IMMUNIZATION PROTOCOL FOR PHARMACISTS

RECOMBINANT HEPATITIS B VACCINE

Revisions as of 1/06:

- Updated adult recommendations for Pre-exposure use focusing on high-risk settings rather than acknowledged high-risk behavior. (Section III) pg.3.
- Post-exposure guidelines are in (Section VI) pg. 6.

I. ORDER

1. Screen for contraindications.
2. Provide a current Vaccine Information Statement (VIS), answering questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Give hepatitis B vaccine to persons according to risk group, age, type of vaccine and vaccine status.
   a. May be given simultaneously with all other vaccines, including travel vaccines.

Note: Give adolescents and adults hepatitis B vaccine by IM injection only in the deltoid.

_____ _____

Pharmacist signature Date

Electronic copy of this protocol available at::
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml.
To request this material in an alternate format (e.g., Braille), please call (971) 673-0300.

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II. A. LICENSED MONOVALENT HEPATITIS B VACCINES[1]			
Product Name	**Vaccine Components**	**Acceptable age range**	**Thimerosal**
Recombivax HB®	Hepatitis B	Birth through Adult	No
Engerix-B®	Hepatitis B	Birth through Adult	No
B. LICENSED COMBINATION HEPATITIS B VACCINES[1]			
Twinrix®[2]	Hepatitis A (Havrix®) and Hepatitis B (EngerixB®)	18 years and older	Trace (< 1 mcg)

[1] The immune response when doses of hepatitis B vaccine from one manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable to the response after a full series using vaccine from a single manufacturer.

[2] Twinrix® is NOT approved for use in persons less than 18 years of age

III. RECOMMENDATIONS FOR USE

Pre-exposure Prophylaxis

1. Hepatitis B vaccination is recommended for all adolescents ages 18 years regardless of whether the patient has a known risk factor for contracting hepatitis B.
2. All unvaccinated adults at risk for hepatitis B virus (HBV) infection and adults seeking protection from HBV infections (e.g., health and public safety workers). Acknowledgment of a specific risk factor is not a requirement for vaccination.
3. In the following settings where a high proportion of adults are likely to have risk factors for HBV infection all unvaccinated adults should receive Hepatitis B vaccine:
   - Sexually transmitted disease (STD) treatment facilities,
   - Human immunodeficiency virus (HIV) testing and treatment facilities,
   - Facilities providing drug abuse treatment and prevention,
   - Correctional facilities,
   - College health services,
   - Chronic hemodialysis facilities and end-stage renal disease programs,
   - Institutions and nonresidential daycare facilities for developmentally disabled persons.
4. Hepatitis C-positive individuals
5. Immigrants, refugees, or adoptees from countries where HBV infection is endemic, and their household members.
6. International travelers spending 6 months or more in an area with high rates of HBV infection and who will have close contact with the local population.
7. Alaska Natives and Pacific Islanders.
8. Individuals engaged in commercial sex work.

IV. VACCINE SCHEDULE

A. Hepatitis B Vaccine Schedule for Adolescents 18 and 19 years of age:

Dosage: 0.5 ml[2]

DOSE	MINIMUM INTERVAL[1]
1	----------
2	4 weeks
3	8 weeks after dose 2, **and** 16 weeks after dose 1.

B. **Hepatitis B Vaccine Schedule for Adults 20 years of age and older:**

Dosage: 1.0 ml[3]

DOSE	MINIMUM INTERVAL[1]
1	----------
2	4 weeks
3	8 weeks after dose 2, **and** 16 weeks after dose 1.

[1] For retrospective checking, doses that violate the minimum interval (to next dose) by 4 or fewer days do not need to be repeated.

[2] If using Engerix-B®, a dose of 1.0 ml is recommended for 18 and 19 year olds at high risk for exposure to the HepB virus or who are traveling to high-risk areas. The schedule for these special populations is 0,1,6 months or 0,1, 2,12 months if prolonged maintenance of protective titers is indicated. See package insert (table 2) for more details.

[3] If using Engerix-B® a 1.0 ml dose schedule of 0,1,2,12 months is recommended for populations at high risk for exposure to HepB, or traveling to high-risk areas.. On this alternate schedule, an additional dose at 12 months is recommended for prolonged maintenance of protective titers. See package insert (table 2) for more details.

C. Hepatitis B Vaccine Schedule for Adults ≥ 20 Years of Age Undergoing Dialysis[1]

DOSE	RECOMBIVAX® VACCINE DOSAGE	MINIMUM SPACING	ENGERIX-B® VACCINE DOSAGE	MINIMUM SPACING
1	1.0 ml		2.0 ml[2]	
2	1.0 ml	4 weeks	2.0 ml[2]	4 weeks
3	1.0 ml	8 wks after dose 2 **and** 16 weeks after dose 1	2.0 ml[2]	4 weeks
4			2.0 ml[2]	4 months

[1] Vaccine-induced protection may be less complete, and may persist only as long as antibody levels are >10 SRU by RIA or are HBsAg-Negative by EIA. For these patients, the need for booster doses should be assessed by annual antibody testing, and a booster dose should be administered when antibody levels decline to <10 SRU by RIA or HBsAg-Negative by EIA.

[2] 2.0 ml total can be given as one dose (2.0 ml) or two doses (1.0 ml each) simultaneously at separate sites.

V. VACCINE INTERCHANGEABILITY

Immune response when one or two doses of vaccine from one manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable to a full course of vaccination with a single vaccine.

VI. POST-EXPOSURE PROPHYLAXIS GUIDELINES[1]

Type of Exposure to HBsAg-positive source	Prophylaxis	
	HB Vax Series[2]	**HBIG[3]**
Perinatal	Yes	Yes[4]
Sexual Contact: ▪ Acute case	Yes[9]	Yes[5]
▪ Chronic carrier	Yes	No[6]
Household Contact: ▪ Acute case	Yes	No[6]
▪ Chronic carrier	Yes	No[6]
▪ Acute case in Primary Care Giver of Infant (≤ 12 months of age)	Yes	Yes[7]
Percutaneous (e.g. needlestick, laceration, bite, or needle-sharing contact) or permucosal exposure (e.g. ocular, mucous membrane)	Yes[9]	Yes[7,8,]

Source: CDC. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination; MMWR 1991; (RR-13), Appendix A, Table 2.

[1] For post-vaccine serology recommendations see Sect. IX.
[2] If the individual has initiated the series but has not yet completed I, give the remaining doses as scheduled using the recommended intervals.
[3] The dosage given to individuals other than newborns varies by type of exposure and weight of the exposed individual. Consult the Hepatitis B Investigative Guidelines for exact dosages, http:/www.dhs.state.or.us/publichealth/odpe/guideln/hepb.pdf (pg.7&8).
[4] Administer both products within 12 hours of delivery. If treatment is held pending mother's test results, give vaccine within 12 hours and HBIG within 7 days of delivery.
[5] Give vaccine and HBIG within 14 days of last exposure; testing for anti-HBc is recommended if it doesn't delay treatment.
[6] Only vaccine is recommended for these persons unless an identifiable percutaneous or permucosal exposure has occurred. If such exposure has occurred, give vaccine and HBIG within 7 days of exposure.
[7] Give HBIG within 7 days of exposure.
[8] For occupational exposures, please refer to your employer's Bloodborne Pathogen exposure plan or OR-OSHA guidelines.
[9] For percutaneous, mucosal, or sexual exposure to blood or body fluids from a source with unknown HBsAg status administer hepatitis B vaccine only to unvaccinated persons.

NOTE: Please refer clients to their primary care provider or local health department if you suspect the client has been exposed to HBV.

VII. CONTRAINDICATIONS

A. Hypersensitivity to baker's yeast, the preservative thimerosal, or any other component of the vaccine.

B. Severe allergic reaction/anaphylactic response after a previous dose.

C. Moderate or severe acute illness with or without fever.

VIII. SIDE EFFECTS AND ADVERSE REACTIONS

Table B. Hepatitis B Vaccine Adverse Reactions

Event	Adults
Pain at injection site	13% - 29%
Mild systemic complaints (fatigue, headache)	11% - 17%
Temperature >37.7 C	1%
Severe systemic reactions	Rare
Source: *Epidemiology and Prevention of Vaccine-Preventable Diseases*, January 2002; 186.	

IX. OTHER CONSIDERATIONS

A. Pregnancy should **not** be considered a contraindication to vaccination. There is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is given to pregnant women (CDC, unpublished data). Hepatitis B infection in a pregnant woman may result in serious disease for the mother and chronic infection of the newborn.

B. DO NOT RESTART A SERIES. Count the number of doses the recipient has had and give the next dose due, observing minimum spacing and ages.

C. Breast-feeding is not a contraindication to vaccination for mother or infant. HBsAg-positive women should be encouraged to breast-feed; breast-feeding does not pose any additional risk of exposure to the infant.

D. Hemodialysis patients require special formulation and/or dosage. See table II C., *Epidemiology and Prevention of Vaccine-Preventable Diseases* or MMWR 11/22/91/Vol.40(RR-13);11-12.

E. Household members of HBsAg-positive children should be vaccinated.

F. Post-Vaccination Serology

1. Post-vaccination testing includes serological screening for two different markers, each for a specific reason:

   a. **HBsAg:** to determine whether they have become infected with the hepatitis B virus; **AND**

   b. **HBsAb (Anti-HBs):** to determine whether the vaccine was effective in mounting an immune response in the recipient.

2. Testing is available through the Oregon State Public Health Lab; see the OSPHL's "Guide to Services" manual or visit website at www.ohd.hr.state.or.us/phl. There is a small charge for testing ordered by private providers.

3. Vaccine recipients who do not develop a serum antibody response (a HBsAb titer of ≥10mIU/ml or "positive" result) after the primary series should be revaccinated with a complete series prior to re-testing. (Serological screening done 1-2 months after 3rd (6th) dose).

4. Testing for persons exposed via household, sexual or percutaneous routes: HBsAb testing is advised 1-2 months after the completion of the vaccine series for:

   - Persons whose subsequent clinical management depends on knowledge of their immune status, such as dialysis patients and staff, and persons with HIV infection.

   - Persons at occupational risk who may have exposures from injuries with sharp instruments. Knowledge of their antibody response will aid in determining appropriate postexposure prophylaxis.

G. Revaccination of non-responders: It is recommended that the series of three doses of vaccine be repeated using the same schedule, at 0, 1, and 6 months and then tested at least one month after the third dose for HBsAb. It is not recommended that more than 3 additional doses be administered. Persons not responding to the first series may respond after the first additional dose (15-25% will respond), or could respond to 3 further doses (30-50% will respond). Persons not responding to the three added doses of vaccine are unlikely to respond to any further doses of vaccine.

H. Should a client object to administering three more doses of vaccine, determine whether it is acceptable to them to give an additional dose of vaccine then test (1 month later), repeating as needed, until immunity is mounted or until an additional three doses have been administered.

I. Booster doses: For clients with normal immune status, a booster dose is not recommended, nor is serologic testing to assess antibody levels. If a protective antibody response develops after vaccination, recipients are virtually 100% protected against clinical illness. The possible need for booster doses will be assessed as additional information becomes available.

For hemodialysis patients, vaccine-induced protection may be less complete and may persist only as long as antibody levels are ≥10 mIU/mL. For these patients, the need for booster doses should be assessed by annual antibody testing, and a booster dose should be administered when antibody levels decline to <10 mIU/mL.

X. ADVERSE EVENT REPORTING:

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510.

Table C. Events Reportable to VAERS

Vaccine	Illness, disability, injury or condition covered	Time period until first symptom or the onset of significant reactions following vaccine administration
Vaccines containing Hepatitis B	1. Anaphylaxis or anaphylactic shock	4 hours
	2. Any acute sequela (including death)	Not applicable

XII. REFERENCES:

1. Hepatitis B. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 8th ed. Washington, DC: Public Health Foundation, 2005: 191-212. Available at: **http://www.cdc.gov/nip/publications/pink/hepb.pdf.**
2. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, MMWR Vol. 54, RR-16, 12/23/05. Available at: http://www.cdc.gov/MMWR/pdf/rr/rr5416.pdf.
3. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the US through Universal Childhood Vaccination, MMWR Vol. 40, RR-13, 11/22/91.
4. General Recommendations on Immunization, MMWR Vol. 51,
5. RR-2, 2/8/02.
6. Hep-B-containing-vaccine package inserts.

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, or contact the Health Services, Immunization Program at (971) 673-0300.