

AAMC Standardized Immunization Form Hepatitis B - Frequently Asked Questions

July 20, 2015

For more information on the AAMC Standardized Immunization Form, please visit <u>www.aamc.org/immunizationform</u>.

Hep B immunization seems to create a fair amount of confusion in terms of which test can be used and what evidence should be submitted to show immune status. To help resolve that confusion we have consulted with college student health center physician experts about the immune status of Hep B and, with their knowledge, developed the following FAQs.

1. What are the Hepatitis B vaccines licensed for use in the United States?

Two single-antigen vaccines and three combination vaccines are currently licensed in the United States.

Single-antigen Hepatitis B vaccines

- ENGERIX-B®
- RECOMBIVAX HB®

Combination vaccines

- COMVAX[®]: Combined Hepatitis B-Haemophilus influenzae type b (Hib) conjugate vaccine.
- **PEDIARIX®:** Combined Hepatitis B, diphtheria, tetanus, acellular pertussis (DTaP), and inactivated poliovirus (IPV) vaccine.
- **TWINRIX®:** Combined Hepatitis A and Hepatitis B vaccine.

2. Can a patient receive the first dose of Hepatitis B vaccine from one manufacturer and subsequent doses from another manufacturer?

Yes. No differences in immune response are observed when vaccines from different manufacturers are used to complete the vaccine series.

3. What are the recommended schedules for Hepatitis B vaccination?

The vaccination schedule used most often is 3 intramuscular injections, the second and third doses administered at 0, 1 and 6 months. Healthcare workers who are not immune to Hepatitis B virus using a QUANTITATIVE Hepatitis B Surface Antibody blood test after their primary series should complete a second Hepatitis B vaccine series. If the individual received their primary Hepatitis B vaccine series a long time ago, such as in childhood, their antibody level may have fallen below the threshold for immunity and giving a 4th dose as a "booster" and rechecking a titer 4-8 weeks later is recommended. If the antibody level is still low, completion of the remainder of the second series is recommended before rechecking the Hep BsAb level again.



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4. If there is an interruption between doses of Hepatitis B vaccine, does the vaccine series need to be restarted?

No, the series does not need to be restarted. The patient should simply resume the vaccination schedule where they left off previously.

5. Can Hepatitis B vaccine be given during pregnancy or lactation?

Yes. Hepatitis B vaccine contains no live virus, so neither pregnancy nor lactation should be considered a contraindication to vaccination of women.

6. Can Hepatitis B vaccine be given to immunocompromised persons, such as persons on hemodialysis or persons with HIV infection?

Yes, although a larger vaccine dose is required to induce protective antibody in hemodialysis patients. Larger doses or additional doses might also be necessary for other immunocompromised persons. Serologic testing of hemodialysis patients and other immunocompromised persons is recommended 1–2 months after administration of the final dose of the primary vaccine series to determine the need for revaccination.

7. How long does protection from Hepatitis B vaccine last?

Studies indicate that immunologic memory remains intact for at least 20 years among healthy vaccinated individuals who initiated Hepatitis B vaccination >6 months of age. The vaccine confers long-term protection against clinical illness and chronic Hepatitis B virus infection. Cellular immunity appears to persist even though antibody levels might become low or decline below detectable levels, therefore, it is not recommended to recheck Hepatitis B surface antibody levels once they are detectable.

8. Who should receive post-vaccination testing?

Testing for immunity is advised only for persons whose subsequent clinical management depends on knowledge of their immune status for all health care workers and public safety workers including students at high risk for continued percutaneous or mucosal exposure to blood or body fluids.

9. When should post-vaccination testing be done?

Post-vaccination testing for antibody to Hepatitis B surface antigen (anti-HBs) should be performed 1–2 months after completion of the vaccine series. If testing is performed more than 2 months after the last dose of vaccine, any negative Anti-HBs serologies are uninterpretable. In these situations, the individual should consult with your Health Service regarding boosting or completing a second hepatitis B vaccine series before rechecking the serologies.



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10. Are booster doses of Hepatitis B vaccine recommended?

Booster doses of vaccine are not recommended except for dialysis or other immunocompromised patients such as HIV, bone marrow transplant recipients or chemotherapy patients. In these rare instances, the individual should have their Hepatitis B Surface Antibody checked annually and booster doses administered as needed.

11. Why is a Quantitative Hepatitis B Surface Antibody Required?

Quantitative Hepatitis B Surface antibody levels are used to determine if the individual is protected from future exposure to Hepatitis B viral infections. The World Health Organization (WHO) as well as the CDC state that whenever the Hepatitis B surface antibody result greater than or equal to 10 mIU/mL the individual is consider immune to the HBV infection. In general, most individuals should have levels much higher than 10 often exceeding 100 mIU/mL and not uncommonly over 1000 mIU/mL.

12. How is a Quantitative vs Qualitative Hepatitis B Surface antibody tests different?

<u>Quantitative</u> hepatitis B surface antibody testing utilizes 3 or more different reference controls to produce a precise line which is used to calculate a specific numerical result, such as 350 mIU/ml.

<u>Qualitative</u> antibody levels are derived using only two controls to generate a non-numerical result such as immune or non-immune, and therefore, cannot be used to determine if the individual is protected from Hepatitis B infections.

13. How long does it take for blood to test HBsAg-positive after exposure to HBV?

HBsAg will be detected in an infected person's blood an average of 4 weeks (range: 1–9 weeks) after exposure to the virus. About 1 of 2 patients will no longer be infectious by 7 weeks after onset of symptoms, and all patients who do not remain chronically infected will be HBsAg-negative by 15 weeks after onset of symptoms.