Model Immunization Protocol

Hepatitis B Immune Globulin (HepaGam B®, Nabi-HB®)	
Last Reviewed	30 November 2022
Last Revised	30 November 2022
This order expires	30 November 2024

Table of contents

1. What's new

Consolidated recommendations for post-exposure prophylaxis.

2. Oregon immunization protocol

A. Screen clients for contraindications and precautions.

B. Provide product information, answering any questions.

C. Record all required data elements in the client's permanent health record.

D. Verify needle length for intramuscular (IM) injection.

E. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.

F. Give the appropriate HBIG dose for age intramuscularly.

G. The hepatitis B vaccine series should be started concurrently, in a separate anatomical injection site (e.g., in different limbs). Incompletely vaccinated patients should receive the next dose in the series as soon as they are eligible, based on minimum spacing.

H. Vaccine non-responders and patients who decline to receive the hepatitis B series should receive a second dose of hepatitis B immune globulin 28 days after dose one.

I. To request HBIG, see instructions available at http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/state-supplied-prophy.pdf.

J. Ask client to remain seated on the premises for 15 minutes to decrease the risk of injury should they faint.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for HBIG[4]

Route: IM			
Dose	**Volume**	**Acceptable age range**	**Minimum acceptable spacing**
1	0.5 mL	Birth–12 months	
	0.06 mL/kg	>12 months	
2*			28 days

*Only necessary for vaccine non-responders and patients refusing vaccination.

4. Licensed HBIG

Product Name	Vaccine Components	Acceptable Age Range	Thimerosal
HepaGam B[1] Nabi-HB[2]	>312 IU/mL anti-HBs human plasma	All ages	None

5. Recommendations for use

A. **Post-exposure Prophylaxis for Newborns[4]**

a. Infants born to **HBsAg-positive mothers** or mothers with an unknown but **suspected positive HBsAg status**: administer HBIG and single-antigen hepatitis B vaccine within 12 hours of birth. Do not count the first dose of hepatitis B vaccine as part of the vaccine series.

b. Infants born to mothers with HBsAg-unknown status: for **infants weighing <2000 g**, administer HBIG and single-antigen hepatitis B vaccine within 12 hours of birth. **Infants weighing ≥2000 g**, administer single-antigen hepatitis B vaccine within 12 hours of birth, and test the mother's HBsAg status.

B. **Post-exposure Prophylaxis for Persons with Percutaneous or mucosal Exposure, including health care or other occupational exposure.**

Vaccination and antibody response status of exposed person	Exposure Source		
	HBsAg-positive	HBsAg-negative	Unknown HBsAg status
Unvaccinated	1 dose HBIG plus initiate hepatitis B vaccine series	Initiate hepatitis B vaccine series	1 dose HBIG plus initiate hepatitis B vaccine series
Previously vaccinated			
Known responder*	No treatment		
Non-responder* after 3 doses	1 dose HBIG and initiate revaccination	Revaccinate health care personnel with one or more additional doses, and re-test anti-HBs level	If known high-risk source, treat as if source were HBsAg-positive.

Vaccination and antibody response status of exposed person	Exposure Source		
	HBsAg-positive	HBsAg-negative	Unknown HBsAg status
Non-responder* after 6 doses	2 doses of HBIG separated by 28 days	No treatment	
Antibody response unknown	Test exposed person for anti-HBs. If ≥10 mIU/mL no treatment; if <10 mIU/mL 1 dose HBIG and vaccine booster dose	Test exposed person for anti-HBs. If ≥10 mIU/mL no treatment; if <10 mIU/mL 1 vaccine booster dose	Test exposed person for Anti-HBs. If ≥10 mIU/mL no treatment; if <10 mIU/mL 1 dose HBIG and vaccine booster dose

* **"response"** is defined as having achieved anti-HBs antibody level ≥10 mIU/mL after having received 3 doses of hepatitis B vaccine.

C. **Post-exposure prophylaxis for sexual contacts**: 1 dose of HBIG as soon as possible and within 14 days of last sexual contact, or if sexual contact will continue, and initiate hepatitis B vaccine series.[6]

D. **Post-exposure prophylaxis for household contacts**: 1 dose of HBIG as soon as possible and within 24 hours if possible and initiate hepatitis B vaccine series.[7]

E. Calculation for patients >12 months:[4]

weight of person in pounds (lb) ÷ 2.2 lb/kg = weight in kilograms (kg).

weight of person in kilograms (kg) X 0.06 mL/kg = dose in mL

Example: (75 lbs ÷ 2.205 lb/kg) = 34.02 kg X 0.06 mL/kg = 2.04 mL ≅ 2 mL per dose.

F. Acceptable volume for a single dose of immune globulin (IG) to inject into either the deltoid or vastus lateralis muscle.[3]

Deltoid:

- Average 0.5 mL
- Range 0.5–2 mL

Vastus Lateralis:

- Average 1–4 mL
- Range 1–5 mL

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the range.

G. Patients who receive HBIG should wait 3 months before receiving MMR- or varicella-containing vaccines.[8]

6. Contraindications:

Patients with anaphylactic reactions to a previous dose of immune globulin should receive HBIG only if the benefits outweigh the risk of a potentially life-threatening reaction.[1,2]

7. Warnings and precautions:[1,2]

A. **Previous allergic reactions**: HBIG should be given with caution to patients with a history of prior systemic allergic reactions following the administration of IG preparations.

B. **IgA deficiency**: Patients deficient in IgA may have the potential for developing antibodies and for potentially life-threatening allergic reactions.

C. **Coagulation disorders**: In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, Hepatitis B Immune globulin (Human) should be given only if the expected benefits outweigh the risks.[1,2]

D. **Glucose monitoring**: HepaGam B may cause interference with blood glucose testing.[1]

8. Other considerations[1,2]

A. HBIG is made from human plasma. Products made from human plasma may contain infectious agents, such as the Creutzfeldt-Jakob disease (CJD) agent, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating or removing certain viruses. Despite these measures, such product can still potentially transmit disease. There is

also the possibility that unknown infectious agents may be present in such products. Individuals who receive transfusions of blood or plasma products may develop signs and or symptoms of some viral infections, particularly hepatitis C.

B. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to VAERS and the IG manufacturer.

C. **Drug interactions**: Live virus vaccines should be deferred until approximately 3 months after HBIG administration. No interactions with other products are known.[8]

D. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[8]

E. **Pregnancy**: No studies have been conducted with HBIG in pregnant women. HBIG should be given to a pregnant woman only if clearly indicated.

F. **Nursing Mothers**: All classes of immunoglobulins can be detected in breast milk. Immunoglobulins from the mother help to support the infant's health.

G. **National Clinician Consultation Center**: Post-Exposure Prophylaxis Consultation: 888-448-4911, 11 a.m. – 8 p.m. Eastern time, 7 days a week. http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.

9. Side effects and adverse reactions[1,2]

Adverse Event	Frequency
Nausea	Rarely, but has been reported.
Dizziness	

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4832).

Product	Temp	Storage Issues	Notes
All[1,2]	Store at 2°–8°C	Do not freeze.	Vial must be used within 6 hours of first puncture.

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination
A. N/A

12. References

1. Cangene Corporation. 2012. HepaGam B® package insert. Available at: www.fda.gov/media/74701/download. Accessed 18 November 2022.
2. Biotest Pharmaceuticals Corporation. 2008. Nabi-HB® package insert. Available at: www.fda.gov/media/74707/download. Accessed 18 November 2022.
3. Immunization Action Coalition. Question of the Week. IAC Express – Issue 1157. Available at: http://immunize.org/askexperts/administering-vaccines.asp. Accessed 18 November 2022.
4. Schillie S, Vellozzi C, Reingold A, et al. Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. MMWR 2018;67(RR-1):1–31. Available at www.cdc.gov/mmwr/volumes/67/rr/6701a1.htm. Accessed 18 November 2022.
5. CDC. Viral Hepatitis–Hepatitis B Information. Available at: www.cdc.gov/hepatitis/hbv/pep.htm. Accessed 18 November 2022.
6. CDC. Appendix B. Postexposure prophylaxis to prevent hepatitis B virus infection. MMWR 2006;55:30–1. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a3.htm?s_cid=rr5516a3_e. Accessed 18 November 2022.
7. CDC. Guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management. MMWR 2013;62:1–19. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm. Accessed 18 November 2022.
8. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 18 November 2022.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 1-800-980-9431 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocol