Standing Order for Administering Hepatitis A / Hepatitis B Combination Vaccine (Adult)

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

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

Procedure

1. Identify all persons ≥18 years of age in need of vaccination against both hepatitis A and hepatitis B based on the following criteria:
    - Lacking documentation of at least 2 doses of hepatitis A vaccine (HepA) and lacking a completed series (2 or 3 doses depending on product) of hepatitis B vaccine (HepB) at the appropriate ages/intervals
    - Anticipated travel to a country with intermediate or high endemicity for hepatitis A and B (generally all except Canada, Japan, Australia, New Zealand, and most of Western Europe; see CDC Yellow Book, TRAVAX, or other travel medicine guidelines)
    - End stage renal disease, hemodialysis; HIV infection; or chronic liver disease, diabetes mellitus (Note: for those age 60 and over with diabetes, at the discretion of the provider)
    - Diagnosis of HIV infection
    - Current or recent use of injectable street drugs
    - Persons at risk for infection by sexual exposure, seeking evaluation or treatment for sexually transmitted infection, sexually active and not in a monogamous relationship, male who has sex with males, sex partner or household member of a person chronically infected with hepatitis B
    - Diagnosis of chronic liver disease, including hepatitis C
    - Persons with occupational risk (e.g., healthcare workers)
    - Residents and staff of facilities for developmentally disabled persons
    - Any other adult who wants to be protected from hepatitis A and B

Note: if patient has completed either the hepatitis A vaccination series or the hepatitis B vaccination series DO NOT give TWINRIX®: see the applicable monovalent standing order for information

2. Screen all patients for contraindications and precautions to TWINRIX® vaccine:
   Contraindications:
    - A history of a serious reaction (e.g., anaphylaxis) after a previous dose of any hepatitis A or B-containing vaccine, or to any component of the vaccine (including neomycin and yeast)
    - For information on vaccine components, refer to the manufacturer's package insert or go to http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

Precautions:

- Moderate or moderate or severe acute illness with or without fever
- The tip caps of the prefilled syringes of Twinrix® contain natural rubber latex that may cause allergic reactions in latex sensitive individuals
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid a falling injury (e.g. 15 minute observation after administration) and to restore cerebral perfusion following syncope
- For questions or concerns, consider consulting the DHA Immunization Healthcare Division at (877) 438-8222, Option 1 or DSN 761-4245

3. Provide all patients (or their parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must provide both the HepA and HepB VISs as there is no VIS for TWINRIX®. You must document, in the patient's medical record, the publication date of the VISs and the date they were 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. Provide vaccine as follows:
   - The combination HepA/HepB vaccine (TWINRIX®) consists of a 3-dose series at 0, 1, and 6 months. Administer 1mL intramuscularly in the deltoid muscle for adults.

Needle Length and Injection Site of IM Injections for Adults		
Use a 22 – 25 gauge needle. Choose needle gauge and length appropriate to administration route and the patient's age and body mass.		
Age Group	**Needle Length**	**Injection Site**
Men and Women (<130 lbs)	1 inch†	Deltoid Muscle of Arm
Men and Women (130-152 lbs)	1 inch	
Men (152-260 lbs)	1-1.5 inches	
Women (152-200 lbs)		
Men (> 260 lbs)	1.5 inches	
Women (>200 lbs)		

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
† Some experts recommend a 5/8 inch needle for men and women who weigh <130 lbs, skin must be stretched tightly (do not bunch subcutaneous tissue)

5. Provide subsequent doses of TWINRIX® vaccine to complete each patient's 3-dose series by observing a minimum interval of 1 month between the 1st and 2nd dose, and 5 months between the 2nd and 3rd dose.

Note: TWINRIX® is also FDA-approved for accelerated dosing (0, 7days, 21-30 days, and 12 months) for impending travel in less than 28 days. This is not recommended by ACIP for routine dosing, and is not covered under these standing orders. Patients must obtain a written order from a privileged provider for this situation

Note: Interchangeability of TWINRIX® and single antigen Hepatitis A and B vaccines:

- A dose of TWINRIX® contains a standard adult dose of hepatitis B vaccine and a pediatric dose of hepatitis A vaccine. A dose of TWINRIX® can be substituted for any dose of the hepatitis B series but not for any dose of the hepatitis A series.
- Any combination of 3 doses of adult hepatitis B or 3 doses of TWINRIX® is a complete series of hepatitis B vaccine
- One dose of TWINRIX® and 2 doses of adult hepatitis A is a complete series of hepatitis A vaccine
- Two doses of TWINRIX® and 1 dose of adult hepatitis A is a complete series of hepatitis A vaccine

6. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. 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 (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.

_____ _____

Medical Director's Signature Date