3, 8 weeks after dose 2.</p> <p>Category 1 planning</p>	<p>PARIS Assessment Plan: This client has completed her 3-dose hepatitis B series and has met all criteria for a complete series. All doses will have a status of 'VALID' in PARIS and no further doses will be planned.</p> <p>Provider Action: No further action required.</p>
10.2	<p>A client started his Hep B series at 2 months and 3 weeks of age. Client received dose 2, 4 weeks later and dose 3, 11 weeks after dose 2.</p> <p>Category 1 planning</p> <p>Managing violation of doses 1-3, 16WK interval</p>	<p>PARIS Assessment Plan: Since this client started their series at 2 months of age, all doses are valid according to PARIS rules; but, after PARIS auto check of criteria, the interval between doses 1-3 was not 16W. PARIS will automatically put an immunization alert on the chart to provide dose 4, the dose will not be added to the plan.</p> <p>Provider Action: Timing and product choice is based on clinical judgment. There are 3 options for providing dose 4. Refer to principles.</p>
10.3	<p>A client started his Hep B series at 5 months of age. Client received dose 2, 8 weeks later and dose 3, 8 weeks after dose 2.</p> <p>Category 2 planning</p>	<p>PARIS Assessment Plan: All doses will have a status of 'VALID' and no further doses will be planned. Client is complete for Hep B.</p> <p>Provider Action: No further action required.</p>

<p>10.4</p>	<p>A client started her Hep B series at 5 months of age. Client received dose 2, 4 weeks later and dose 3, 8 weeks after dose 2.</p>	<p>PARIS Assessment Plan: Dose 3 will have a status of 'INVALID' and will be re-planned 3 months after last 'VALID' dose due to violation of doses 1–3, 16WK interval.</p> <p>Provider Action: Timing and product choice is based on clinical judgment. There are 3 options for providing dose 4. Refer to principles.</p>
	<p>Category 2 planning and managing violation of doses 1–3, 16WK interval</p>	
<p>10.5</p>	<p>A client who started their series at 2 months of age received a dose 2-3 interval of 6 weeks and 6 days.</p>	<p>PARIS Assessment Plan: Dose 2 to 3 has violated the 8 WK interval rule. Thus, dose 3 of Hep B is invalid and will need to be re-planned. However, PARIS will mark the entire group as invalid – min interval and will re-plan the entire grouping.</p>
	<p>Category 1 planning Managing violation of doses 2–3, 8WK interval</p>	 <p>The screenshot displays two windows from the PARIS software. The top window, 'Planned Immunizations (Antigen Group View)', shows a list of vaccines with columns for Antigen, Age Due, Due Date, Min Date, and Overdue Date. The bottom window, 'Immunization History (Antigen Group View)', shows a list of administered vaccines with columns for Antigen, Date, Age Given, Status, Status Reason, Live, and Est. Date.</p>
		<p>Provider Action:</p> <ol style="list-style-type: none"> 1) Only the Hep B antigen requires a repeat 2) Send the record to your local COC immunization lead for a manual record adjustment. The grouping will be changed to VALID and an alert will be posted on the chart to provide Hep B only as it will no longer be planned once the entire grouping is validated. 3) The alert will read: dose 2-3<8WKS: Provide dose 4. End date alert when dose 4 provided. <p>Grace period note: due to new grace period allowance of ≤ 4 days early, some of these cases will be resolved through full validation and no repeat required.</p>

<p>10.6</p>	<p>A client who started their series at 2 months of age received their third dose 7 days prior to 6 months of age due to travel reasons</p>	<p>PARIS Assessment Plan: Dose 3 has violated 6 MOA rule and status of Hep B antigen will be invalid. The Hep B component will require a repeat. All the other components are valid based on a 4 week interval between dose 2 to 3.</p> <p>The components view of the antigen group (double click on the group to see this view) will show that the DPTPoHib were all 'VALID' but the Hep B was 'INVALID' with a status reason of 'Min Age'.</p>																																																
	<p>Category 1 planning and Violation of 24 weeks of age rule</p>	<table border="1" data-bbox="597 590 1442 869"> <thead> <tr> <th colspan="6">Components</th> </tr> <tr> <th>Antigen</th> <th>Date</th> <th>Age Given</th> <th>Dose #</th> <th>Status</th> <th>Status Reason</th> </tr> </thead> <tbody> <tr> <td>Diphtheria</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>VALID</td> <td></td> </tr> <tr> <td>Hepatitis B</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>INVALID</td> <td>Min Age</td> </tr> <tr> <td>HIB</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>VALID</td> <td></td> </tr> <tr> <td>Pertussis</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>VALID</td> <td></td> </tr> <tr> <td>Polio</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>VALID</td> <td></td> </tr> <tr> <td>Tetanus</td> <td>09/03/2014</td> <td>0y 5m</td> <td>3</td> <td>VALID</td> <td></td> </tr> </tbody> </table> <p>Provider Action: Timing and product choice is based on clinical judgment. There are 3 options for providing dose 4. Refer to principles.</p>	Components						Antigen	Date	Age Given	Dose #	Status	Status Reason	Diphtheria	09/03/2014	0y 5m	3	VALID		Hepatitis B	09/03/2014	0y 5m	3	INVALID	Min Age	HIB	09/03/2014	0y 5m	3	VALID		Pertussis	09/03/2014	0y 5m	3	VALID		Polio	09/03/2014	0y 5m	3	VALID		Tetanus	09/03/2014	0y 5m	3	VALID	
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Tetanus	09/03/2014	0y 5m	3	VALID																																														
<p>10.7</p>	<p>Client presents for their 18 month DPTPOHIB booster. Upon assessment of chart, client received 3 valid doses of Pediacel by 24 weeks of age, no Hep B received to date.</p>	<p>PARIS Assessment Plan: PARIS will group antigens and plan for DPTPOHIBHEPB at 18 months and 2 more doses of monovalent hepatitis B at intervals from last dose of 1 month and 3 months.</p> <p>Provider Action: Give INFANRIX <i>hexa</i>TM for the 18 month booster as planned in PARIS. <i>Rationale:</i> It is acceptable to interchange products once the 3-dose primary series has been completed. This practice also reduces the number of injections.</p>																																																
	<p>Principle Product choice when primary series complete for DPTPOHIB</p>	<p>Continue as per PARIS plan. For hepatitis B dose 2, use monovalent Hep B vaccine. Clinically, this client can be manually planned using the provincial minimum intervals if needed (e.g. travel, risk for return). When the doses are entered they will be validated based on the Hep B provincial minimum intervals.</p> <p>Following dose 2, if the client is planned to return sooner than PARIS interval planning and the interval will be ≥ 16 W between dose 1-3, communicate plan in the chart using an alert and casenote. Alert type: Immunization Schedule Alert: IMSCHEDCN (description: Imm schedule – refer to case note)</p>																																																

<p>10.8</p>	<p>Client received 2 valid doses of Pediacel before age 12 months, no Hep B received to date. Client presents again at 18 months.</p>	<p>PARIS Assessment Plan: PARIS will group antigens and plan for DPTPOHIBHEPB.</p> <p>Provider Action:</p> <ol style="list-style-type: none"> 1. Give Pediacel to complete the primary series and monovalent Hep B. <i>Rationale:</i> There are no clinical studies to assess the effectiveness of interchanging products within a primary series. 2. Provide dose 2 and 3 as per PARIS plan. Product choice for future immunizations depends upon when client returns.
	<p>Principle</p> <p>Product choice when primary series incomplete for DPTPOHIB</p>	
<p>10.9</p>	<p>Client received 3 doses of hepatitis B in 2007 while living in Africa. Dose 1 was received at birth and dose 2 was received at 3 weeks of age. Dose 3 was given 6 months after dose 2. The history was entered into PARIS in 2010.</p>	<p>PARIS Assessment Plan: PARIS will validate all doses, as all doses were received prior to July 8, 2008.</p> <p>Provider Action: No further action required.</p>
	<p>Principle</p> <p>Histories prior to July 8, 2008</p>	
<p>10.10</p>	<p>A client received dose 1 of INFANRIX hexa™ on their fifth birthday. 4 weeks later they received dose 2 of Pediacel®. On their 6th birthday they received a monovalent dose of Hep B only.</p>	<p>PARIS Assessment Plan: PARIS will plan for a DPTPOHIBHB grouping for next dose to 6 years of age inclusive.</p> <p>Provider Action:</p> <p>If client returns before they turn 7 years, give INFANRIX hexa™ to complete their primary series of DPTPOHIB and to provide their dose 2 of Hep B. Interchanging is OK because products have already been interchanged during the series.</p> <p>Follow PARIS plan to complete dose 3 of Hep B.</p>
	<p>Principle</p> <p>Product choice when interchanging of products has occurred for primary series of DPTPOHIB</p>	

<p>10.11</p>	<p>Two children who started their series at 2 months of age received their second dose of INFANRIX hexa™ on the same day. The PARIS due date for dose 3 is different for these two clients.</p>	<p>PARIS Assessment Plan: PARIS is planning correctly for children who present on time. Check their birthdates. In this scenario, PARIS is DUE planning dose 3 on a 2 calendar month interval from dose 2 and also an age requirement of not before 6 months of age for dose 3.</p> <p>Provider Action: To ensure your client is immunized according to Hep B planning criteria, it's best to book clients according to the DUE plan in PARIS.</p>
	<p>Category 1 planning and 6 months of age criteria for dose 3</p>	
<p>School Age Children</p>		
<p>10.12</p>	<p>An unimmunized child presents at age 6 years for their immunizations.</p>	<p>PARIS Assessment Plan: PARIS will group antigens and plan for a DPTPOHIBHB grouping to ensure more accurate validation.</p> <p>Provider Action:</p> <ol style="list-style-type: none"> 1. Give INFANRIX hexa™ for their primary series as per the PARIS DUE plan if client can complete series before age 7. If not, clinicians can manually plan using Hepatitis B minimum intervals and the doses will be validated. <i>Rationale:</i> Providing extra doses of HIB is acceptable and reduces the number of injections. <p>If client is unable to complete their series before age 7, start client on DPTPO-containing product (e.g. Quadracel®) and monovalent Hep B product. If they return before their series is complete and they are now age 7, switch them to Tdap-IPV – containing product as per licensing restrictions of products.</p>
	<p>Category 2 planning and product choice based on age at presentation</p>	
<p>10.13</p>	<p>Client received 1, 0.5mL dose of hepatitis B in infancy and presents again at age 11 years for dose 2.</p>	<p>PARIS Assessment Plan: PARIS will correctly plan 2 more doses.</p> <p>Provider Action:</p> <ol style="list-style-type: none"> 1. Provide schedule as per PARIS DUE planning. For program reasons (e.g. reduced risk for error, less products to manage at clinic etc.) 2 X 1.0 mL doses can be offered in the school-based setting.
	<p>Principle Moving between hep B, 3 and 2 dose schedules</p>	

<p>10.14</p>	<p>Client received 1, 1mL dose in grade 6 when they were 11 years, and presents again at age 18 years to complete their series.</p>	<p>PARIS Assessment Plan: PARIS will correctly plan two more doses.</p> <p>Provider Action:</p> <ol style="list-style-type: none"> 1. Provide 2 X 0.5mL doses, as per PARIS plan. The PARIS Due for dose 3 is 5 months after dose 2 (based on the 0–1–6 schedule). <p><i>Rationale:</i> The 2–dose study that led to the grade 6 schedule change found a better response in younger adolescents. Thus the switch back to a 3–dose schedule starting at age 16 years.</p>
	<p>Principle Moving between hep B, 3 and 2 dose schedules</p>	
<p>10.15</p>	<p>Two clients were immunized in youth clinic for Hepatitis B. One client age 18 had further planning on their chart while the other client age 20 had no further planning.</p>	<p>PARIS Assessment Plan: PARIS will correctly plan a 3–dose series for all clients that were created in PARIS when they were ≤ 19 years of age. Clients created in PARIS >19 years of age will not have an immunization plan.</p> <p>Provider Action: Clients 20 years of age and older will require manual immunization planning if they do not have a plan in PARIS. Plan for a 0–1–6 month, 3–dose series.</p>
	<p>Principle PARIS standard template planning. No planning for adults.</p>	
<p>10.16</p>	<p>Grade 6 student, age 11 years, received 2 doses of Hepatitis B (RecombivaxHB product), 16 weeks apart.</p>	<p>PARIS Assessment Plan: PARIS planning for the adolescent 2–dose series is a DUE interval of 6 months and a min interval of 24 weeks.</p> <p>Provider Action:</p> <ol style="list-style-type: none"> 1. When 2 doses of RecombivaxHB product have been provided to a client 16 weeks apart, <u>enter the trade name</u> and PARIS will automatically validate the dose as this is a product dependent interval. 2. If the trade name was not entered, the second dose will be 'INVALID'. If you know what the trade name was, delete the dose and re-enter with the trade name and PARIS will validate the dose properly (<i>NOTE: this dose needs to be completely removed and re-entered, for the validation to work properly</i>). <p>If the trade name for either dose remains blank, an overnight script will notify the PARIS team. They will send an email to the provider of the dose asking them to enter a trade name. If it was an external provider, your immunization lead will be notified to follow up.</p>
	<p>Principle Product choice and documentation</p>	

<p>10.17</p>	<p>Client received 2 x 0.5mL hepatitis B doses at age 10 years. The doses were received 8 weeks apart. Client presents for dose 3, 8 weeks after dose 2.</p>	<p>PARIS Assessment Plan: PARIS will be correctly planning a 3–dose series.</p> <p>Provider Action: Provide dose 3 as per PARIS DUE planning. Min planning can be used where clinically indicated.</p>
	<p>Category 3 planning</p>	<p>Dosage options: a 1.0 mL dose can be offered in the school-based setting. Rationale is based on program reasons (e.g. reduced risk for error, less products to manage at clinic etc.)</p>

Appendix A:

Historical Timeline of Hepatitis B 3-Dose Minimum Schedule Recommendations

Timeline	Hepatitis B Minimum interval Recommendations for 3-Dose Series
2005	<p>Local practice included a minimum interval of 0–1–2 months. This was associated with the use of RecombivaxHB vaccine. As well, any client with a 3–dose hepatitis B immunization history was considered complete for series regardless of interval between doses and age received. This primarily involved clients from jurisdictions outside of BC.</p> <p>Rise Conversion Clients (Vancouver and Richmond, 2005): All clients with <i>valid/queried</i> electronic records in RISE were converted to PARIS as valid even if their record did not match the current PARIS planning. A forced status marker was applied. The record will show as <i>forced</i> and the dose will show as <i>valid</i>. This applies to dose 2 and 3 only. Doses that go beyond this such as dose 4, 5, and 6 were not impacted.</p>
2006	<p>In 2006, the Canadian Immunization Guide (NACI) recommended longer intervals between doses and introduced a minimum schedule of 4 weeks between dose 2–3 and 16 weeks between dose 1–3. The first 2 hepatitis B doses are considered the priming doses and the third dose is the booster dose. The longer the interval to the third dose, the higher the titre achieved and the height of the titre post third dose correlates to duration of protection.</p> <p>No immediate changes to the BC hepatitis B recommendations occurred following the Canadian recommendation.</p> <p>At this time in BC, any 3 doses, 4 weeks apart could be considered a valid hepatitis B series.</p>
2007	<p>The Canadian Immunization Guide interval recommendations were reflected in the BCCDC Immunization Manual by June 2007 (Dose 1–2 = 4 weeks; Dose 2–3 = 8 weeks; AND 16 weeks between dose 1–3). PARIS rules engine was not slated for an update at this time.</p>
2008	<p>PARIS rules were updated July 8, 2008 with some variances to reflect the provincial changes in 2007. Thus, local practice minimums of any 3, 4 weeks apart and clients from other jurisdictions, with any 3–dose hepatitis B immunization history, regardless of interval or age, were also considered complete until this time.</p> <p>PARIS Due rules were 2–4–6 months of age. Minimum intervals were 4 weeks between dose 1–2 and 8 weeks between dose 2–3 that reflected a dose 1–3 variance from provincial recommendations of 4 weeks.</p>
2011	<p>iPHIS conversion for Coastal clients. The doses from iPHIS were run through the current PARIS rules and as such display as <i>Valid</i>, <i>Queried</i>, or <i>Invalid</i> (unless forced as <i>Valid</i> as part of an existing overnight script).</p> <p>VCH clinicians were recommended to manually plan for clients to ensure dose 1–3 had a 16 week interval (beginning summer 2011).</p>
2014	<p>PARIS rules rewrite and new clinical actions to ensure provincial minimum intervals are met for each client were introduced. During this project the PARIS rules update team was informed that a new criteria of minimum age of 6 months of age for dose 3 was implemented in Panorama and was also integrated into PARIS rules. This new information was not communicated in the BCCDC Immunization Manual to this point in time.</p>