STANDING ORDERS FOR
Administering Hepatitis B Vaccine to Adults

Purpose

To reduce morbidity and mortality from hepatitis B virus (HBV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other health care professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1 **Assess Adults for Need of Vaccination** against HBV infection[1,2,3] according to the following criteria:

- All adults age 19 through 59 years
- All adults age 60 or older with risk factors for HBV infection due to
  - ▶ Sexual exposure risk
    - sex partners of hepatitis B surface antigen [HBsAg]-positive people
    - sexually active people not in monogamous relationships
    - people seeking treatment for a sexually-transmitted infection
    - men who have sex with men
  - ▶ Percutaneous or mucosal exposure to blood
    - current or recent injection-drug use
    - household contacts of HBsAg-positive people
    - residents and staff of facilities for developmentally disabled people
    - healthcare and public safety workers with risk for exposure to blood or blood-contaminated body fluids
    - hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients
    - patients with diabetes at the discretion of the treating clinician
  - ▶ Other factors
    - anticipated travel to countries with high or intermediate endemic hepatitis B
    - people with hepatitis C infection
    - chronic liver disease (including, but not limited to people with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
    - HIV infection
    - incarceration
- Any adult age 60 or older who does not meet the risk-based recommendations above may be vaccinated.

NOTES

1. In general, people who have documented completion of a HepB series at any point or who have a history of previous HBV infection should not receive additional HepB vaccine, although there is no evidence that additional vaccination is harmful.
2. Revaccination may be indicated for certain high-risk adults, including healthcare workers who are documented non-responders to an initial HepB series, and certain dialysis patients. For revaccination guidance, see the 2018 ACIP recommendations for the prevention of hepatitis B at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf (pages 23-24).
3. In settings where the patient population has a high rate of previous HBV infection, prevaccination testing, which may be performed at the same visit when the first dose of vaccine is administered, might reduce costs by avoiding complete vaccination of people who are already immune. However, prevaccination testing is not required and should not create a barrier to vaccination.

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2 Screen for Contraindications and Precautions

Contraindications

Do not give hepatitis B vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

Moderate or severe acute illness with or without fever

Pregnancy

Pregnancy testing is not needed before vaccination; however, data on Heplisav-B and PreHevbrio are currently insufficient to reach any conclusions concerning vaccine-associated risks in pregnancy. Thus, providers should vaccinate pregnant people needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix.

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	⅝"*–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm
Female or male, any weight	22–25	1"*–1½"	Anterolateral thigh muscle

* Alternative needle lengths may be used for IM injections if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin as follows: a) a 5/8" needle for patients weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

5 **Administer Hepatitis B Vaccine** according to the criteria and guidance in the tables below:

TYPE OF VACCINE	AGE GROUP	DOSE	ROUTE
Heplisav-B (Dynavax)	18 yrs & older	0.5 mL	Intramuscular (IM)
Pediatric formulation of Engerix-B (GSK) or Recombivax HB (Merck)	19 yrs & younger	0.5 mL	Intramuscular (IM)
Adult formulation of Engerix-B (GSK) or Recombivax HB (Merck)	20 yrs & older	1.0 mL	Intramuscular (IM)
PreHevbrio (VBI Vaccines)	18 yrs & older	1.0 mL	Intramuscular (IM)

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Schedules for vaccination

HISTORY OF PREVIOUS VACCINATION	FOR PATIENTS WHOSE BRAND OF VACCINE IS KNOWN, CONTINUE WITH THE SAME BRAND AS SHOWN BELOW. IF PREVIOUS BRAND IS NOT KNOWN OR IS NOT AVAILABLE, COMPLETE SERIES WITH A TOTAL OF 3 DOSES OF VACCINE. USE THE 3-DOSE SCHEDULE DOSING INTERVALS EXCEPT WHEN ADMINISTERING 2 DOSES OF HEPLISAV-B (GIVEN 4 WEEKS APART AS A COMPLETE 2-DOSE SERIES).	
	SCHEDULE FOR ADMINISTRATION OF HEPLISAV-B[1,2]	SCHEDULE FOR ADMINISTRATION OF ENGERIX-B, RECOMBIVAX HB, OR PREHEVBRIO[1,2]
None or unknown	Give a 2-dose series at 0 and 1 month.	Give a 3-dose series at 0, 1, and 6 mos.
1 dose	Give dose #2 at least 4 wks after dose #1 to complete the series.	Give dose #2 at least 4 wks after #1; then, give dose #3 at least 8 wks after dose #2 and at least 16 wks after dose #1.
2 doses		Give dose #3 at least 8 wks after dose #2 and at least 16 wks after dose #1.

NOTES

1. For patients receiving hemodialysis or with other immunocompromising conditions, use one of the following alternative dosing schedules: (a) Recombivax HB: series of 3 doses (1 mL each) of 40 mcg/mL at 0, 1, and 6 mos, OR (b) Engerix-B: series of 4 doses (2 mL each) as a single 2-mL dose or as two 1-mL doses on a 0-, 1-, 2-, 6-month schedule. The safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis.
2. The hepatitis B vaccine series does not need to be restarted, regardless of the time that has elapsed between doses.

Information on serologic testing

- CDC recommends screening all adults age 18 years or older at least one time for hepatitis B using a triple panel serologic test, regardless of vaccination status. Periodic testing of susceptible individuals at increased risk of infection is also recommended. Vaccination should proceed and should not be deferred if a screening test is unavailable or is declined when the opportunity to vaccinate is present. Ideally, serologic testing may be performed at the same visit as vaccination, with the first dose of vaccine administered after the blood draw. If the patient is found to be HBsAg-positive, appropriate medical follow-up should be provided; if the patient is HBsAg-positive or shows evidence of immunity to HBV (qualitatively reported as "positive" or quantified at least 10 IU/mL), no further doses of hepatitis B vaccine are indicated. See 2023 CDC screening recommendations for details at www.cdc.gov/mmwr/volumes/72/rr/pdfs/rr7201a1-H.pdf.
- Certain people need testing for immunity (anti-HBs) 1–2 months following vaccination. Check 2018 ACIP recommendations for details at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf (page 25).

6 Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

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7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Adult Patients," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report All Adverse Events to VAERS

Report all adverse events following the administration of hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to http://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ (NAME OF PRACTICE OR CLINIC)

effective _____ (DATE) until rescinded or until _____ (DATE) .

Medical Director _____ (PRINT NAME) / _____ (SIGNATURE) _____ (DATE)