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**SUBJECT:** Recombivax HB dialysis formulation to complete a Hepatitis B (HB) series started with Engerix-B

Date: January 30, 2023

Pages: 3

To: Hospitals

From: Dr. Matthew Tenenbaum, Associate Medical Officer of Health

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Individuals who are on dialysis, have chronic renal failure, or have certain immunocompromising conditions are at increased risk of Hepatitis B (HB) disease and should be vaccinated against HB as soon as the risk is identified.<sup>1</sup> These individuals require a higher dose of monovalent HB vaccine.<sup>1</sup>

Age Group	Recommended HB Vaccine Dose
<b>Children</b> (0 to <16 yrs)	Double the routine dose of monovalent HB vaccine for their age
<b>Adolescents/Young Adults</b> (16 to <20 years)	40 mcg dose of ENGERIX®-B vaccine OR Double the routine dose of RECOMBIVAX HB® vaccine for their age
<b>Adults</b> (20 yrs and older)	40 mcg dose of monovalent HB vaccine

Public Health Ontario has provided the following recommendations related to the use of Recombivax HB Dialysis formulation to complete a HB series started with Engerix-B. These recommendations apply to adults aged 20 years and older who are on dialysis, have chronic renal failure and some immunocompromised adults.<sup>1</sup>

The Canadian Immunization Guide (CIG) states that monovalent HB vaccines may be used interchangeably, according to the recommended dosage and schedule<sup>2</sup>. Therefore, **Recombivax HB-dialysis formulation (40ug) may be used to complete the HB series for patients on dialysis who started with a double standard dose of Engerix-B (2x20ug).**

As per the US Advisory Committee on Immunization Practices (ACIP)<sup>3</sup>, 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. In this case, Engerix-B is a 4-dose series, whereas Recombivax HB is a 3-dose series. 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. This advice is also provided by Alberta Health Services<sup>4</sup> and the British Columbia Centre for Disease Control.<sup>5</sup>

For example:

- if a patient received a double standard dose of Engerix-B (2.0mL) at 0 month of a four dose series, 3 doses of Recombivax dialysis formulation (1.0 mL) at the appropriate intervals would be required to complete series followed by post-immunization serologic testing described below.
- if a patient received four double standard doses of Engerix-B, 2.0 mL each at months 0,1,2,6 the series is considered complete and recommendations for post-immunization serologic testing should be followed as described below.

## WDG Public Health Physician Update

### Recombivax HB dialysis formulation to complete a Hepatitis B (HB) series started with Engerix-B

January 30, 2023

Page 2 of 3

Patients on dialysis are at high risk of HB infection or complications<sup>2</sup> 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. (CIG<sup>6</sup>)

Most individuals undergoing chronic dialysis will not develop an immune memory<sup>2</sup> and HB antibody levels should be **monitored on an 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, the higher dose should be used for all subsequent immunizations. (CIG<sup>7</sup>)

If you have any further questions, please contact public health at 1-800-265-7293 ext. 7006.

#### References:

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**WDG Public Health Physician Update**

**Recombivax HB dialysis formulation to complete a Hepatitis B (HB) series started with Engerix-B**

**January 30, 2023**

**Page 3 of 3**

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