Managing an Exposure Event

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Good to Know!

- Handouts under the Handouts TAB. Click on the link to obtain.

- You must be REGISTERED and LOGGED IN to receive CE credit.
- CE credit will be emailed by August 25 .

2

Disclosure

- Employed by Total Medical Compliance
- SciCan Consultant
- Hu-Friedy KOL

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Objectives

At the end of this session, the attendee will be able to:

- List three measures to prevent exposure events.
- Discuss three different types of exposure events.
- Discuss the post exposure process for the source patient and the exposed individual.

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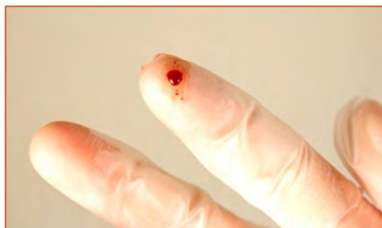
Bloodborne Pathogens

- Located in the blood or other body fluids
- Virus or bacteria
- Exposure may lead to infection
  - HIV
  - Hepatitis B
  - Hepatitis C



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Worker Safety

- Focus on prevention
- Exposure determination
- Measures to protect
  - Training
  - Appropriate use of PPE
  - Work practice controls
  - Engineering controls
- Hepatitis B vaccination
- Post-exposure plan

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Hepatitis B Vaccine

- After training
- Within 10 working days of assignment
- Titer for at-risk employees

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EMPLOYEE MEDICAL RECORD - HEPATITIS B VACCINE

Name ______________________________ Last 4 of SS# ____________

Select the appropriate box:

- ☐ Hepatitis B vaccination series documentation and positive titer. Records attached.
- ☐ Never received a vaccination. Vaccine series and a follow-up titer offered.
- ☐ Official documentation of vaccination, but no documented titer. Hepatitis B titer offered.
- ☐ History of vaccination or incomplete vaccination series, but no official documentation:
  - ☐ Attempt to obtain official records by contacting previous employers, healthcare provider or the employee working with the health department to access records.
  - ☐ If records reveal an incomplete series, the missing doses will be provided, and a titer performed.
  - ☐ If records are not located, the worker is considered unvaccinated and will be offered vaccination series with titer.

Workers can accept or decline the vaccination(s) or a titer by signing one of the boxes below.

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Immunization Action Coalition

IAC

immunize.org

Hepatitis B and Healthcare Personnel

IAC answers frequently asked questions about how to protect healthcare personnel

Experts from the Immunization Action Coalition (IAC) answer your questions about hepatitis B (HepB) vaccine. You'll find additional Q&As about hepatitis B vaccine on the "Ask the Experts" section of immunize.org 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)

Engerix-B (GSK) or Recombivax HB (Merck) may be completed with Heplisav-B. 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

should be vaccinated against hepatitis B if they haven't been previously vaccinated. Receipt of the vaccine is not a reason to discontinue breast-feeding.

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

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Vaccine Non-responder

- A non-responder is defined as a person with anti-HBs <10 mIU/mL after 2 complete series of Hep B 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.

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Evaluation

- Vaccinated HCP whose anti-HBs remains <10 mIU/mL after revaccination (i.e., after receiving a total of 6 doses)
  - Tested for HBsAg and anti-HBc to determine infection status.
  - If not HBV infected (vaccine non-responders) should be considered susceptible to HBV infection.
  - No specific work restrictions are recommended for vaccine non-responders.

Hepatitis B surface antigen (HBsAg): The presence of HBsAg indicates that the person is infectious.

Total hepatitis B core antibody (anti-HBc):. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.

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Requirements of the Standard

- Written Exposure Control Plan
- Hep B vaccination at no cost to the employee
- Labels and signs to communicate hazards
- PPE
- Enforcement of work practice controls
- Use of engineering controls
- Post exposure follow-up
- Record keeping
  - Employee training
  - Employee medical records
  - OSHA 300 and OSHA300A

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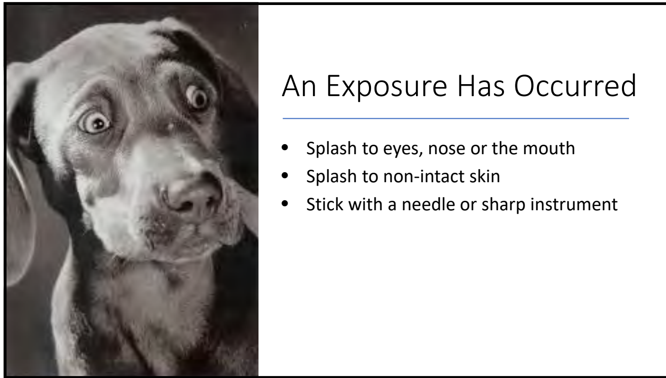

An Exposure Has Occurred

- Splash to eyes, nose or the mouth
- Splash to non-intact skin
- Stick with a needle or sharp instrument

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Signs and Symptoms

HIV: .23%
- Flu-like illness 2-4 weeks after exposure or no symptoms
- Treatments allow for undetectable virus status

Hepatitis B : 6 – 30%
- Joint and abdominal pain, dark urine, n/v, clay-colored stools within 90 days of exposure.
- Reported new cases stable over the last decade.
- Best protection: vaccine

Hepatitis C: .2%
- Joint and abdominal pain, dark urine, n/v, clay- colored stools 2 – 12 weeks after exposure or no symptoms
- Testing recommended for individuals 18 and older and during each pregnancy.

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Statistics Don't Matter

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Post Exposure Evaluation and Follow-up

(3) Following a report of an exposure incident, the employer shall make **immediately available** to the exposed employee a **confidential medical evaluation and follow-up**, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(iii) Collection and testing of blood for HBV and HIV serological status;

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

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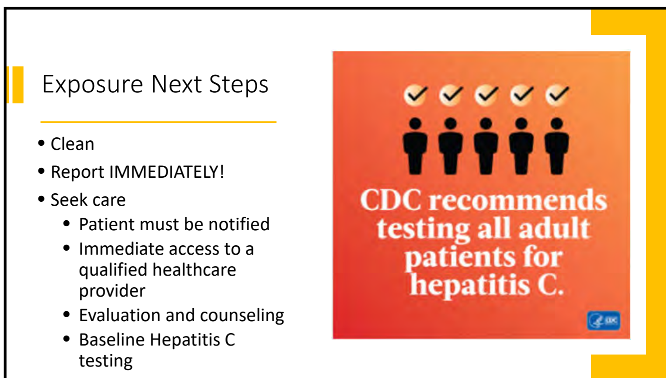
Exposure Next Steps

- Clean
- Report IMMEDIATELY!
- Seek care
  - Patient must be notified
  - Immediate access to a qualified healthcare provider
  - Evaluation and counseling
  - Baseline Hepatitis C testing



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Outsource or Onsite?

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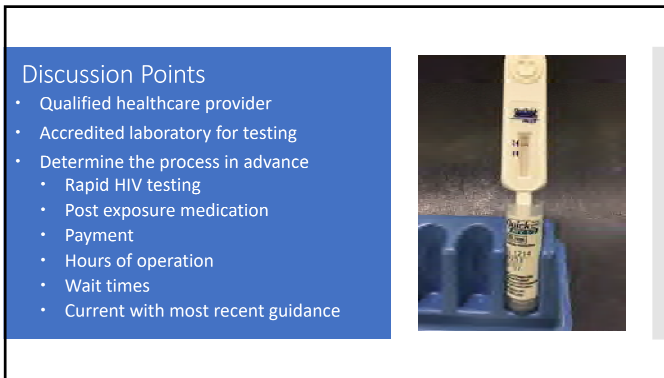

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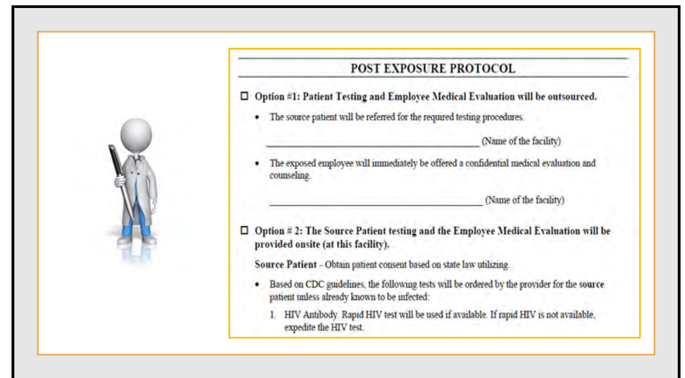

POST EXPOSURE PROTOCOL

☐ **Option #1: Patient Testing and Employee Medical Evaluation will be outsourced.**

- The source patient will be referred for the required testing procedures.

  ______________________ (Name of the facility)

- The exposed employee will immediately be offered a confidential medical evaluation and counseling.

  ______________________ (Name of the facility)

☐ **Option # 2: The Source Patient testing and the Employee Medical Evaluation will be provided onsite (at this facility).**

Source Patient - Obtain patient consent based on state law utilizing.

- Based on CDC guidelines, the following tests will be ordered by the provider for the source patient unless already known to be infected:
  1. HIV Antibody. Rapid HIV test will be used if available. If rapid HIV is not available, expedite the HIV test.

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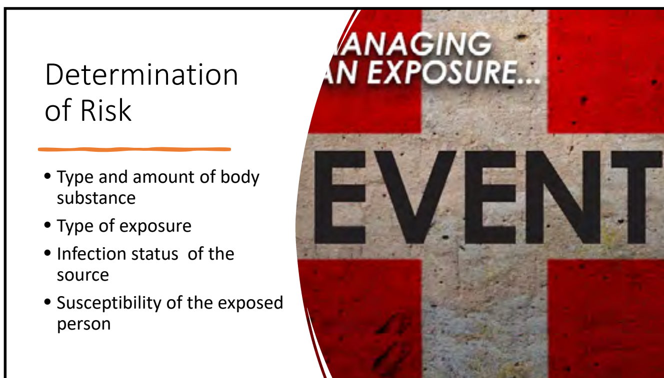

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Incident Report – CDC Guidance

- Date and time of exposure
- Details of the procedure being performed
  - Where and how the exposure occurred
  - What type of device caused the exposure
- Details of the exposure
  - Type and amount of fluid
  - Percutaneous vs. Skin or mucous membrane - volume of material, the duration of contact, and skin condition
- Details about individuals involved
  - Source patient infected/worker infected or immune compromised

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Source Patient Testing

- Obtain patient consent based on state law
- HIV Antibody: Exposed to HIV
  - Rapid HIV test
  - If rapid HIV is not available, expedite the HIV test
- Hepatitis B Surface Antigen (HBsAG): *Currently infected*
  - Source patient testing is not indicated if exposed worker has documented immunity
- Hepatitis (HCV)
  - Nucleic acid test (NAT) for HCV RNA (known/suspected to have recent behaviors that increase risk in past 4 months)
  - Testing for anti-HCV with reflex to a NAT if positive

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CDC Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (*MMWR*)

Recommendations and Reports / July 24, 2020 / 69(6);1–8

Anne C. Moorman, MPH[1]; Marie A. de Perio, MD[2]; Ronald Goldschmidt, MD[3]; Carolyn Chu, MD[3]; David Kuhar, MD[4]; David K. Henderson, MD[5]; Susanna Naggie, MD[6]; Saleem Kamili, PhD[1]; Philip R. Spradling, MD[1]; Stuart C. Gordon, MD[7]; Mark B. Russi, MD[8]; Eyasu H. Teshale, MD[1] (View author affiliations)

View suggested citation

Summary

Exposure to hepatitis viruses is a recognized occupational risk for health care personnel (HCP). This report establishes new CDC guidance that includes recommendations for a testing algorithm and clinical management for HCP with potential occupational exposure to hepatitis C virus (HCV). Baseline testing of the source patient and HCP should be performed as soon as possible (preferably within 48 hours) after the exposure. A source patient refers to any person receiving health care services whose blood or other potentially infectious material is the source of the HCP's exposure. Two options are recommended for testing the source patient. The first option is to test the source patient with a nucleic acid test (NAT) for HCV RNA. This option is preferred, particularly if the source patient is known or suspected to have recent behaviors that increase risk for HCV acquisition (e.g., injection drug use within the previous 4 months) or if risk cannot be reliably assessed. The second option is to test the source patient for antibodies to

Article Metrics

Altmetric:

News (10)
Blogs (1)
Twitter (41)
Facebook (4)

Citations: 0

Views: 4,989

Views equals page views plus PDF downloads

Metric Details

24

Testing Definitions

- Anti—HCV
  - The **HCV** antibody **test**, sometimes called the **anti-HCV test**, looks for antibodies to the **hepatitis C** virus in blood. Antibodies are chemicals released into the bloodstream when someone gets infected.
- HCV NAT for HCV RNA
  - **HCV RNA** in blood, by nucleic acid testing (**NAT**), is a marker for **HCV** viremia and is detected only in persons who are currently infected. Persons with reactive results after **HCV** antibody testing should be evaluated for the presence of **HCV RNA** in their blood.
  - Detected within 1 – 2 weeks after exposure.

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Availability of Rapid HIV Test

Therefore, an employer's failure to use rapid HIV antibody testing when testing as required by paragraph 1910.1030(f)(3)(ii)(A) *would usually be considered a violation of that provision.*

OSHA Standard Interpretation

"Rapid HIV testing of source patients facilitates timely decision making regarding the need for administration of HIV PEP after occupational exposure to sources whose HIV status is unknown."

Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. 9.25.13

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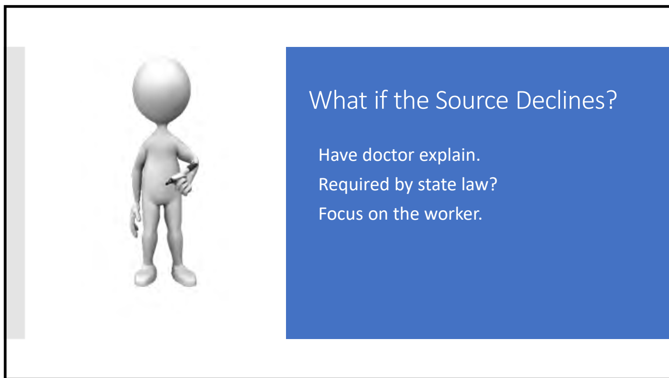

What if the Source Declines?

Have doctor explain.

Required by state law?

Focus on the worker.

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Exposed Worker Documents

- Bloodborne Pathogen Standard
- Job description
- Incident report
- Medical records of the worker
- Source individual's blood testing if available

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Exposed Worker Testing Options

- Conduct baseline testing for all exposures:
  - HIV Antibody
  - Hepatitis B Surface Antigen (HBsAG)
    - Testing of employee is not indicated, if documented serologic evidence indicates immunity to hepatitis B.
  - Anti-Hepatitis C Virus (Anti-HCV)

Or

  - Anti-Hepatitis C Virus (Anti-HCV)
  - HIV/Hep B: Test only if source patient testing indicates disease or in an unknown exposure
- Follow-up for any indication of illness with additional testing for worker for up to 6 months.

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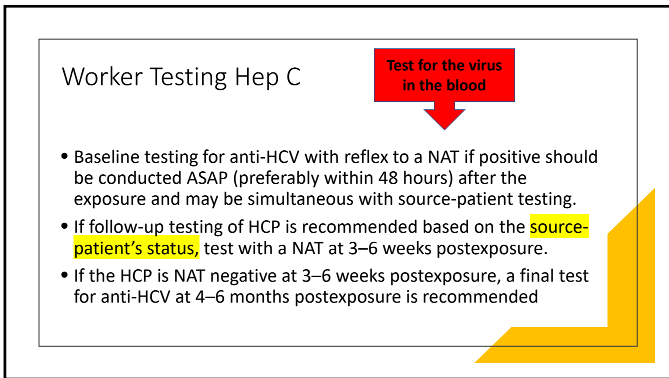
Worker Testing Hep C



- Baseline testing for anti-HCV with reflex to a NAT if positive should be conducted ASAP (preferably within 48 hours) after the exposure and may be simultaneous with source-patient testing.
- If follow-up testing of HCP is recommended based on the source-patient's status, test with a NAT at 3–6 weeks postexposure.
- If the HCP is NAT negative at 3–6 weeks postexposure, a final test for anti-HCV at 4–6 months postexposure is recommended

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POST EXPOSURE EVALUATION DECLINATION

I have been trained on the risk of being exposed to blood and/or other potentially infectious materials as required by OSHA's Bloodborne Pathogens Standard. I understand that I may have been exposed to an infectious disease including HIV, Hepatitis B or Hepatitis C because of the exposure incident. I also understand the risk of contracting these diseases. I have been offered, without charge, the opportunity for a medical evaluation which may include blood testing, counseling and if indicated evaluation of reported illnesses by a qualified healthcare professional.

I decline this post exposure evaluation, counseling, blood testing and any follow-up based on reported illnesses.

Signature: ______________________ Date: ______________

Witness: ______________________ Date: ______________

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Employee Confidentiality

- Exposed worker – source patient results
- Doctor is both the employer and the evaluating healthcare professional
- Medical information is not to be discussed with or revealed to others

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Written Letter of Opinion

PHYSICIAN WRITTEN OPINION

Patient Name: ______________________ Date of Birth: __________

Post-Exposure Evaluation and Treatment Date of visit: __________

- ☐ The employee has been informed of the results of the evaluation
- ☐ The employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

Hepatitis B Vaccination Date of visit: __________

- ☐ Hepatitis B vaccination is indicated
- ☐ Hepatitis B vaccination has been administered.

____

Treating Physician Signature

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Medical Record

- Required for all employees at risk of exposure to BBP
- Employee name and social security number
- Copy of HBV vaccination status and results of examinations, medical testing, follow-up procedures
- Incident reports – info provided to provider
- Employer's copy of healthcare professional's written opinion
- Retained for duration of employment plus 30 years.
- If records requested provide a copy:
  - To the employee or anyone with the employee's written consent by end of next business day
  - Director of NIOSH or HHS and/or Assistant Secretary of Labor

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Occupational Safety and Health Administration

ABOUT OSHA · WORKERS · EMPLOYERS · REGULATIONS · ENFORCEMENT · TOPICS · NEWS & PUBL

Report a Fatality or Severe Injury

- All employers are required to notify OSHA when an employee is killed on the job or suffers a work-related hospitalization, amputation, or loss of an eye.
- A fatality must be reported within 8 hours.
- An in-patient hospitalization, amputation, or eye loss must be reported within 24 hours.

Emerg

To Make a Report

- Call the nearest OSHA office.
- Call the OSHA 24-hour hotline at 1-800-321-6742 (OSHA).
- Report online

https://www.osha.gov/pls/ser/serform.html

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Clinical Resources

https://www.cdc.gov/niosh/topics/bbp/guidelines.html

Bloodborne Infectious Diseases: Management & Treatment Guidelines

Resources for Management and Treatment Guidelines

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Thank You!

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888.862.6742

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Resources/References

- OSHA Bloodborne Pathogens Standard website: https://www.osha.gov/bloodborne-pathogens/standards
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11): pp. 20.
- NIOSH Website - Bloodborne Diseases https://www.cdc.gov/niosh/topics/bbp/emergnedl.html.
- Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. Nov 2013.
- CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. Dec 2013.
- Moorman AC, de Perio MA, Goldschmidt R, et al. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020. MMWR Recomm Rep 2020;69(No. RR-6):1–8. DOI: http://dx.doi.org/10.15585/mmwr.rr6906a1.
- CDC. National Institute for Occupational Safety and Health. Bloodborne Infectious Diseases website. HIV/AIDS, Hepatitis B, Hepatitis C: Preventing Needlesticks and Sharps Injuries

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EMPLOYEE MEDICAL RECORD - HEPATITIS B VACCINE

Name ____ Last 4 of SS# _______________

Select the appropriate box:

- ☐ Hepatitis B vaccination series documentation and positive titer. Records attached.
- ☐ Never received a vaccination. Vaccine series and a follow-up titer offered.
- ☐ Official documentation of vaccination, but no documented titer. Hepatitis B titer offered.
- ☐ History of vaccination or incomplete vaccination series, but no official documentation:
  - ☐ Attempt to obtain official records by contacting previous employers, healthcare provider or the employee working with the health department to access records.
  - ☐ If records reveal an incomplete series, the missing doses will be provided, and a titer performed.
  - ☐ If records are not located, the worker is considered unvaccinated and will be offered vaccination series with titer.

Workers can accept or decline the vaccination(s) or a titer by signing one of the boxes below.

HEPATITIS B VACCINE CONSENT (No vaccination series or lack of documentation)

I consent to move forward with Hepatitis B Virus (HBV) vaccine and titer. I understand the injections are given over a period of several months before it is effective in preventing the disease.

The titer will provide documentation of immunity. If a titer reveals inadequate immunity, based on public health guidance, workers will be provided additional doses of the vaccine, not to exceed six (6) doses to obtain immunity.

Signature: ____________________________________ Date: ______________________

TITER CONSENT (Documentation of Hepatitis B vaccine series but no titer obtained)

I consent to move forward with Hepatitis B Virus (HBV) and titer. The titer will provide documentation of immunity. If a titer reveals inadequate immunity, based on public health guidance, workers will be provided additional doses of the vaccine, not to exceed six (6) doses to obtain immunity.

Signature: ____________________________________ Date: ______________________

TITER DECLINED

Signature: ____________________________________ Date:______________________

HEPATITIS B VACCINE DECLINATION

I understand that due to my occupational exposure to blood or other potentially infectious material I may be at risk of acquiring a Hepatitis B Virus infection. I have been given the opportunity to be vaccinated at no charge to myself. I understand that by declining this vaccine I continue to have occupational exposure to blood or be at risk of acquiring Hepatitis B, a serious disease.

If in the future I continue to have occupational exposure to blood or other potentially infectious materials, and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signature: ____________________________________ Date: ______________________

Reference:
Hepatitis B and the Healthcare Personnel: CDC Answers Frequently Asked Questions
Centers for Disease Control and Prevention. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. MMWR 2013;62(No.10)

 Maintain for duration of employment plus 30 years

POST EXPOSURE PROTOCOL

☐ **Option #1: Patient Testing and Employee Medical Evaluation will be outsourced.**

- The source patient will be referred for the required testing procedures.

  ____ (Name of the facility)

- The exposed employee will immediately be offered a confidential medical evaluation and counseling.

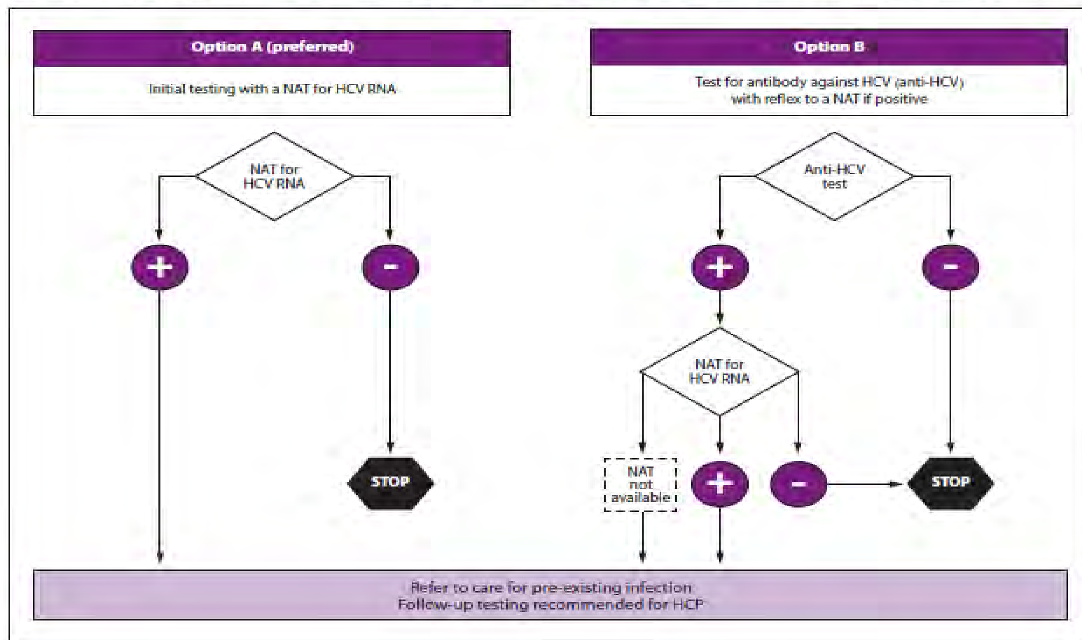
  ____ (Name of the facility)

☐ **Option # 2: The Source Patient testing and the Employee Medical Evaluation will be provided onsite (at this facility).**

Source Patient - Obtain patient consent based on state law utilizing.

- Based on CDC guidelines, the following tests will be ordered by the provider for the **source** patient unless already known to be infected:
  1. HIV Antibody. Rapid HIV test will be used if available. If rapid HIV is not available, expedite the HIV test.
  2. Hepatitis B Surface Antigen (HBsAG) - Source patient testing is not indicated if **exposed worker** has documented serologic evidence of hepatitis B immunity.
  3. Hepatitis C: Review attached CDC guidance on source patient testing. (MMWR: July 24, 2020)

FIGURE 1. Testing of source patients after potential exposure of health care personnel to hepatitis C virus — CDC guidance, United States, 2020*



- The results of the source patient tests will be reviewed by the ordering provider. If requested by the source patient, forward the results to another provider.

Exposed Worker - Obtain consent or declination from the exposed employee for treatment and blood tests. If exposed employee declines HIV testing, offer the option to draw and hold blood for 90 days.

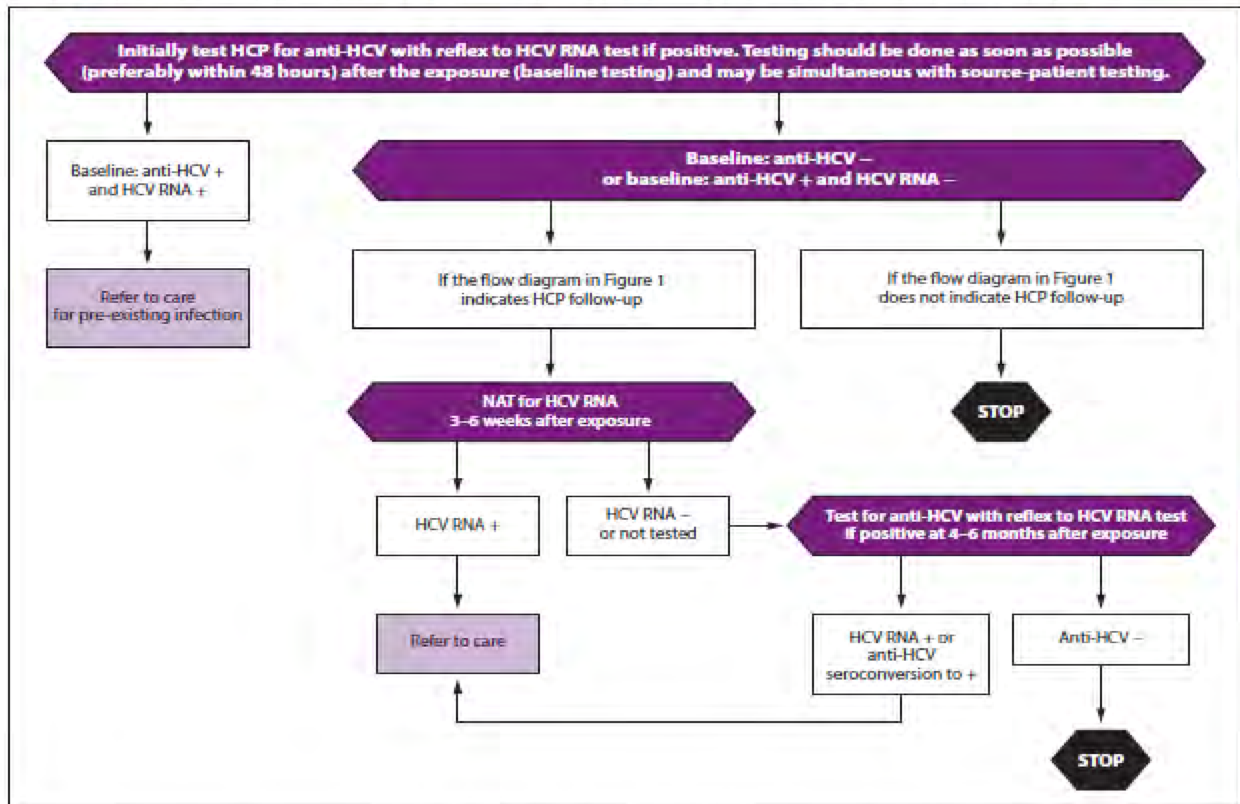
Testing for the exposed worker will be ordered based on the following criteria:

- Hepatitis C will be obtained with all exposures.
- HIV, Hepatitis B will be obtained for exposures with an unknown source.
- ☐ HIV, Hepatitis B will be obtained for ALL exposures
- ☐ HIV and Hepatitis B testing will be performed only if the source patient testing indicated presence of one or both viruses.

Unless already known to be infected, the tests listed below are identified in the CDC guidelines for testing of the exposed workers.0

1. HIV Antibody
2. Hepatitis B Surface Antigen (HBsAG) -Testing of employee is not indicated, if documented serologic evidence indicates immunity to hepatitis B.
3. Anti HCV and if positive NAT HCV RNC: Review attached CDC guidance on exposed worker testing. (MMWR: July 24, 2020)

FIGURE 2. Testing of health care personnel after potential exposure to hepatitis C virus — CDC guidance, United States, 2020*



Abbreviations: AASLD-IDSA = American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; HCP = health care personnel; HCV = hepatitis C virus; NAT = nucleic acid test.

4. **Provide counseling to exposed worker based on CDC Guidelines**

   HCP exposed to HBV or HCV infected blood do not need to take any special precautions to prevent secondary transmission during the follow up period.

   HCP exposed to HIV should be advised to use precautions to prevent secondary transmission during the follow up period. For exposure for which PEP is prescribed, the HCP should be informed about possible drug toxicities and the need for monitoring and possible drug interactions.

For **all** exposure situations, the following information will be made available to the **treating provider**:

- Medical records relevant to the appropriate treatment of the employee including the information on Hepatitis B vaccinations and titers.
- A description of the employee's duties as they relate to the exposure incident.
- Documentation of the exposure incident. May use form **OSHA 301.**
- A copy of the OSHA 1910.1030- Bloodborne Pathogen Standard.
- A copy of form Physician Written Opinion. This form is to be completed by the treating physician and a copy must be provided to the employer/employee within 15 days of examination.

Physician Written Opinion to Employer - As required by OSHA 1910.1030(f) (5), a letter must be sent to the employer of the exposed employee within 15 days of the initial treatment. All other findings or diagnoses shall remain confidential and shall not be included in the written report to the employer.

Additional Resources for Post Exposure Management:

- PEPline at http://www.nccc.ucsf.edu/about_nccc/pepline/; telephone 888-448-4911
- Moorman AC, de Perio MA, Goldschmidt R, et al. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020. MMWR Recomm Rep 2020;69(No. RR-6):1–8. DOI: http://dx.doi.org/10.15585/mmwr.rr6906a1.
- CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management – 2013
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis – 2013/2018
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis – 2001
- www.cdc.gov/niosh/topics/bbp/guidelines.html
- Moorman AC, de Perio MA, Goldschmidt R, et al. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020. MMWR Recomm Rep 2020;69(No. RR-6):1–8. DOI: http://dx.doi.org/10.15585/mmwr.rr6906a1

Hepatitis B and Healthcare Personnel

Immunize.org answers frequently asked questions about how to protect healthcare personnel

Experts from Immunize.org answer your questions about hepatitis B (HepB) vaccine. You'll find additional Q&As about hepatitis B vaccine on the "Ask the Experts" section of immunize.org at www.immunize.org/askexperts/experts_hepb.asp

Hepatitis B Vaccination

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

CDC recommends hepatitis B vaccination of everyone age 59 years and younger plus people 60 years and older who are at increased risk, including all healthcare personnel (HCP). In addition, the Occupational Safety and Health Administration (OSHA) requires that hepatitis B vaccine be offered to 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 and PreHevbrio be used for vaccinating healthcare professionals?

Yes. Heplisav-B (Dynavax) 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.

PreHevbrio (VBI Vaccines) is a hepatitis B surface antigen (HBsAg) recombinant vaccine with aluminum hydroxide adjuvant that was approved by the FDA in 2021 for use in people 18 years and older. It is given as a 3-dose series (1.0 mL dose at 0, 1, and 6 months) and administered IM.

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

A HepB vaccine series that was begun with one brand of hepatitis B vaccine may be completed with a different brand. 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. Both Engerix-B [GSK] and Recombivax HB [Merck]) may be administered during pregnancy. Many years of experience with these two 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. HCP who breastfeed their babies 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 breast-feeding.

There are no clinical studies of Heplisav-B or PreHevbrio during pregnancy. Available data are insufficient to assess vaccine-associated risks in pregnancy. Until safety data are available for these products, providers should continue to use Engerix-B or Recombivax HB during pregnancy. CDC does not recommend pregnancy testing before vaccination.

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 HCP 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 challenge dose of hepatitis B vaccine and be retested 1–2 months later (see Figure 1). Those who test positive following the challenge 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 HCP (including the challenge dose) initially vaccinated with a vaccine from a different manufacturer in the 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 a 2- or 3-dose HepB vaccine series (depending on vaccine brand) and test for anti-HBs 1–2 months after the final dose of the repeat series. Any HepB vaccine brand may be used for revaccination following an

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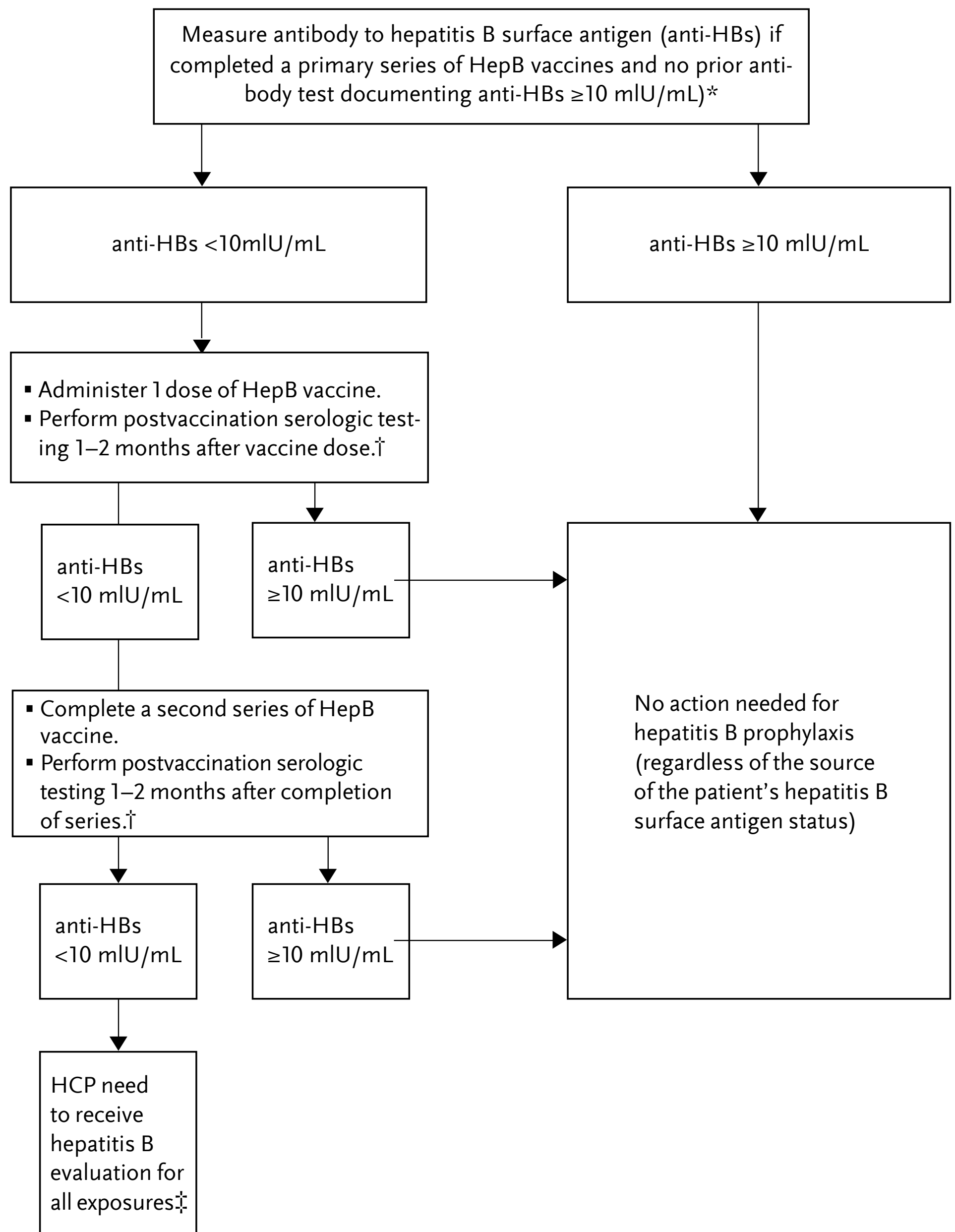
FIGURE 1.

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 stand-alone 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 below 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.

initial hepatitis B vaccine series from a different manufacturer. Any vaccine brand 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.

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. Postvaccination 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, no further antibody testing should be done, and no further HepB vaccine doses are recommended, even if subsequent antibody tests showed a titer of less than 10 mIU/mL. 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 assessment 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

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seek counsel from a review panel comprised of experts with a balanced perspective (e.g., 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

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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.

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.

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 CDC. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022, *MMWR* 2022; 71(13), available at www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7113a1-H.pdf.

4 Immunize.org. "Healthcare Personnel Vaccination Recommendations," www.immunize.org/catg.d/p2017.pdf

5 Immunize.org. "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

Resources + References

- OSHA Bloodborne Pathogens Standard website: https://www.osha.gov/bloodborne-pathogens/standards
- Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11): pp. 20.
- NIOSH Website - Bloodborne Diseases www.cdc.gov/niosh/topics/bbp/emergnedl.html.
- Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. Nov 2013.
- CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. Dec 2013.
- Moorman AC, de Perio MA, Goldschmidt R, et al. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020. MMWR Recomm Rep 2020;69(No. RR-6):1–8. DOI: http://dx.doi.org/10.15585/mmwr.rr6906a1.
- CDC. National Institute for Occupational Safety and Health. Bloodborne Infectious Diseases website. HIV/AIDS, Hepatitis B, Hepatitis C: Preventing Needlesticks and Sharps Injuries
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