

## FREQUENTLY ASKED QUESTIONS

# Hepatitis B Vaccines and Schedules

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## Introduction

In Ontario, hepatitis B (HB) vaccine is offered as part of the publicly funded school-based immunization program, typically delivered by public health units to grade 7 students.<sup>1</sup> HB vaccine is also offered as part of the high risk immunization program for individuals at high risk of HB infection or complications.<sup>1</sup>

This FAQ is intended to support public health units (PHU) and health care providers in their assessment of HB immunization schedules to provide catch-up to individuals who have not yet completed their HB immunization series.

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# Background

## Key Principles of Immunization Scheduling

The following key principles will help address common questions regarding routine and catch-up immunization scheduling for HB vaccines.

- **The hepatitis B series does not need to be re-started for individuals whose immunization series was interrupted.**

In general, interruption of an immunization series does not require restarting the series, regardless of the interval between doses.<sup>2</sup> Delays between doses do not result in a reduction in final antibody concentrations for most multi-dose products; however, maximum protection may not be attained until the series is complete.<sup>3</sup>

- **Individuals who have missed dose(s) of the hepatitis B immunization series should complete the series using the age-appropriate dose and schedule.**

Individuals who present with interrupted HB immunization schedules should be vaccinated using the age-appropriate dose and schedule, as recommended by the Canadian Immunization Guide (CIG), based on their age at presentation.<sup>3,4</sup> HB immunization schedules authorized by Health Canada vary in dose and antigen content in relation to the age of the vaccine recipient.<sup>4</sup>

- **Observe recommended intervals between doses in a vaccine series.**

The minimum interval is the shortest time between two vaccine doses in a multi-dose series in which a protective response can be expected. Even though doses given at the minimum intervals are considered valid in the series, it is preferable to maintain the **recommended interval** when possible, with a few exceptions, as this will provide optimal protection or has the best evidence of efficacy.<sup>1</sup>

- **Hepatitis B vaccine products are interchangeable.**

Monovalent HB vaccines (i.e., Recombivax HB, Engerix-B) may be used interchangeably, even though their antigen content is not the same, using the dose and schedules recommended by the manufacturer for the vaccine recipient's age group.<sup>5</sup> Hepatitis A and hepatitis B combination vaccines (i.e., HAHB vaccines Twinrix and Twinrix Jr.) may also be used to start or complete the primary HB series.

## Monovalent Hepatitis B Vaccine Products

Doses and schedules for monovalent HB vaccines used in Canada are outlined below.

**Table 1. Doses and Schedules for Monovalent Hepatitis B Vaccines<sup>6</sup>**

Recipients	Recombivax HB (µg)	Recombivax HB (mL)	Recombivax HB Schedule (months)	Engerix-B (µg)	Engerix-B (mL)	Engerix-B Schedule (months)
Infants and children <11 years of age <sup>a</sup>	5.0	0.5	0, 1, 6	10	0.5	0, 1, 6
11 to 19 years of age (inclusive)	5.0	0.5	0, 1, 6	10	0.5	0, 1, 6 <sup>b</sup>
11 to <16 years of age (alternative adolescent two-dose schedule)	10.0	1.0	0, 4-6	20	1.0	0, 6
20 years of age and older	10.0	1.0	0, 1, 6	20	1.0	0, 1, 6 <sup>b</sup>
16 to 19 years of age (inclusive)						
Dialysis, chronic renal failure, and some immunocompromised	10.0 <sup>c</sup>	1.0	0, 1, 6	40	2.0	0, 1, 2, 6
20 years of age and older						
Dialysis, chronic renal failure, and some immune-compromised	40.0	1.0	0, 1, 6	40	2.0	0, 1, 2, 6

<sup>a</sup> Refer to the CIG for more details on HB immunization schedules for infants and children based on weight and risk factors.

<sup>b</sup> An accelerated schedule of 0, 1, 2, and 12 months for infants and children <11 years of age, which may be offered when rapid protection is needed (e.g., travel to endemic countries), is also outlined in the CIG for Engerix-B.

<sup>c</sup> Double the µg dose for a healthy individual of the same age

# Frequently Asked Questions

## School-based Hepatitis B Immunization Program

**Q1. If an individual received only the first dose of the adolescent HB two-dose schedule in grade 7, how would you complete the series when they present in grade 12 (≥16 years of age)?**

In this scenario, the HB immunization series should be completed using the age-appropriate dose and schedule. Two doses using the paediatric formulation (i.e., 0.5 ml of the 5 µg Recombivax HB or the 10 µg product of Engerix-B), which is indicated for adolescents 16-19 years of age (inclusive) is recommended to complete the three-dose series recommended for HB protection in this age group. A recent statement from the Ontario Immunization Advisory Committee (OIAC) is also supportive of this approach and provides additional rationale.<sup>7</sup>

**Q2. If an individual received one dose adult formulation (1.0mL) HB vaccine in grade 7, and inadvertently received a second 1.0mL dose of HB vaccine at 16 to 19 years of age, would the series be considered complete?**

If an individual received one dose of the adult formulation HB vaccine (i.e., 1.0 ml of the 10 µg Recombivax HB or the 20 µg product of Engerix-B) between ages 11 to <16 years, but inadvertently received a second 1.0mL dose at 16 to 19 years of age, the second dose would be considered valid. However, a third dose using an age-appropriate dose should be provided to complete the series. In this scenario, the third dose should be 0.5mL of Recombivax HB (5 µg) or Engerix-B (10 µg) based on age at presentation, and administered at least five months after the second dose.

The following tables detail how to complete a hepatitis B immunization series.

**Table 2: School-based program – completing the hepatitis B series**

Age	Immunization history	Vaccine	mL	Dose/Interval
11 to < 16 years	None	HB (adult)	1.0	<b>Dose 1:</b> 0 <b>Dose 2:</b> 4 to 6 months after dose 1
		<b>OR</b>		
		HB (pediatric)	0.5	<b>Dose 1:</b> 0 <b>Dose 2:</b> 1 month after dose 1 <b>Dose 3:</b> 6 months after dose 2
16 to 19 years	None	HB (pediatric)	0.5	<b>Dose 1:</b> 0 <b>Dose 2:</b> 1 month after dose 1 <b>Dose 3:</b> 6 months after dose 2

**Table 3. School-based program – *catch-up schedule* to complete the hepatitis B series**

Age	Immunization history	Vaccine	mL	Dose/Interval
11 to < 16 years	1 dose HB (pediatric)	HB (pediatric)	0.5	<b>Dose 2:</b> at least 1 month after dose 1 <b>Dose 3:</b> 5 months after dose 2
		<b>OR</b> HB (adult)	1.0	<b>Dose 2:</b> at least 1 month after dose 1 <b>Dose 3:</b> 4 to 6 months after dose 1
11 to < 16 years	2 doses HB (pediatric)	HB (pediatric)	0.5	<b>Dose 3:</b> at least 5 months after dose 2
		<b>OR</b> HB (adult)	1.0	<b>Dose 3:</b> at least 5 months after dose 2
16 to 19 years	1 dose HB (adult)	HB (pediatric)	0.5	<b>Dose 2:</b> at least 1 month after dose 1 <b>Dose 3:</b> 5 months after dose 2

**Q3. What interval should be used if a different monovalent hepatitis B product is used for the second dose of the adolescent two-dose schedule?**

When interchanging products within the adolescent two-dose HB immunization schedule, the minimum interval is based on what is recommended for the product given as the first dose.

**Table 4: Minimum and recommended intervals for mixed product two-dose hepatitis B schedule**

Dose 1	Dose 2	Recommended Interval	Minimum Interval
Recombivax HB	Recombivax HB	4 to 6 months	4 months
Recombivax HB	Engerix-B	4 to 6 months	4 months
Engerix-B	Engerix-B	6 months	6 months
Engerix-B	Recombivax HB	6 months	6 months

## Hepatitis B Vaccination Series Started in Infancy

**Q4. If a grade 7 student presents with a history of two valid doses of HB-containing vaccine received in infancy, how should the HB immunization series be completed?**

Having received two doses of a three-dose series in infancy and now presenting in grade 7, there are two options for completing the HB immunization series for this student: with one dose of pediatric formulation (i.e., 0.5 ml of the 5 µg Recombivax HB or the 10 µg product of Engerix-B); or depending on operational feasibility and vaccine availability at the school-based clinic, one dose of the adult formulation (i.e., 1.0 ml of the 10 µg Recombivax HB or the 20 µg product of Engerix-B) may be given to complete the series, as these products are approved for this age.

**Q5. A grade 7 student presents with a history of two doses of HB-containing vaccine received in infancy, but only one dose is valid. How should the HB immunization series be completed?**

This student needs two additional doses to complete the three-dose HB immunization series that was initiated. There are two options: with two doses of pediatric formulation (i.e., 0.5 ml of the 5 µg Recombivax HB or the 10 µg product of Engerix-B); or depending on operational feasibility and vaccine availability at the school-based clinic, two doses of the adult formulation (i.e., 1.0 ml of the 10 µg Recombivax HB or the 20 µg product of Engerix-B) may be given to complete the series, as these products are approved for this age.

## Combination Hepatitis B Vaccine Products

For reference, the doses and schedules for combined hepatitis A and B (HAHB) vaccines are indicated below as found in the CIG. Note: HAHB vaccine products are not publicly funded and not provided by public health at school-based immunization clinics.

**Table 5: Schedule and Dosage for Combined Hepatitis A and B Vaccine<sup>6</sup>**

Vaccine	Antigen	Volume	Schedule	Age
Twinrix	720 ELISA units HAV; 20 µg HBsAg	1.0 mL	0, 1, 6 months	19 years and older
Twinrix rapid schedule	720 ELISA units HAV; 20 µg HBsAg	1.0 mL	0, 7 days, 21 days, 12 months	19 years and older
Twinrix Junior	360 ELISA units HAV; 10 µg HBsAg	0.5 mL	0, 1, 6 months	6 months to 18 years
Twinrix	720 ELISA units HAV; 20 µg HBsAg	1.0 mL	0, 6-12 months	6 months to <16 years

**Q6. What is the recommended management for a grade 7 student who presents with a history of one dose of Twinrix?**

There are two options for series completion in this scenario: provide one dose of Twinrix to complete the HAHB series if their parent/guardian is interested in privately purchasing this vaccine; or provide one dose of a monovalent HB vaccine product (i.e., 1.0 ml of the 10 µg Recombivax HB or the 20 µg product of Engerix-B) to complete the adolescent two-dose HB series, noting that the HA series would be incomplete in this scenario. The student should be informed that although they are protected from hepatitis B, they would still need to complete their HA vaccine series.

**Q7. What is the recommended management for a grade 7 student who presents with a history of one dose of Twinrix Junior?**

If a grade 7 student has a history of one dose of Twinrix Junior (containing 10 µg HBsAg) and their parent/guardian is interested in privately purchasing this vaccine, the HAHB series should be completed using the age-appropriate dose and schedule. Twinrix Junior is a three-dose HAHB series with a schedule of 0, 1, and 6 months for individuals one to 18 years of age; therefore, two additional doses of Twinrix Junior are needed to complete the HAHB series.

There is also the option of completing the HB series only with one of two approaches: complete the three-dose series that was started by administering two doses of 0.5 ml of Recombivax HB (or the 10 µg product of Engerix-B); or depending on operational feasibility and vaccine availability at the school-based clinic, complete the series using two doses of a 1.0 mL HB vaccine product. For both of these approaches, the student would need to be informed that they would still need to complete their HA series.

**Q8. What is the recommended management for a grade 7 student who presents with a history of two doses of Twinrix Junior?**

Twinrix Junior is a three-dose HAHB series with a schedule of 0, 1, and 6 months; therefore, if their parent/guardian is interested in privately purchasing this vaccine, one dose of Twinrix Junior is needed to complete the series.

At a school-based clinic, there are two options for completing the HB series only: administer one dose of the paediatric formulation of monovalent HB (i.e., 0.5 ml of the 5 µg Recombivax HB or the 10 µg product of Engerix-B), or depending on operational feasibility and vaccine availability at the school-based clinic, complete the series using one dose of the adult formulation (i.e., 1.0 ml of the 10 µg Recombivax HB or the 20 µg product of Engerix-B). The student should be informed that although they are protected from hepatitis B, they would still need to complete their hepatitis A vaccine series.

**Q9. Is a fourth dose of hepatitis B vaccine required for infants/children who received combination vaccines containing hepatitis B (e.g., DTap-IPV-Hib-HB)?**

If a child has received DTap-IPV-Hib-HB at 2, 4, and 6 months, the 18 month booster dose (i.e., DTap-IPV-Hib) does not need to contain HB. The 2, 4, and 6 month schedule of DTap-IPV-HiB-HB is considered a complete HB immunization series and no further doses of HB vaccine are needed.

## Titres and Duration of Protection

### **Q10. When is post-immunization serology recommended?**

Routine serologic testing for immunocompetent individuals following the completion of an authorized HB immunization schedule is not recommended with the exception of infants born to HB-infected mothers, healthcare workers, and other groups at high risk of HB infection or complications.<sup>8</sup> The optimal timing of post-immunization serologic testing is at least 1 month, but no later than 6 months, after the last dose of vaccine.<sup>8</sup> Periodic monitoring of the anti-HBs titre following immunization is indicated for persons with chronic renal disease and those on dialysis, and immunocompromised persons.<sup>8</sup>

### **Q11. What is the recommended management for an individual with a documented history of a complete HB immunization series, but recent anti-HBs titre results demonstrate a non-adequate anti-HBs titre (i.e., <10 IU/L)? Should an additional dose of HB vaccine be provided?**

In this scenario, if the serologic testing was performed within 6 months of completion of the HB immunization series, and the anti-HBs titre is <10 mIU/mL, re-immunization should be undertaken. This is particularly the case in individuals who are at higher risk of hepatitis B infection or complications (e.g., household contacts of chronic carriers of HB, immunocompromised persons, persons with chronic renal disease or on dialysis, etc.).<sup>8</sup> Please see the [Booster Doses and Re-immunization](#) section in the Hepatitis B chapter of the CIG for further details about managing individuals who fail to respond to the primary vaccine series.<sup>9</sup>

An alternative scenario is if anti-HBs titres were ordered on a healthy individual who received a complete primary HB immunization series several years earlier. Although anti-HBs titres may fall below an adequate level or become non-detectable over time, immune memory persists in immunocompetent individuals as evidenced by rapid and high levels of antibody production following a challenge with a subsequent dose of vaccine (an anamnestic response).<sup>10,11</sup> On this basis, at present there is no recommendation for routine serology testing among immunocompetent individuals who completed a HB immunization series or administration of booster doses of HB vaccine. Therefore, in this situation, there is no recommendation to offer an additional dose of vaccine.

### **Q12. On recent serology, an individual was found to have protective levels of immunity for both hepatitis A and B. However, they have a history of receiving only two doses of a three-dose series of Twinrix. Does this individual require another dose of Twinrix when they have demonstrated protective levels to both hepatitis A and B?**

Despite protective levels of immunity found on serologic testing, it is recommended that this individual receive the third dose of Twinrix in order to complete the HAHB series if they are interested in privately purchasing vaccine. For completing the HB series only, they should be provided an age appropriate dose of HB vaccine. The third dose of the HB series confers the maximum level of seroprotection but acts primarily as a booster and appears to provide optimal long-term protection.<sup>12</sup>

### **Q13. Does a HB immunization series completed in infancy provide long-term or lifelong protection? Is a booster dose recommended in adolescence or adulthood?**

Seroprotection rates following a complete HB immunization series is 95-100% and there is evidence that the duration of protection against chronic infection following hepatitis B vaccination is long (at least 30 years) but the immune correlates of protection is an area of active study.<sup>10</sup>

Canada's National Advisory Committee on Immunization (NACI) Hepatitis Working Group reviewed and assessed the evidence on long-term efficacy and effectiveness of HB vaccines in immunocompetent individuals, with particular focus on individuals immunized as infants and health care workers.<sup>13</sup> Their review was based on findings of a joint Viral Hepatitis Prevention Board/World Health Organization (VHPB/WHO) conference, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization updated review of evidence on long-term protection of HB vaccination, as well as results of a meta-analysis.<sup>13</sup> Based on their review, NACI concluded there is fair evidence to support that routine booster doses of HB vaccine for immunocompetent individuals following the completion of a recommended HB immunization schedule given in infancy is not recommended.<sup>14</sup> This aligns with recommendations from the United States' Advisory Committee on Immunization Practices (ACIP) which indicate that revaccination (i.e., booster dose, challenge dose, or revaccination with a complete series) is not generally recommended for immunocompetent persons who were vaccinated as infants, adolescents, or adults.<sup>12</sup>

## High-risk Individuals and Hepatitis B Vaccine

**Q14. Can higher dose monovalent hepatitis B products be used interchangeably for renal clients? We have received supply of Recombivax HB 40µg, but many of our renal clients have already initiated their HB series using a double dose of Engerix-B (2 x 20µg). Can we complete their series with Recombivax-HB?**

The below recommendations apply to adults aged 20 years and older.

The CIG states that monovalent hepatitis B vaccines may be used interchangeably, according to the recommended dosage and schedule.<sup>5</sup> Therefore, Recombivax HB – dialysis formulation (40ug) may be used to complete the HB series for patients on dialysis who started with Engerix-B (2x20ug). However, Engerix-B is a four-dose series, whereas Recombivax HB is a three-dose series. As per the US ACIP, if different brands of a particular vaccine require a different number of doses for series completion and a provider mixes brands in the primary series, the higher number of doses is recommended for series completion.<sup>15</sup> Therefore, in the scenario where any dose in the series was Engerix-B, a total of 4 doses of vaccine should be administered to promote optimal immunogenicity.<sup>16,17</sup>

It should be noted that patients on dialysis are at high risk of HB infection or complications and therefore post-immunization serologic testing of anti-HBs titres, at least 1 month (up to 6 months) after completion of the vaccine series, is recommended. Individuals who do not develop anti-HBs titres of at least 10 IU/L (protective anti-HBs titre) after the initial HB vaccine series should receive a second HB vaccine series. Those who fail to respond to a second series are unlikely to benefit from further immunization and should be counselled on alternative risk reduction measures.<sup>13</sup>

Most people undergoing chronic dialysis will not develop an immune memory and HB antibody levels should be monitored on annual basis. A booster dose may be required if anti-HBs fall below 10 IU/L. If a higher vaccine dose was indicated for the initial vaccine series, a higher dose should be used for all subsequent immunizations.<sup>14</sup>

**Q15. What are the high risk eligibility criteria for publicly-funded HB vaccine in Ontario?**

In addition to the school-based HB immunization program, the following individuals are eligible to receive publicly funded HB vaccine as outlined in the [Publicly Funded Immunization Schedules for Ontario](#)<sup>1</sup>:

- Children <7 years old whose families have immigrated from countries of high prevalence for HBV and who may be exposed to HBV carriers through their extended families (3 doses)

- Household and sexual contacts of chronic carriers and acute cases (3 doses)
- History of a sexually transmitted disease (3 doses)
- Infants born to HBV-positive carrier mothers:
  - premature infants weighing <2,000 grams at birth (4 doses)
  - premature infants weighing  $\geq$ 2,000 grams at birth and full/post term infants (3 doses)
- Persons who use intravenous drugs (3 doses)
- Liver disease (chronic), including hepatitis C (3 doses)
- Awaiting liver transplants (2nd and 3rd doses only)
- Men who have sex with men (3 doses)
- Multiple sex partners (3 doses)
- Needle stick injuries in a non-health care setting (3 doses)
- On renal dialysis or those with diseases requiring frequent receipt of blood products (e.g., haemophilia) (2nd and 3rd doses only)

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