

Hepatitis B and Healthcare Personnel



CDC answers frequently asked questions about how to protect healthcare personnel

The Immunization Action Coalition thanks experts at the Centers for Disease Control and Prevention for answering the following questions. Additional Q&As are available in the Hepatitis B Ask the Experts topic at www.immunize.org/askexperts/experts_hepb.asp.

Hepatitis B Vaccination

Which people who work in healthcare settings need hepatitis B vaccine?

The Occupational Safety and Health Administration (OSHA) requires that hepatitis B vaccine be offered to healthcare personnel (HCP) who have a reasonable expectation of being exposed to blood or body fluids on the job. This requirement does not include personnel who would not be expected to have occupational risk (e.g., general office workers).

At what anatomic site should hepatitis B vaccine be administered to adults? What needle size should be used?

For adults, administer hepatitis B vaccine intramuscularly (IM) in the deltoid muscle. A 22- to 25-gauge, 1–1½-inch needle should be used. The gluteus muscle should *not* be used as a site for administering hepatitis B vaccine. For optimal protection, it is crucial that the vaccine be administered IM, not subcutaneously.

Can Heplisav-B be used for vaccinating healthcare professionals?

Yes. Heplisav-B was approved by the Food and Drug Administration in November 2017 for persons 18 years of age and older. Heplisav-B contains a novel immunostimulatory adjuvant (CpG 1018) that binds to Toll-like receptor 9 to stimulate a directed immune response to HBsAg. It is provided in a single dose 0.5 mL vial and given as a 2-dose schedule. The doses should be separated by at least 4 weeks.

Can Heplisav-B be used to complete a vaccination series started with Engerix-B or Recombivax HB?

Yes. However, data are limited on the safety and immunogenicity effects when Heplisav-B

is interchanged with hepatitis B vaccines from other manufacturers. When feasible, the same manufacturer's vaccines should be used to complete the series. However, vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable.

The 2-dose hepatitis B vaccine series only applies when both doses in the series consist of Heplisav-B. Series consisting of a combination of 1 dose of Heplisav-B and a vaccine from a different manufacturer should consist of 3 total vaccine doses and should adhere to the 3-dose schedule minimum intervals of 4 weeks between dose 1 and 2, 8 weeks between dose 2 and 3, and 16 weeks between dose 1 and 3. Doses administered at less than the minimum interval should be repeated. However, a series containing 2 doses of Heplisav-B administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer.

If a person who works in a healthcare setting had one dose only of hepatitis B vaccine 1 year ago, should the series be restarted?

No. The hepatitis B vaccine series should not be restarted when doses are delayed; rather, the series should be continued from where it stopped.

Is it safe for HCP to be vaccinated during pregnancy?

Yes. Many years of experience with hepatitis B vaccines indicate no apparent risk for adverse events to a developing fetus. Current hepatitis B vaccines contain noninfectious hepatitis B surface antigen (HBsAg) and should pose no risk to the fetus. If not vaccinated, a pregnant woman may contract an HBV infection during pregnancy, which might result in severe disease for the newborn. Women who breastfeed their babies and are healthcare professionals can and should be vaccinated against hepatitis B if they haven't been previously vaccinated. Receipt of the vaccine is not a reason to discontinue breastfeeding.

There are no clinical studies of Heplisav-B in pregnant women. Available human data on

Heplisav-B administered to pregnant women are insufficient to assess vaccine-associated risks in pregnancy. Until safety data are available for Heplisav-B, providers should continue to vaccinate pregnant women needing hepatitis B vaccination with a vaccine from a different manufacturer.

Is there a recommendation for routine booster doses of hepatitis B vaccine?

No. HCP who have documentation of receiving a complete series of hepatitis B vaccine and who subsequently tested positive for anti-HBs (defined as anti-HBs of ≥ 10 mIU/mL) are considered to be immune to hepatitis B. Immunocompetent persons who also have followed the protocol, have long-term protection against HBV and do not need further testing or vaccine doses. Some immunodeficient persons, including those on hemodialysis, may need periodic booster doses of hepatitis B vaccine.

We have a new employee with documentation of having received a series of hepatitis B vaccine as an adolescent. He now tests negative for hepatitis B surface antibody (anti-HBs). How should we manage him?

ACIP recommends that healthcare personnel with written documentation of having received a properly spaced series of hepatitis B vaccine in the past (such as in infancy or adolescence) but who now test negative for anti-HBs should receive a single "booster" dose of hepatitis B vaccine and be retested 1–2 months later (see Figure 1). Those who test positive following the "booster" dose are immune and require no further vaccination or testing. Those who test negative should complete a second series of hepatitis B vaccine on the usual schedule and be tested again 1–2 months after the last dose. Heplisav-B may be used to revaccinate new healthcare personnel (including the challenge dose) initially vaccinated with a vaccine from a different manufacturer in the distant past who have anti-HBs less than 10 mIU/mL upon hire or matriculation. For more information, see www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF, pages 21–22.

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Post-vaccination Anti-HBs Testing

Which HCP need serologic testing after receiving a hepatitis B vaccine series?

All HCP, including trainees, who have a high risk of occupational percutaneous or mucosal exposure to blood or body fluids (for example, HCP with direct patient contact, HCP at risk of needlestick or sharps injury, laboratory workers who draw, test or handle blood specimens) should have postvaccination testing

for antibody to hepatitis B surface antigen (anti-HBs). Postvaccination testing should be done 1–2 months after the last dose of vaccine. Postvaccination testing for persons at low risk for mucosal or percutaneous exposure to blood or body fluids (for example, public safety workers and HCP without direct patient contact) likely is not cost-effective; however, those who do not undergo post-vaccination testing should be counseled to seek immediate testing if exposed.

What should be done if a person’s post-vaccination anti-HBs test is negative (less than 10 mIU/mL) 1–2 months after the last dose of vaccine?

Repeat the 2- or 3-dose series (depending on vaccine brand) and test for anti-HBs 1–2 months after the final dose of the repeat series. Heplisav-B may be used for revaccination following an initial hepatitis B vaccine series

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FIGURE 1. Pre-exposure Management for Healthcare Personnel with a Documented Hepatitis B Vaccine Series Who Have Not Had Post-vaccination Serologic Testing

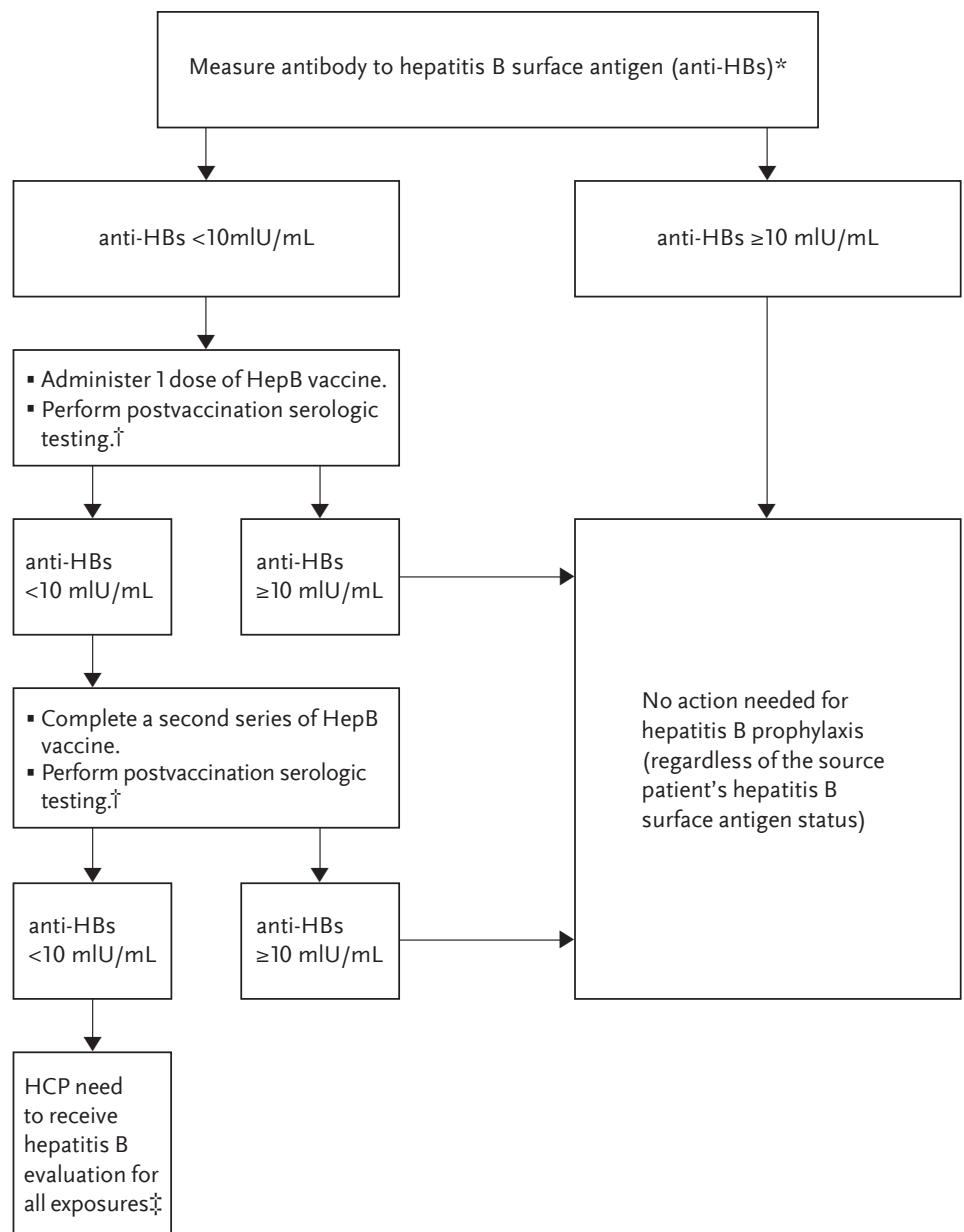
Healthcare personnel (HCP) with documentation of a complete series of HepB vaccine but no documentation of anti-HBs ≥ 10 mIU/mL who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation. The algorithm at right will assist in the management of these people. It was adapted from CDC. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, *MMWR* 2018; 67(RR-1), available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

NOTE: Also available as standalone form at www.immunize.org/catg.d/p2108.pdf.

* Pre-exposure serologic testing may be recommended for all previously vaccinated HCP who were not tested 1 to 2 months after the third dose (such as people vaccinated as children or adolescents). Trainees, HCP in certain occupations, and HCP practicing in certain populations are at greater risk of exposure. Vaccinated HCP in these settings or occupations could benefit from pre-exposure serologic testing.

† Should be performed 1–2 months after the last dose of vaccine using a quantitative method that allows detection of the protective concentration of anti-HBs (≥ 10 mIU/mL) (e.g., enzyme-linked immunosorbent assay [ELISA]).

‡ A nonresponder is defined as a person with anti-HBs < 10 mIU/mL after 2 complete series of HepB vaccine. Persons who do not have a protective concentration of anti-HBs after revaccination should be tested for HBsAg. If positive, the person should receive appropriate management. See *MMWR* 2018;67(RR-1) at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf for guidance on management of persons who do not respond to 2 complete series of HepB vaccine.



that consisted of doses of Heplisav-B or doses from a different manufacturer. Heplisav-B may also be used to revaccinate new healthcare personnel (including the challenge dose) initially vaccinated with a vaccine from a different manufacturer in the distant past who have anti-HBs less than 10 mIU/mL upon hire or matriculation.

If the test is still negative after a second vaccine series, the person should be tested for HBsAg and total anti-HBc to determine their HBV infection status. People who test negative for HBsAg and total anti-HBc should be considered vaccine non-responders and susceptible to HBV infection. They should be counseled about precautions to prevent HBV infection and the need to obtain hepatitis B immune globulin (HBIG) prophylaxis for any known or likely exposure to HBsAg-positive blood. Those found to be HBsAg negative but total anti-HBc positive were infected in the past and require no vaccination or treatment. If the HBsAg and total anti-HBc tests are positive, the person should receive appropriate counseling for preventing transmission to others as well as referral for ongoing care to a specialist experienced in the medical management of chronic HBV infection. They should not be excluded from work.

How often should I test HCP after they've received the hepatitis B vaccine series to make sure they're protected?

For immunocompetent HCP, periodic testing or periodic boosting is not needed. Post-vaccination testing (anti-HBs) should be done 1–2 months after the last dose of the hepatitis B vaccine series. If adequate anti-HBs (at least 10 mIU/mL) is present, nothing more needs to be done. This information should be made available to the individual and recorded in his or her health record. If postvaccination testing is less than 10 mIU/mL, the vaccine series should be repeated and anti-HBs testing should be completed 1–2 months after the last dose of the second series.

Does CDC now recommend routine pre-exposure anti-HBs testing for all HCP who were previously vaccinated but not tested?

In general, no, but the type of testing (pre-exposure or post-exposure) depends on the healthcare worker's profession and work setting. The risk for hepatitis B virus (HBV) infection for vaccinated HCPs can vary widely by setting and profession. The risk might be low enough in certain settings that assess-

ment of hepatitis B surface antibody (anti-HBs) status and appropriate follow-up can be done at the time of exposure to potentially infectious blood or body fluids. This approach relies on HCP recognizing and reporting blood and body fluid exposures and might be applied on the basis of documented low risk, implementation, and cost considerations. Trainees, some occupations (such as those with frequent exposure to sharp instruments and blood), and HCP practicing in certain populations are at greater risk of exposure to blood or body fluid exposure from an HBsAg-positive patient. Vaccinated HCP in these settings/occupations would benefit from a pre-exposure approach.

At our facility we do routine pre-employment anti-HBs testing regardless of whether the employee has documentation of a hepatitis B vaccination series and consider those with a positive antibody to be immune. Is this the recommended strategy?

No. HCP with written documentation of receipt of a complete, properly spaced series of hepatitis B vaccine AND a positive anti-HBs can be considered immune to HBV and require no further testing or vaccination. Testing unvaccinated or incompletely vaccinated HCP (including those without written documentation of vaccination) is not necessary and is potentially misleading because anti-HBs of 10 mIU/mL or higher as a correlate of vaccine-induced protection has only been determined for persons who have completed a hepatitis B vaccination series. Persons who cannot provide written documentation of a complete hepatitis B vaccination series should complete the series, then be tested for anti-HBs 1 to 2 months after the final dose.

Several physicians in our group have no documentation showing they received hepatitis B vaccine. They are relatively sure, however, that they received the doses many years ago. What do we do now?

Because there is **no documentation of vaccination, a vaccination series should be administered and postvaccination testing should be performed 1–2 months after the final dose of vaccine.** There is no harm in receiving extra doses of vaccine. Postvaccination testing results should also be documented, including the date testing was performed. All healthcare settings should develop policies or guidelines to assure valid hepatitis B immunization.

I'm a nurse who received a documented series of hepatitis B vaccine more than 10 years ago and had a positive follow-up titer (at least 10 mIU/mL). At present, my titer is negative (<10 mIU/mL). What should I do now?

Nothing. Data show that vaccine-induced anti-HBs levels might decline over time; however, immune memory (anamnestic anti-HBs response) remains intact following immunization. People with adequate anti-HBs concentrations that have declined to less than 10 mIU/mL are still protected against HBV infection. For HCP with normal immune status who have demonstrated adequate anti-HBs (≥ 10 mIU/mL) following full vaccination, booster doses of vaccine or periodic anti-HBs testing are not recommended.

Non-responders or HCP with Chronic HBV Infection

If an employee does not respond to hepatitis B vaccination (employee has had two full series of hepatitis B vaccine), does s/he need to be removed from activities that expose her/him to bloodborne pathogens?

No. There are no regulations that require removal from job situations where exposure to bloodborne pathogens could occur; this is an individual policy decision within an organization. OSHA regulations require that employees, in jobs where there is a reasonable risk of exposure to blood, be offered hepatitis B vaccine. In addition, the regulation states that adequate personal protective equipment be provided and that standard precautions be followed. Check your state OSHA regulations regarding additional requirements. If there are no state OSHA regulations, federal OSHA regulations should be followed. Adequate documentation should be placed in the employee record regarding non-response to vaccination. HCP who do not respond after 2 complete series of vaccine should be tested for HBsAg and total anti-HBc to determine if they have chronic HBV infection. If the HBsAg and total anti-HBc tests are positive, HCP should receive appropriate counseling for preventing transmission to others as well as referral for ongoing care to a specialist experienced in the medical management of chronic HBV infection. People who are HBsAg-positive and who perform exposure-prone procedures should seek counsel from a review panel comprised of experts with a balanced perspective (e.g.,

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infectious disease specialists and their personal physician[s] regarding the procedures that they can perform safely. They should not be excluded from work.

Nonresponders who test negative for HBsAg should be considered susceptible to HBV infection. They should be counseled about precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known exposure to blood that is HBsAg-positive or if the HBsAg status of the source is unknown (see Table 1 below).

Can a person with chronic HBV infection work in a healthcare setting?

Yes. HCP should not be discriminated against because of their hepatitis B status. All HCP should practice standard precautions, which are designed to prevent HBV transmission, both from patients to HCP and from HCP to patient. There is, however, one caveat concerning HBV-infected HCP. Those who have HBV levels 1000 IU/mL or 5000 genomic equivalents/mL or higher should not perform exposure-prone procedures (e.g., gynecologic, cardiothoracic surgery) unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures. For more information on this issue, see Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students, *MMWR*, 2012; 61 (RR03):1-12. This document is available at www.cdc.gov/mmwr/pdf/rr/rr6103.pdf. **CONTINUED ON THE NEXT PAGE ►**

TABLE 1. Post-exposure management of healthcare personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by healthcare personnel HepB vaccination and response status

Healthcare personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing [†]
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	
Documented responder [§] after complete series	No action needed				
Documented nonresponder [¶] after 2 complete series	Positive/unknown	Not indicated	HBIG x2 separated by 1 month	—	No
	Negative	No action needed			
Response unknown after complete series	Positive/unknown	<10mIU/mL**	HBIG x1	Initiate revaccination	Yes
	Negative	<10mIU/mL	None		
	Any result	≥10mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	—**	HBIG x1	Complete vaccination	Yes
	Negative	—	None	Complete vaccination	Yes

* HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 mL/kg.

† Should be performed 1–2 months after the last dose of the HepB vaccine series (and 6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).

§ A responder is defined as a person with anti-HBs ≥10 mIU/mL after 1 or more complete series of HepB vaccine.

¶ A nonresponder is defined as a person with anti-HBs <10 mIU/mL after 2 complete series of HepB vaccine.

** HCP who have anti-HBs <10mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.

ABBREVIATIONS

- HCP** = healthcare personnel
- HBsAg** = hepatitis B surface antigen
- anti-HBs** = antibody to hepatitis B surface antigen
- HBIG** = hepatitis B immune globulin

Adapted from CDC. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, *MMWR* 2018; 67(RR-1), available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

Post-exposure Management

How should a fully vaccinated employee with an unknown anti-HBs response be managed if they have a percutaneous or mucosal exposure to blood or body fluids from an HBsAg-positive or HBsAg-unknown source?

Management of the exposed HCP depends on both the anti-HBs status of the HCP and the HBsAg status of the source patient. The HCP should be tested for anti-HBs and the source patient (if known) should be tested for HBsAg as soon as possible after the exposure. Testing the source patient and the HCP should occur simultaneously; testing the source patient should not be delayed while waiting

for the HCP anti-HBs test results, and likewise, testing the HCP should not be delayed while waiting for the source patient's HBsAg results. See Table 1 for management recommendations based on the results of testing.

If an employee receives both HBIG and hepatitis B vaccine after a needlestick from a patient who is HBsAg positive, how long should one wait to check the employee's response to the vaccine?

Anti-HBs testing for HCP who receive both hepatitis B immune globulin (HBIG) and hepatitis B vaccine can be conducted as soon as 6 months after receipt of the HBIG.

For more information on vaccination recommendations for healthcare personnel, see the following:

- 1 CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management, *MMWR*, 2013; 62(10):1–19, www.cdc.gov/mmwr/pdf/rr/rr6210.pdf
- 2 CDC. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, *MMWR* 2018; 67(RR-1), available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.
- 3 Immunization Action Coalition. "Healthcare Personnel Vaccination Recommendations," www.immunize.org/catg.d/p2017.pdf
- 4 Immunization Action Coalition. "Pre-exposure Management for Healthcare Personnel (HCP) with a Documented Hepatitis B Vaccine Series Who Have Not Had Post Vaccination Serologic Testing," www.immunize.org/catg.d/p2108.pdf