Standing Orders for Administering Hepatitis B Vaccine (ENGERTIX-B®) to Children and Adolescents

Purpose: To reduce morbidity and mortality from Hepatitis B disease by vaccinating all children and adolescents who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices, The Food and Drug Administration (FDA) product labeling, and the Department of Defense (DoD).

Policy: Under these standing orders, eligible nurses and other healthcare professionals working within their scope of practice may vaccinate children and adolescents patients who meet the criteria below.

Procedure

1. Identify infants, children, and adolescents who have not begun or have not completed a hepatitis B vaccination series.
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
   - **Contraindications:**
     - a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component (including yeast).
     - For information on vaccine components, refer to the manufacturers' package insert or go to http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf
   - **Precautions:**
     - moderate or severe acute illness with or without fever
     - the tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals
     - syncope (fainting) can occur in association with administration of injectable vaccines, including ENGERIX-B. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
     - because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is strongly recommended
     - For questions or concerns, consider consulting the DHA Immunization Healthcare Branch at 877-438-8222, Option 1.
3. Provide all patients (or their parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient’s medical record, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL hepatitis B vaccine intramuscularly in the anterolateral thigh muscle for infants and toddlers or in the deltoid muscle of the arm for children and adolescents ages 3 -

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19 years of age. The anterolateral thigh muscle may be used if deltoid is inadequate. Use a 22–25 gauge needle. Choose needle length appropriate to the patient’s age and body mass.

Note: all patients birth through 19 years of age should receive the 0.5mL (10mcg) dose. Patients aged 20 years and older should receive the 1mL (20mcg) dose. Please see appropriate standing orders for administration of Hepatitis B vaccine to adults for details.

5. Provide subsequent doses of hepatitis B vaccine to complete each patient’s 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 16 weeks between the first and third doses. The last dose in the infant series should not be administered earlier than age 24 weeks.

Note: It is necessary to give a total of 4 doses of hepatitis B-containing vaccine when COMVAX® or PEDIARIX® vaccines are administered after the birth dose of hepatitis B.

6. Documentation
   • Document all immunizations administered in the electronic health record. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.

7. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

8. Adverse Events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online at https://vaers.hhs.gov.

9. This policy and procedure shall remain in effect for all patients of the ______________________ until rescinded and/or upon a change in the Medical Director, whichever is earlier.

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Medical Director’s Signature Date