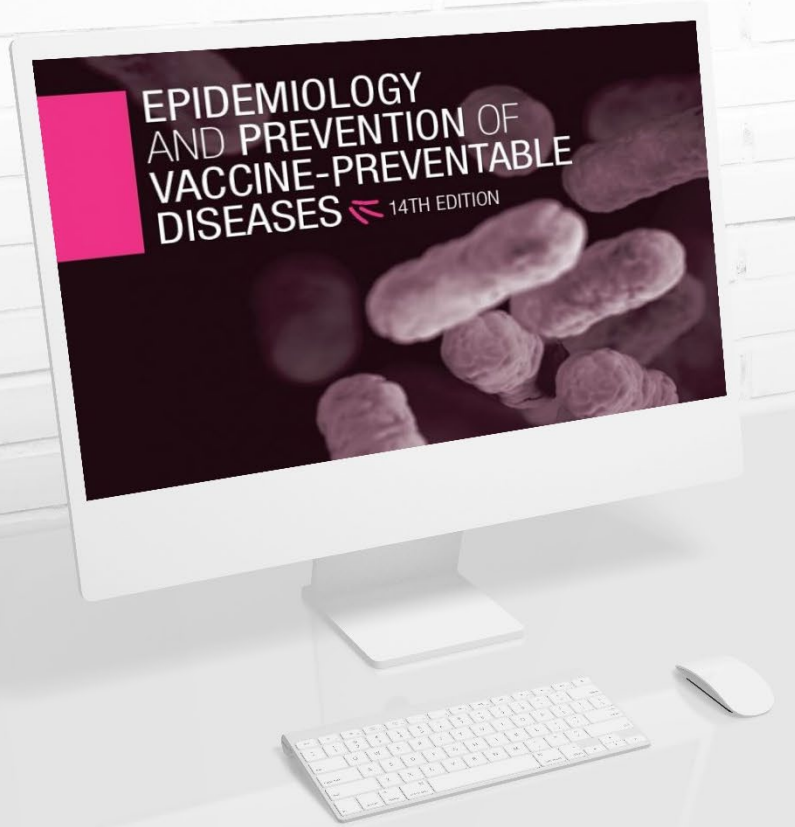
National Center for Immunization and Respiratory Diseases

Hepatitis B Vaccines



Pink Book Web-on-Demand Series

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Nurse Educator
Immunization Service Division

Learning Objectives

- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

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- **CDC did not accept financial or in-kind support from any ineligible company for this continuing education activity.**
- **The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.**

1

Hepatitis B Disease

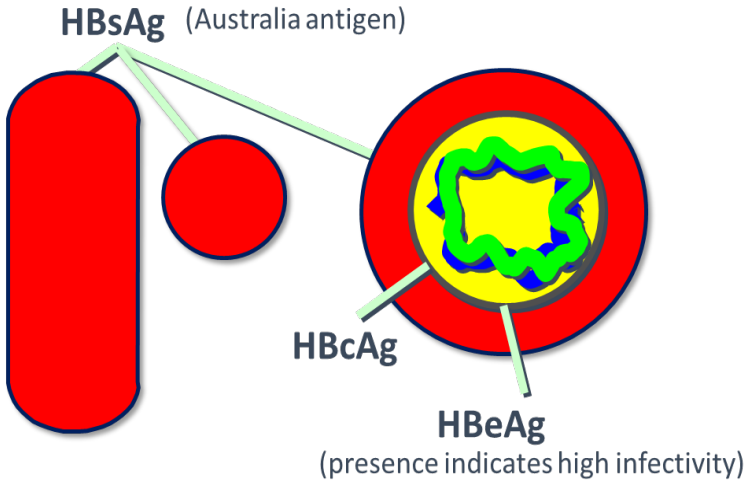
Hepatitis B Virus (HBV) Abbreviations

- anti-HBc = antibody to hepatitis B core antigen
- anti-HBe = antibody to hepatitis B e antigen
- anti-HBs = antibody to hepatitis B surface antigen
- HBeAg = hepatitis B e antigen
- HBsAg = hepatitis B surface antigen
- HBV DNA = hepatitis B virus deoxyribonucleic acid
- HBIG = hepatitis B immune globulin
- HepB = hepatitis B
- HBV = hepatitis B virus
- IgM = immunoglobulin class M

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Hepatitis B Virus (HBV)

- **Hepadnaviridae family**
  - Small, double-stranded DNA virus
  - Multiple serologic markers for infection
- **Highly infectious and transmissible**
  - Viable on surfaces for at least 7 days
  - Transmissible in the absence of visible blood



Chapter 10: Hepatitis B | Pink Book | CDC

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Hepatitis B Epidemiology

Reservoir	Human
Transmission	Percutaneous (i.e., puncture through the skin) or mucosal (i.e., direct contact with mucous membranes) exposure to infectious blood or body fluids (i.e., semen).
Communicability	Persons with acute or chronic HBV infection are infectious any time HBsAg present in blood. Persons with acute HBV infection can have HBsAg in blood 1–2 months before and after onset of symptoms.

Chapter 10: Hepatitis B | Pink Book | CDC

Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)

Hepatitis B Clinical Features

- **Incubation period from exposure to onset of:**
  - Abnormal serum alanine aminotransferase (ALT) levels, average 60 days (range: 40–90 days)
  - Jaundice, average 90 days (range: 60–150 days)
- **Infants, children ages 5 years and younger, and immunosuppressed adults with newly acquired HBV infection are typically asymptomatic.**
- **30%–50% of older children, adolescents, and adults are symptomatic.**

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Acute Hepatitis B Clinical Course

- **Prodromal phase lasts 3 to 10 days**
  - Abrupt onset of fever, malaise, anorexia, nausea, abdominal discomfort, and dark urine before jaundice
- **Icteric phase lasts 1 to 3 weeks**
  - Jaundice, light or gray stools, hepatic tenderness, or hepatomegaly
- **Convalescent phase lasts weeks to months**
  - Malaise and fatigue persist while jaundice, anorexia, and other symptoms disappear

Chapter 10: Hepatitis B | Pink Book | CDC
Clinical Signs and Symptoms of Hepatitis B | Hepatitis B | CDC

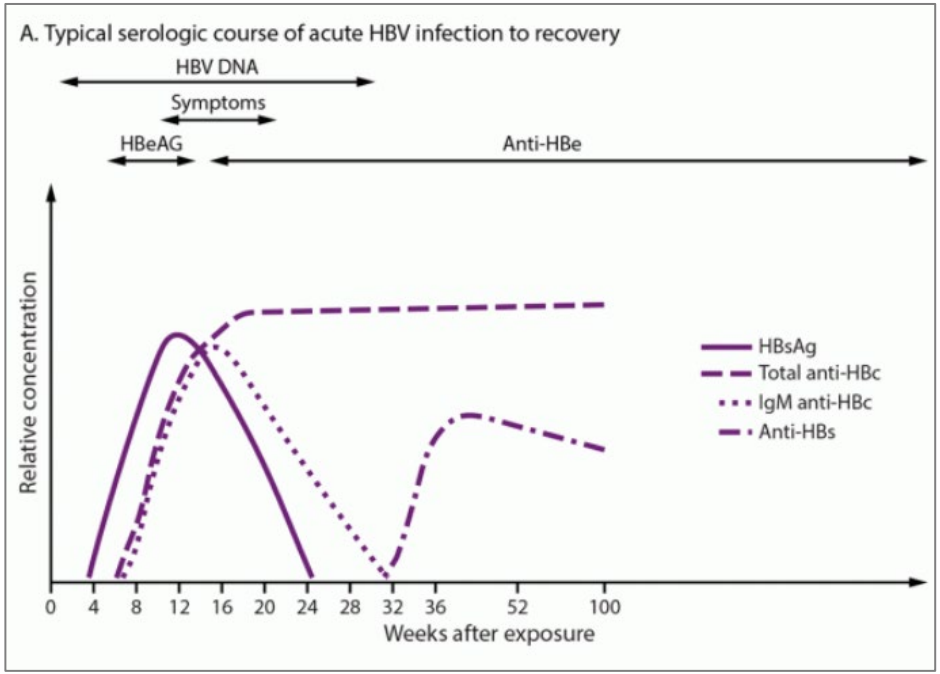
Hepatitis B Complications

- **Acute infection → → Fulminant hepatitis (fewer than 1%)**
- **Chronic infection → → Cirrhosis, hepatocellular carcinoma, and death**
- **Extrahepatic manifestations of disease (e.g., glomerulonephritis, vasculitis, skin rash, arthralgias, and arthritis) may occur.**

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Course of Acute HBV Infection to Recovery

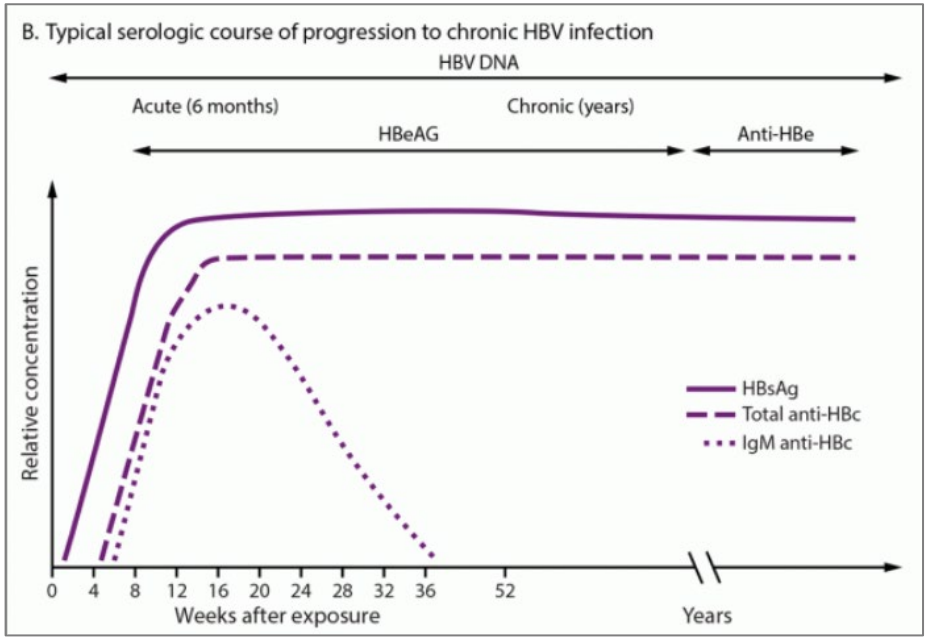
- **HBsAg indicates HBV active infection and is eliminated in recovery.**
- **Total anti-HBc (IgM and IgG) appears 1–2 weeks after HBsAg.**
- **Anti-HBs is generally indicative of immunity to HBV infection.**



Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 | MMWR

Course of Progression to Chronic HBV Infection

- **Presence of HBsAg for at least 6 months indicates active chronic HBV infection.**
- **Total anti-HBc develops in all HBV infections.**
  - During a chronic infection, HBsAg and total anti-HBc will be present.
  - IgM anti-HBc will disappear.
- **For persons with HBV immunity from vaccination, anti-HBc will not be present.**



Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 | MMWR

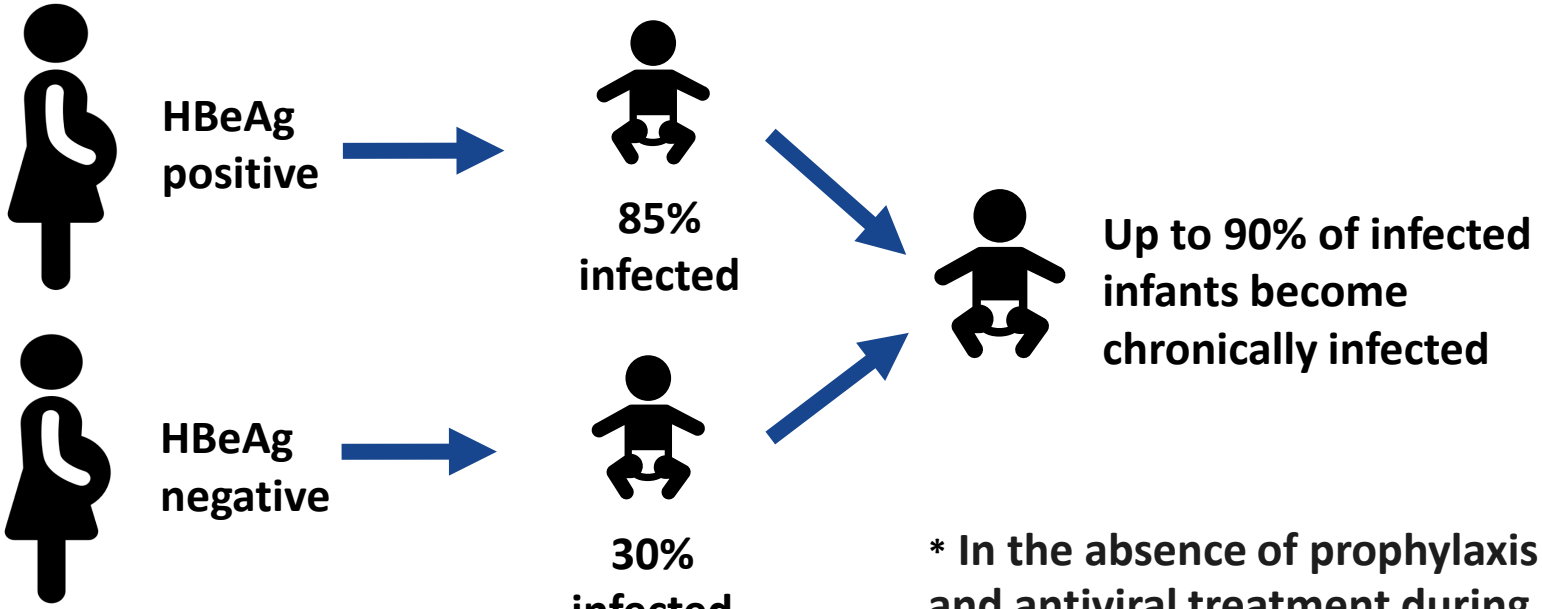
Chronic HBV Infection

- **Develops in:**
  - 80%–90% of persons infected during infancy
  - 30% of persons infected before age 6 years
  - 1%–12% of persons infected as an older child or adult

- **Leads to premature death from cirrhosis or liver cancer in:**
  - 25% of persons infected during childhood
  - 15% of persons infected after childhood

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR (cdc.gov)

Perinatal HBV Transmission Among Infants Born to HBsAg-positive Mothers*



* In the absence of prophylaxis and antiviral treatment during pregnancy.

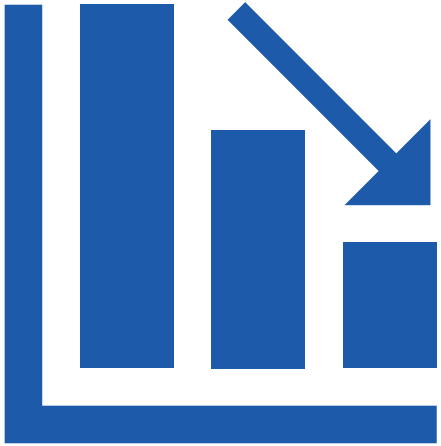
Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR (cdc.gov)

Hepatitis B Secular Trends in the United States

1982:
9.6 per 100,000

Acute cases before vaccine introduction

90% decrease



2022:
0.6 per 100,000

Acute cases

Chapter 10: Hepatitis B | Pink Book | CDC
Hepatitis B Basics | Hepatitis B | CDC, Hepatitis B Surveillance | 2022 Hepatitis Surveillance | CDC
Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)

Hepatitis B Burden in the United States in 2022

Acute hepatitis B

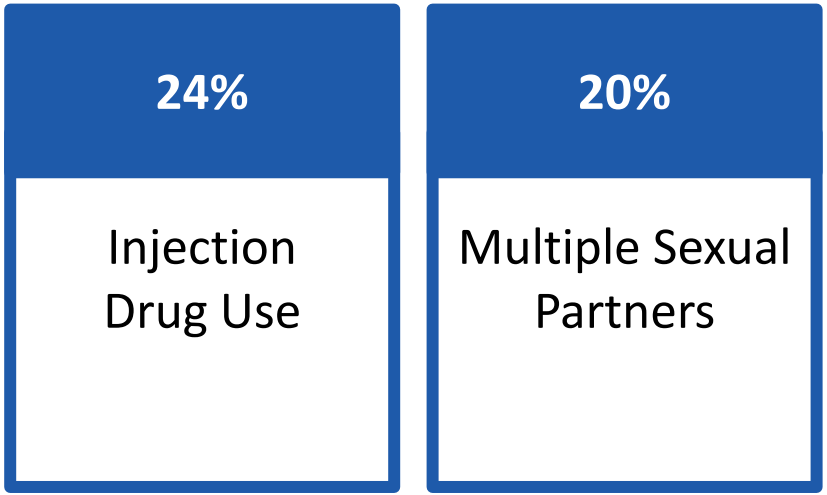
- **2,126 acute hepatitis B cases**
  - 52% were among persons ages 40–59 years of age
  - Rate 1.7 times higher among Non-Hispanic Black compared to non-Hispanic white persons

Chronic hepatitis B

- **16,729 newly reported chronic hepatitis B cases**
  - 89% of newly reported chronic hepatitis B cases occurred in persons 30 years and older.
  - Rate 11.2 times higher among non-Hispanic Asian and Pacific Islander compared to non-Hispanic White persons

2022 Viral Hepatitis Surveillance Report | 2022 Hepatitis Surveillance | CDC
Hepatitis B Surveillance | 2022 Hepatitis Surveillance | CDC

Exposure and Risk Behaviors Identified Among Acute Hepatitis B Cases* Reported in 2022



*For whom risk factor information is available.

Table 2.3 – Acute – Risk & Exposure Data | 2022 Hepatitis Surveillance | CDC

Strategy to Eliminate Hepatitis B Virus (HBV) Transmission—United States





Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR (cdc.gov)
Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 | MMWR
Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)

Strategy to Eliminate Hepatitis B Virus (HBV) Transmission—United States

Universal screening of all adults 18 years and older at least once in their lifetime

Routine testing for HBsAg during each pregnancy

Universal vaccination of all infants at birth

Routine vaccination of previously unvaccinated children, adolescents, and adults younger than 60 years

Vaccination of adults 60 years or older at risk for HBV infection

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Hepatitis B Virus Screening and Risk-Based Testing Recommendations—CDC, 2023

- **Risk-based testing includes:**
  - Testing for all persons with a history of increased risk for HBV infection, regardless of age, if they might have been susceptible during the period of increased risk[†]
  - Periodic testing for susceptible persons, regardless of age, with ongoing risk for exposures, while risk for exposures persists[†]

[†] Susceptible persons include those who have never been infected with HBV (i.e., total anti-HBc negative) and either did not complete a HepB vaccine series per Advisory Committee on Immunization Practices recommendations or who are known to be vaccine nonresponders.

Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 | MMWR

Persons, Activities, Exposures, and Conditions Associated with an Increased Risk for HBV Infection

- Infants born to mothers who are HBsAg-positive
- Persons born in regions with HBV infection prevalence of ≥2%
- U.S.-born persons not vaccinated as infants whose parents were born in regions with HBV infection prevalence of ≥8%
- Injection drug use
- **Incarceration in a jail, prison, or other detention setting (new recommendation)**
- HIV infection
- **Hepatitis C virus infection (new recommendation)**
- Men who have sex with men
- **Sexually transmitted infections or multiple sex partners (new recommendation)**
- Household contacts of persons with known HBV infection
- Needle-sharing or sexual contacts of persons with known HBV infection
- Maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis
- Elevated alanine aminotransferase or aspartate aminotransferase levels of unknown origin
- **Persons who request HBV testing (new recommendation)**

Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 | MMWR

2

Hepatitis B Vaccines

Hepatitis B Single Component Vaccines

Vaccine Products	Age Indications
Engerix-B	
Pediatric formulation	Birth–19 years
Adult formulation	20 years and older
Recombivax HB	
Pediatric formulation	Birth–19 years
Adult formulation	20 years and older
Heplisav-B	18 years and older

Package Insert - ENGERIX-B (fda.gov)
Package Insert - Recombivax HB (fda.gov)
Package Insert - HEPLISAV-B (fda.gov)

Hepatitis B Combination Vaccines

Vaccine Products	Components	Age Indications
Pediarix	DTaP-HepB-IPV	6 weeks–6 years
Vaxelis	DTaP-IPV-Hib-HepB	6 weeks–4 years
Twinrix	HepA-HepB	18 years and older

Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)
Twinrix (fda.gov)

Hepatitis B Single Component Vaccine Schedules

	Engerix-B	Recombivax HB	Heplisav-B
Composition	Recombinant Adjuvanted HBsAg	Recombinant Adjuvanted HBsAg	Novel Adjuvanted Recombinant HBsAg
Schedule	3 doses	3 doses	2 doses
Route	IM	IM	IM

Package Insert - ENGERIX-B
Package Insert - Recombivax HB
Package Insert - HEPLISAV-B

Combination Vaccines: Pediarix and Vaxelis

- **Pediarix (DTaP-HepB-IPV) and Vaxelis (DTaP-IPV-Hib-HepB)**
  - Approved for doses 2, 3, and 4 of HepB series (do ***not*** use for the birth dose)
    - 4 doses of HepB is acceptable when a combination vaccine containing HepB is used after the birth dose.
- **Pediarix contains a pediatric dose of Engerix-B.**
- **Vaxelis contains the pediatric formulation of Recombivax HB but in a higher dose than the single component formulation.**

Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)

Combination Vaccine: Twinrix

- **Twinrix (HepA-HepB)**
  - Ages: 18 years of age and older
  - Routine schedule:
    - 3 doses at 0, 1, 6 months
  - Accelerated schedule:
    - 0, 7, 21–30 days *and* a booster dose at 12 months
- **Twinrix contains an adult dose of Engerix-B.**

Twinrix (fda.gov)

PreHevbrio: Voluntary Nationwide Recall

- **On November 15, 2024, the vaccine manufacturer (VBI Vaccines Inc.) initiated a voluntary nationwide recall of all remaining PreHevbrio (Hepatitis B Vaccine, Recombinant) due to restructuring of the company and discontinuing operations.**
- **Further distribution or use of any remaining PreHevbrio vaccine by health care providers or others should cease immediately.**

Hepatitis B Vaccine Administration | Hepatitis B | CDC

PREHEVBRIO | FDA

VBI Vaccines Issues Voluntary Nationwide Recall of All PreHevbrio Vaccine Due to Discontinuation of Company Operations - VBI Vaccines

HepB Vaccine Immunogenicity

- **Over 90% of infants, adolescents, and healthy adults younger than 40 years of age develop a protective antibody response after a complete vaccine series.**
  - Declines to 75% in adults 60 years of age and older
- **Larger doses or an increased number of doses are needed to induce protective antibody in dialysis patients and other immunocompromised persons 20 years of age and older.**
- **Vaccine induced antibody levels decline with time, but immune memory remains intact for more than 30 years.**
  - Exposure to HBV results in anamnestic antibody response.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

HepB Vaccines Are Highly Effective

After complete HepB vaccine series:

80-100 % Effective at preventing infection or clinical hepatitis

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HepB vaccine administered alone beginning within 24 hours of birth:

70-95 % Effective at preventing perinatal HBV infection

Chapter 10: Hepatitis B | Pink Book | CDC
Updated Recommendation for Universal Hepatitis B Vaccination in Adults Aged 19–59 Years — United States, 2024 | MMWR

3

Hepatitis B Vaccination Schedule

Hepatitis B Routine Vaccination Recommendations Child and Adolescent Immunization Schedule

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	◄---- 2nd dose ----►			◄---------- 3rd dose ----------►												

Range of recommended ages for all children

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

Hepatitis B Routine Vaccination Recommendations Child and Adolescent Immunization Schedule

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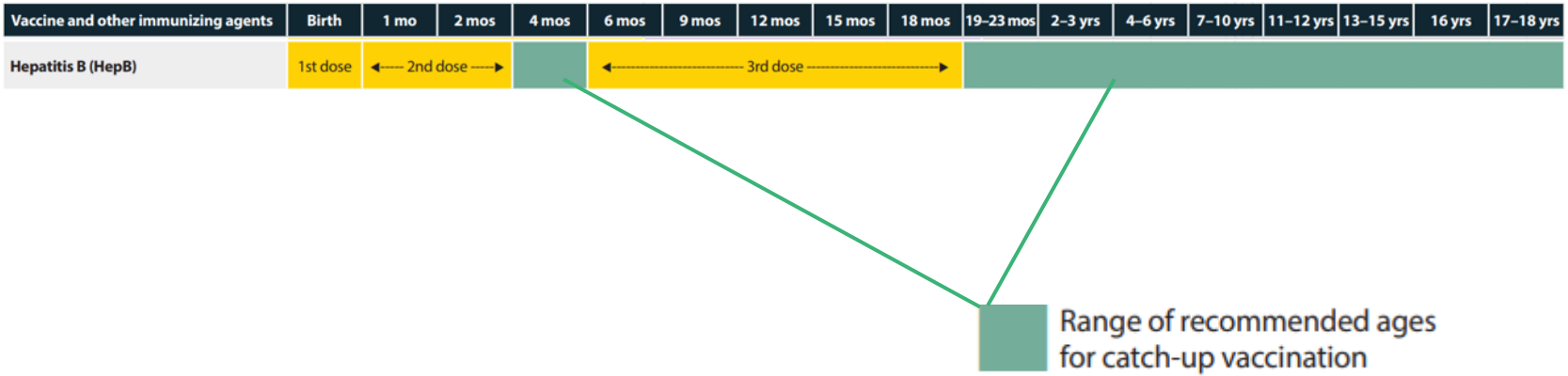

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

Routine Infant HepB Vaccination Schedule

Dose*	Routine Age
Dose 1	Birth†
Dose 2	1–2 months
Dose 3	6–18 months§

* An additional dose at 4 months is acceptable if the clinician prefers to use a combination vaccine that contains hepatitis B vaccine for doses 2, 3, or 4.

† The birth dose of single-component hepatitis B vaccine should be administered within 24 hours of birth for medically stable infants weighing ≥2,000 grams born to HBsAg-negative mothers. The birth dose of single-component hepatitis B vaccine should be administered within 12 hours of birth for infants born to HBsAg-positive mothers or infants born to mothers whose HBsAg status is unknown.

§ Infants born to mothers who are HBsAg-positive or whose HBsAg status is unknown should receive the third dose at 6 months of age.

Child and Adolescent Immunization Schedule by Age (Addendum updated June 27, 2024) | Vaccines & Immunizations | CDC

Birth Dose Considerations: Birth Weight *2000 Grams or More*

HBsAg-Negative mother

Administer Hepatitis B vaccine within 24 hours of birth.

HBsAg-Positive mother

Administer Hepatitis B vaccine and HBIG within 12 hours of birth.

HBsAg-Unknown mother

Administer Hepatitis B vaccine within 12 hours of birth and test to determine mother's HBsAg status ASAP.

HBIG = Hepatitis B immune globulin

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

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*Administer Hepatitis B vaccine and HBIG in separate limbs

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*Administer Hepatitis B vaccine and HBIG in separate limbs

Birth Dose Considerations:
Birth Weight *Less Than 2000 Grams*

HBsAg-*NEGATIVE* mother

Administer Hepatitis B vaccine at hospital discharge or at 1 month of age, whichever comes first.

HBsAg-*POSITIVE* mother

Administer Hepatitis B vaccine and HBIG within 12 hours of birth.

HBsAg-*UNKNOWN* mother

Administer Hepatitis B vaccine within 12 hours of birth. Give HBIG if the mother's HBsAg status cannot be determined within 12 hours of birth.*

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Birth Dose Considerations:
Birth Weight *Less Than 2000 Grams*

HBsAg-*NEGATIVE* mother

Administer Hepatitis B vaccine at hospital discharge or at 1 month of age, whichever comes first.

HBsAg-*POSITIVE* mother

Administer Hepatitis B vaccine and HBIG* within 12 hours of birth.

HBsAg-*UNKNOWN* mother

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*Administer Hepatitis B vaccine and HBIG in separate limbs.

Birth Dose Considerations:
Birth Weight *Less Than 2000 Grams*

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HBsAg-*POSITIVE* mother

Administer Hepatitis B vaccine and HBIG* within 12 hours of birth.

HBsAg-*UNKNOWN* mother

Administer Hepatitis B vaccine within 12 hours of birth. Give HBIG if the mother's HBsAg status cannot be determined within 12 hours of birth.*

*Administer Hepatitis B vaccine and HBIG in separate limbs.

Medical Considerations: Infants Whose Mothers Are Hepatitis B Surface Antigen-*Positive*

- **Administer HepB vaccine *and* HBIG within 12 hours of birth.**
  - Can administer at the same time, in different limbs
  - IM injections
- **Complete vaccination series at 6 months of age**
  - First dose does not count when administered to infants weighing less than 2000 grams: Birth, 1 month, 2–3 months, 6 months
- **Perform Post-Vaccination Serologic Testing (PVST) after completion of vaccine series and between 9–12 months of age.**
  - Check HBsAg and anti-HBs

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

Medical Considerations: Infants Whose Mothers Are Hepatitis B Surface Antigen-*Unknown* (1)

- **Infants born to mothers without HBsAg test results, but for whom other evidence suggests maternal HBV infection exists, *should* receive both HepB vaccine and HBIG within 12 hours of birth.**

- **Test mother for HBsAg status as soon as possible**
  - **Infants weighing 2000 grams or more:** If the mother tests HBsAg-positive, give HBIG as soon as possible, but no later than age 7 days.
  - **Infants weighing less than 2000 grams:** If the mother tests HBsAg-positive or HBsAg status cannot be determined, administer HBIG within 12 hours of birth.

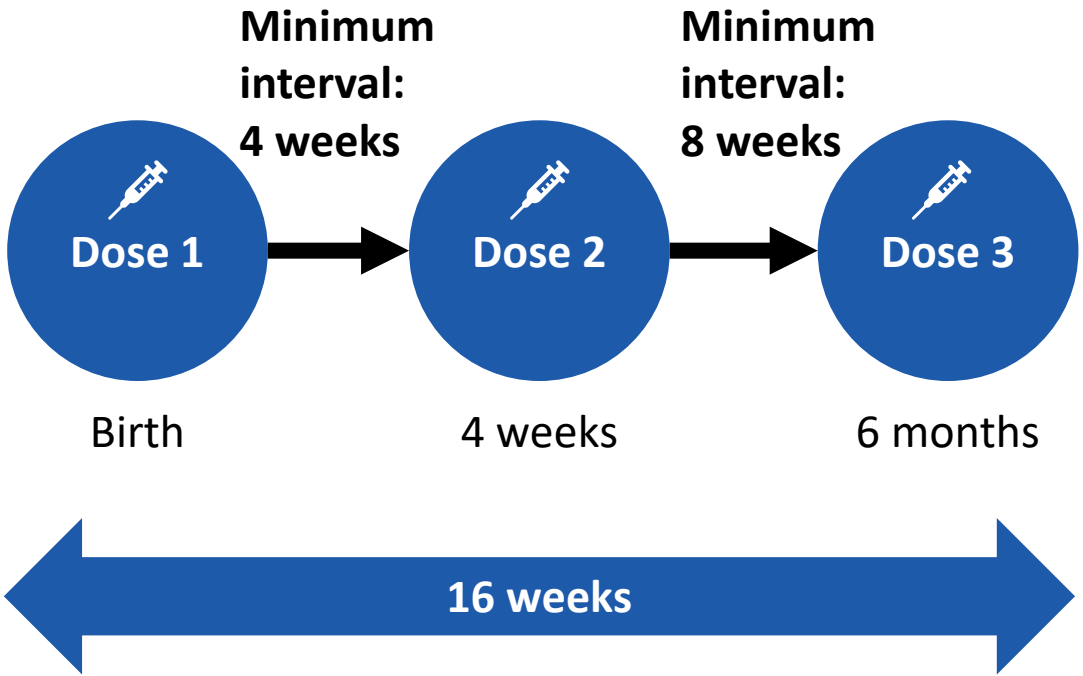
Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

Medical Considerations: Infants Whose Mothers Are Hepatitis B Surface Antigen-*Unknown* (2)

- **The vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers.**
- **The final dose in the series should not be administered before age 24 weeks (164 days).**
- **Should receive PVST after completion of the vaccine series and between age 9–12 months, and revaccination if necessary.**

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

HepB Vaccine Schedule: Minimum Age and Intervals

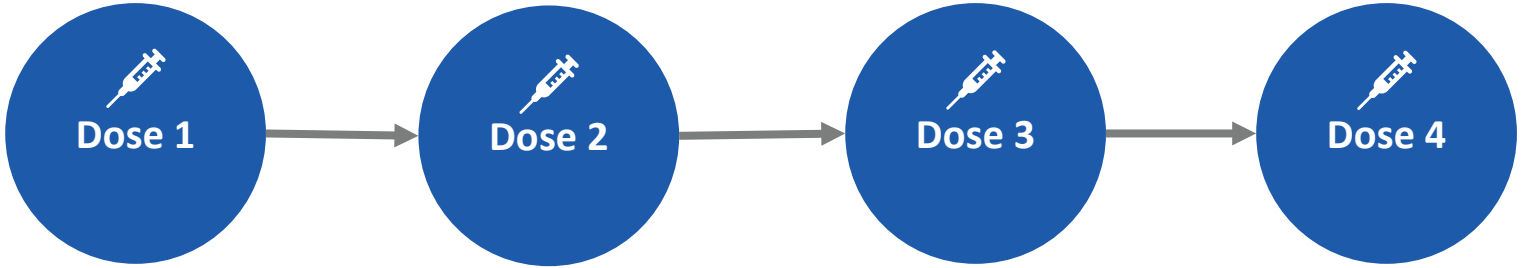


- **6 months is the minimum age for the final dose.**

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

Combination Vaccines Schedule Considerations: Pediarix and Vaxelis

- **Do *not* use for the birth dose**
- **Can be given to infants who received HepB vaccine at birth = 4 doses**



Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)

Knowledge Check

Which of the following is the appropriate post-exposure prophylaxis for an infant weighing 2,437 grams born to a mother who is HBsAg-positive?

A. HepB vaccine within 12 hours of birth

B. HepB vaccine within 24 hours of birth

C. HBIG within 12 hours of birth

D. HepB vaccine and HBIG within 12 hours of birth

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D. HepB vaccine and HBIG within 12 hours of birth

HepB Recommendations: Adult Immunization Schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Recommended Adult Immunization Schedule for ages 19 years or older; 2025 U.S.

Adults Aged 60 Years and Older with Risk Factors for Hepatitis B

- Sex partners of persons testing positive for HBsAg
- Sexually active persons who are not in a long-term, mutually monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted infection
- Men who have sex with men
- Persons with current or recent injection drug use
- Household contacts of persons testing positive for Hepatitis B
- Residents and staff members of facilities for persons with developmental disabilities
- Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Persons on maintenance dialysis, including in-center or home hemodialysis, peritoneal dialysis, and predialysis
- Persons with diabetes (clinician's discretion)

Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR (cdc.gov)

HepB Recommendations: Adult Immunization Schedule by Medical Condition or Other Indication

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count		Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End–stage renal disease or on dialysis	Chronic liver disease; alcoholism[a]	Diabetes	Health care Personnel[b]
			<15% or <200mm³	≥15% and ≥200mm³							
Hep B	See Notes									Age ≥ 60 years	

Recommended for all adults who lack documentation of vaccination, **OR** lack evidence of immunity

Not recommended for all adults, but recommended for some adults based on either age **OR** increased risk for or severe outcomes from disease

Recommended Adult Immunization Schedule for ages 19 years or older; 2025 U.S.

Adult HepB Vaccination Schedule: Recombivax HB, or Engerix-B

Dose	Routine Interval	Minimum Interval
Dose 1	0 month	---
Dose 2	1 month	• 4 weeks after Dose 1
Dose 3	6 months	• 8 weeks after Dose 2 *and* • 16 weeks after Dose 1

Adult Immunization Schedule Notes | Vaccines & Immunizations | CDC

Adult HepB Vaccination Schedule: Heplisav-B (HepB-CpG)

- **2 doses separated by 4 weeks**
- **2-dose Hepatitis B series applies only when *both* doses are Heplisav-B, administered at least 4 weeks apart.**
  - Any 2 doses of Heplisav-B separated by 4 weeks is considered complete, even if the patient has had other HepB vaccine products.

Adult Immunization Schedule Notes | Vaccines & Immunizations | CDC

Scenarios Using Heplisav-B

Scenario 1

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Heplisav-B 03/01/2018

- Completed series
- No additional doses are needed

Scenario 2

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Engerix-B or Recombivax HB 05/01/2018

- Completed series
- No additional doses are needed

Scenario 1 Using Heplisav-B

Scenario 1

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Heplisav-B 03/01/2018

- **Completed series**
- **No additional doses are needed**

Scenario 2

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Engerix-B or Recombivax HB 05/01/2018

- Completed series
- No additional doses are needed

Scenario 2 Using Heplisav-B

Scenario 1

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Heplisav-B 03/01/2018

- Completed series
- No additional doses are needed

Scenario 2

Engerix-B or Recombivax HB 01/01/2018

Heplisav-B 02/01/2018

Engerix-B or Recombivax HB 05/01/2018

- **Completed series**
- **No additional doses are needed**

Completing HepB Vaccination Series for Adults Who Received PreHevbrio

- **For vaccine series started with PreHevbrio as dose 1 or doses 1 and 2, vaccine from a different manufacturer should adhere to the 3-dose schedule.**
  - If PreHevbrio was given as dose 1, another vaccine licensed for adults (i.e., Engerix-B or Recombivax HB) should be given as dose 2 and dose 3 in accordance with the schedule.
  - The 2-dose Heplisav-B vaccine series can also be given as dose 2 and dose 3 to complete a 3-dose vaccine series when the manufacturer of a previously administered dose 1 is unknown, or PreHevbrio was given as dose 1.

Hepatitis B Vaccine Administration | Hepatitis B | CDC

PREHEVBRIO | FDA

VBI Vaccines Issues Voluntary Nationwide Recall of All PreHevbrio Vaccine Due to Discontinuation of Company Operations - VBI Vaccines

4

Clinical Considerations

HepB Vaccination for Patients on Dialysis

Complete a 3- or 4-dose series

- **3-dose series of Recombivax HB**
  - 0, 1, 6 months
  - Dialysis formulation 1 mL = 40 mcg
- **4-dose series of Engerix-B**
  - at 0, 1, 2, 6 months
  - 2 mL dose instead of the normal adult dose of 1 mL

Adult Immunization Schedule Notes | Vaccines & Immunizations | CDC

HepB Vaccination for Adults Ages 20 Years and Older with an Immunocompromising Condition

Complete a 2-, 3- or 4-dose series

- **3-dose series of Recombivax HB**
  - 0, 1, 6 months
  - Dialysis Formulation 1 mL = 40 mcg
- **4-dose series of Engerix-B**
  - at 0, 1, 2, 6 months
  - 2 mL dose instead of the normal adult dose of 1 mL
- **2-dose series of Heplisav-B at 0, 1 months**

Adult Immunization Schedule Notes | Vaccines & Immunizations | CDC

HepB Vaccination During Pregnancy

- **ACIP recommends universal HepB vaccination for all adults aged 19–59 years, including during pregnancy.**
- **On September 11, 2024, the FDA approved updates to the package insert for Heplisav-B to include human data that do not suggest an increased risk for both major birth defects and miscarriage.**
- **Engerix-B, Heplisav-B, Recombivax HB, or Twinrix can be used during pregnancy when HepB vaccination is needed.**

Package Insert - HEPLISAV-B

Updated Recommendation for Universal Hepatitis B Vaccination in Adults Aged 19–59 Years — United States, 2024 | MMWR

Postvaccination Serologic Testing (PVST)

- **Serologic testing is *not* routinely recommended following vaccination of most persons.**
- **Recommended for:**
  - Infants born to mothers who are HBsAg-positive or whose HBsAg status is unknown
  - Health care personnel and public safety workers
  - Chronic hemodialysis patients and others who might require hemodialysis
  - Persons with HIV infection
  - Other immunocompromised persons
  - Sex partners of HBsAg-positive persons

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

PVST Recommendations for Infants

- **To assess for response to vaccine and the need for revaccination, infants born to HBsAg-positive mothers should have PVST performed:**
  - HBsAg
  - Anti-HBs
- **Testing should occur at 9–12 months of age.**

Management of Infants Born to Women with Hepatitis B Virus Infection for Pediatricians (cdc.gov)

PVST Considerations for Infants

- **PVST *should not* be performed before age 9 months**
  - To avoid detection of anti-HBs from HBIG* administered at birth
  - To maximize the likelihood of detecting late HBV infection
- **Anti-HBc testing of infants is not recommended**
  - Infants who are born to HBsAg-positive mothers and who do not become infected might have detectable anti-HBc for up to 24 months after birth.
- **Delayed PVST may result in false negative anti-HBs and unnecessary revaccination.**

*HBIG = Hepatitis B immune globulin

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Importance of Both HBsAg and anti-HBs Testing in Infants

- **A negative HBsAg test result by itself does not indicate whether the infant is protected by vaccination or remains susceptible.**

- **An anti-HBs result <10 mIU/mL is insufficient to determine whether the infant is HBV-infected.**
  - Alone, an anti-HBs result ≥10 mIU/mL does not confirm that the infant is protected; the HBsAg result also must be negative.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

PVST Interpretation in Infants

- **HBsAg negative infants with anti-HBs ≥10 mIU/mL are protected and need no further medical management.**
  - Immunocompetent persons remain protected, even if anti-HBs later declines to <10 mIU/mL.
- **HBsAg negative infants with anti-HBs <10 mIU/mL *should* be revaccinated with either:**
  - A single HepB dose and PVST 1–2 months later, after the final does of vaccine
  - If anti-HBs remains <10 mIU/mL, administer 2 more doses to complete the 2nd series and again perform PVST 1–2 months after the final does of vaccine.
  - A second 3-dose series and PVST 1–2 months after the final dose of vaccine
- **HBsAg positive infants *should* receive appropriate follow-up.**

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

HepB Vaccination Considerations: Health Care Personnel

- **All health care personnel (HCP) with an increased risk due to:**
  - Work
  - Training
  - Volunteerism

- **All HCPs with a reasonably anticipated risk for exposure to blood or body fluids should be vaccinated with a complete HepB vaccine series.**

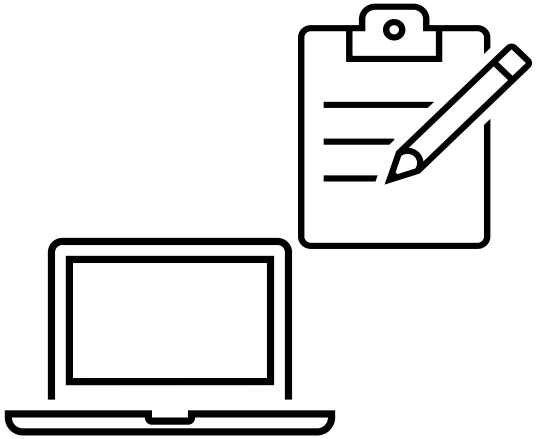
Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Evidence of Vaccine-induced Seroprotection for HCP

- **Written documentation of a complete HepB vaccine series**

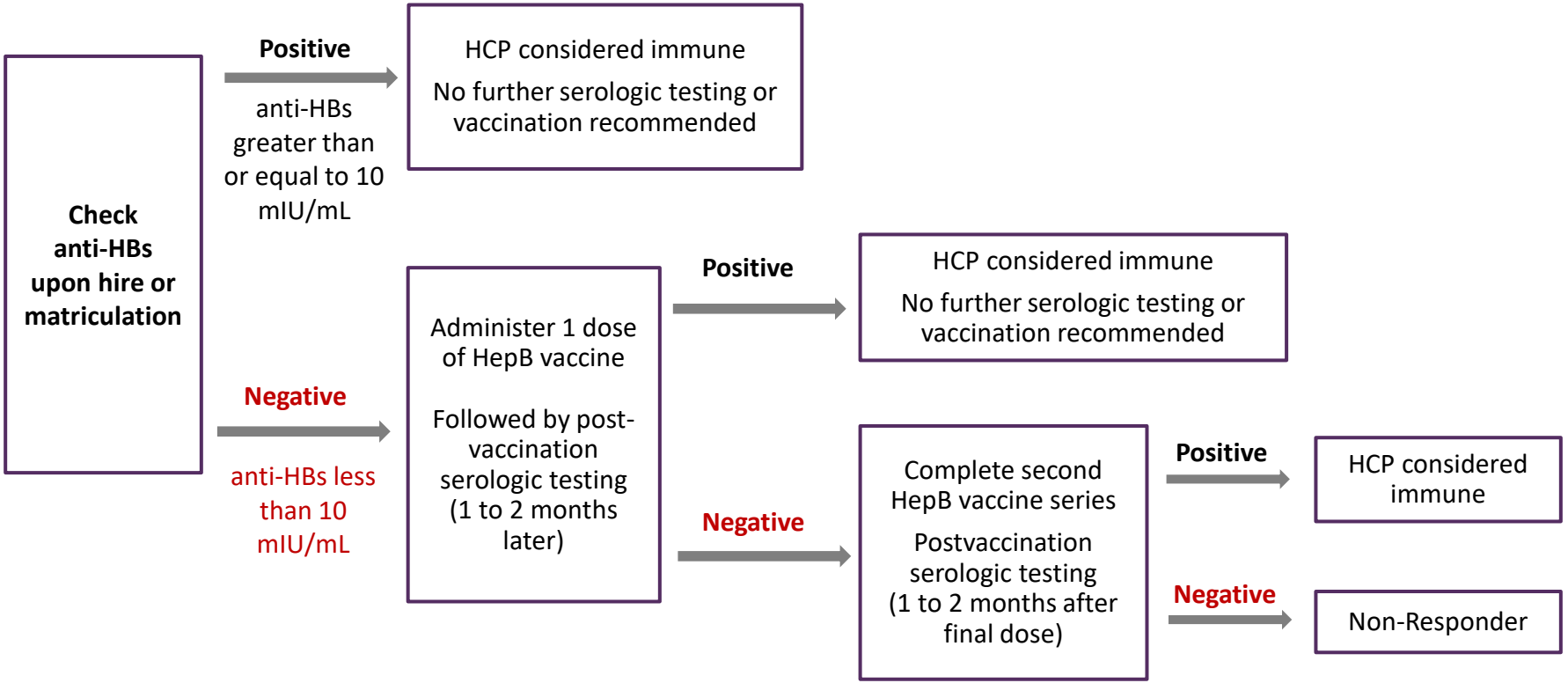
  AND

- **Subsequent documented anti-HBs ≥10 mIU/mL**

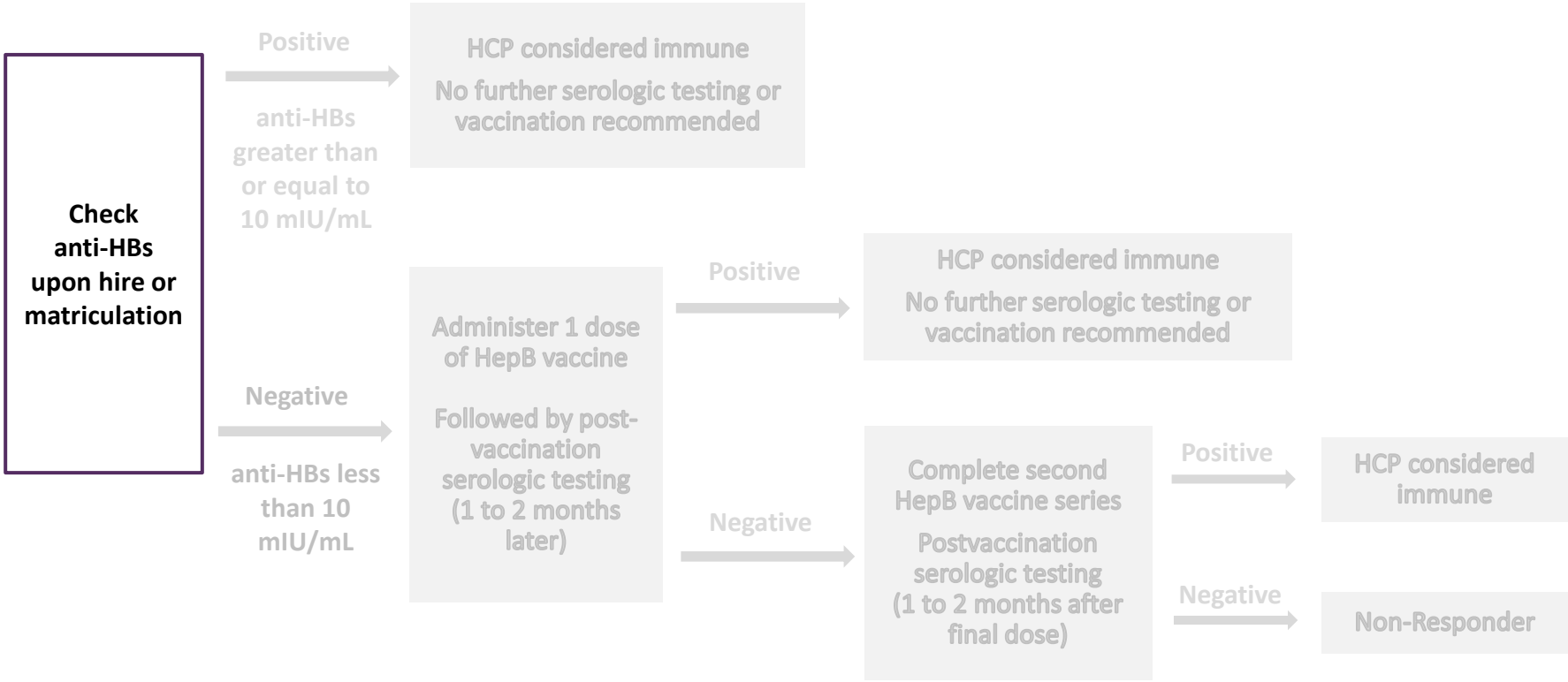


Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

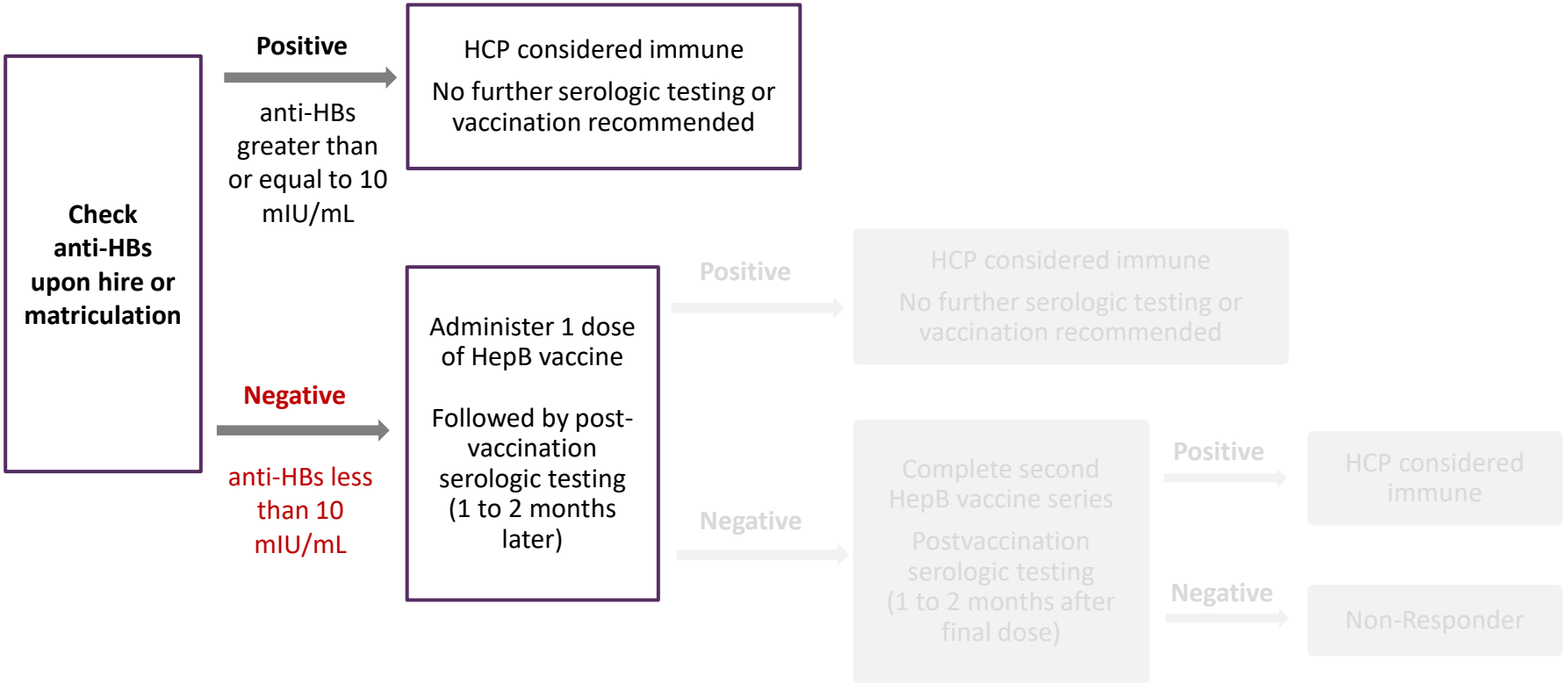
HCP with Documentation of Complete Vaccine Series But No Anti-HBs Results



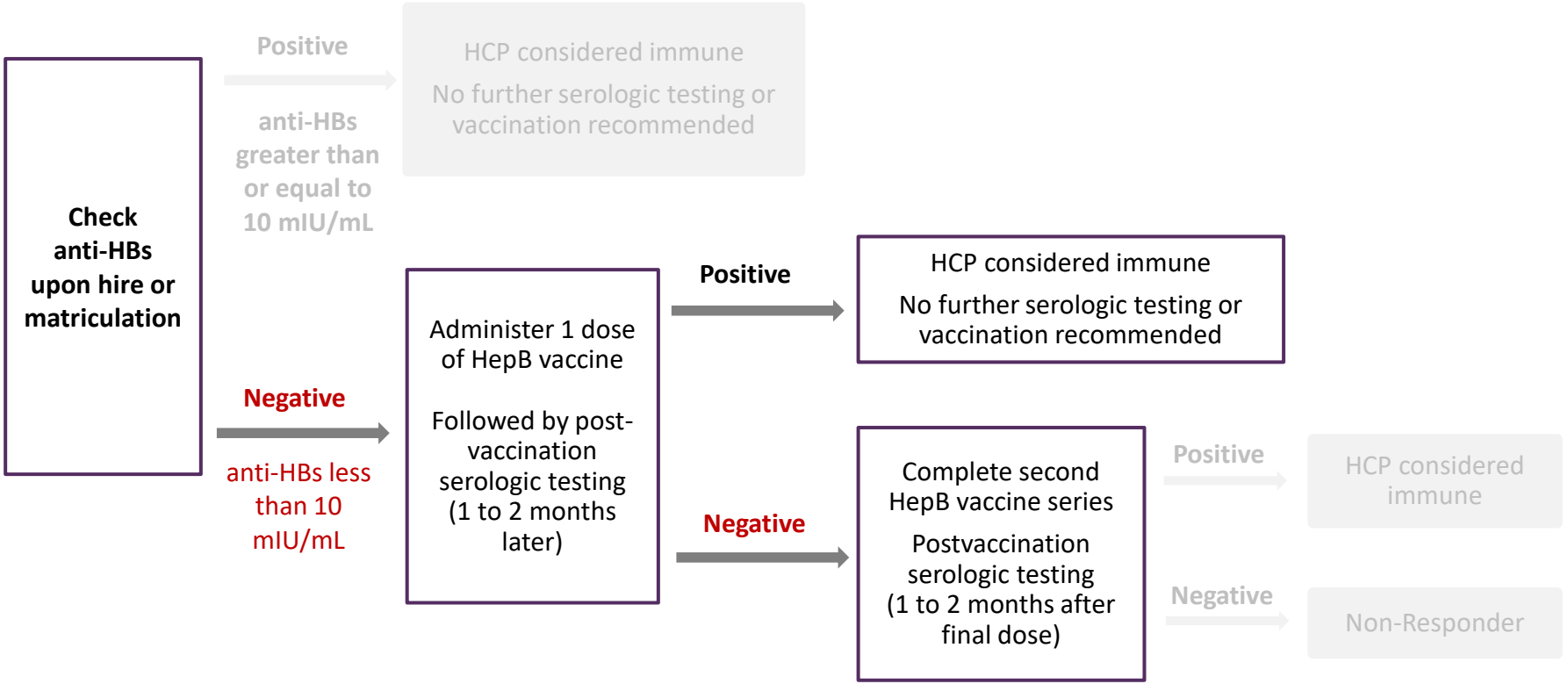
HCP with Documentation of Complete Vaccine Series But No Anti-HBs Results



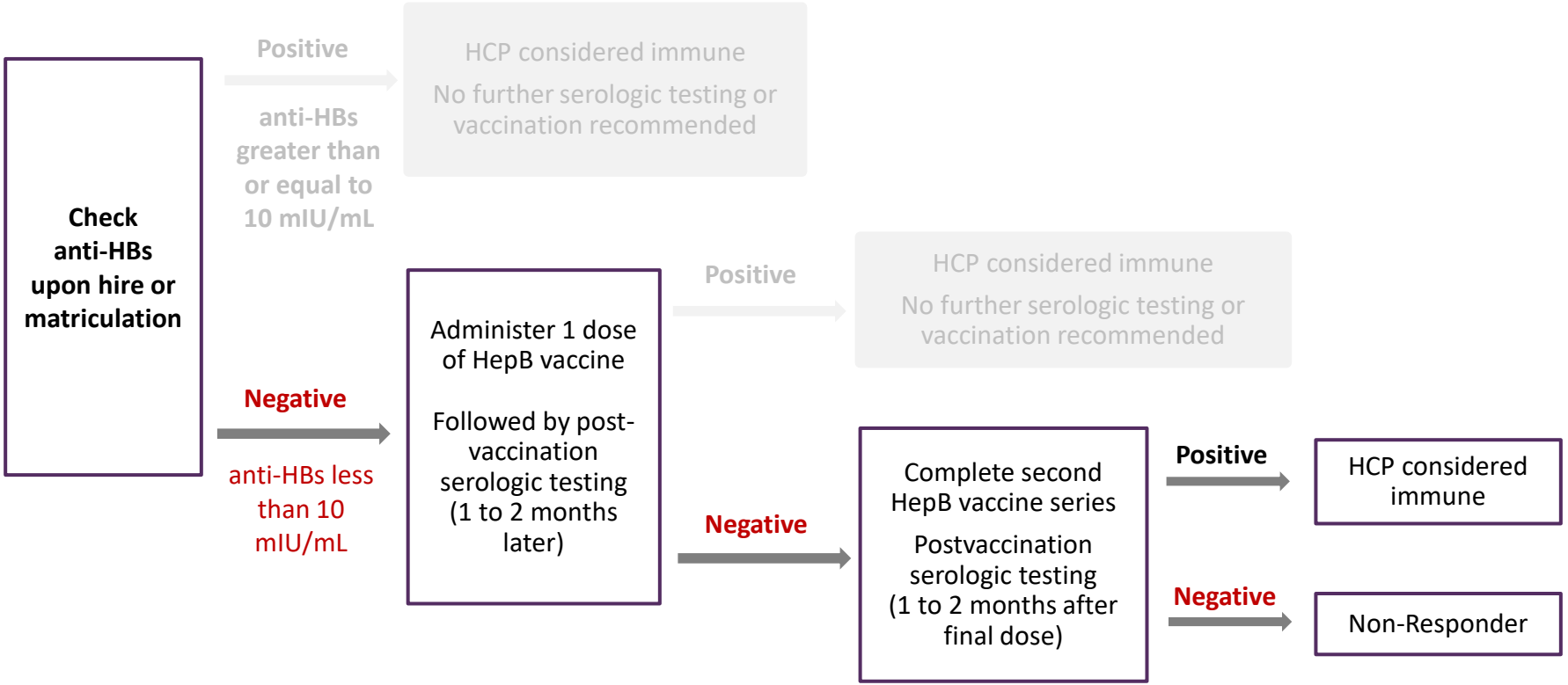
HCP with Documentation of Complete Vaccine Series But No Anti-HBs Results



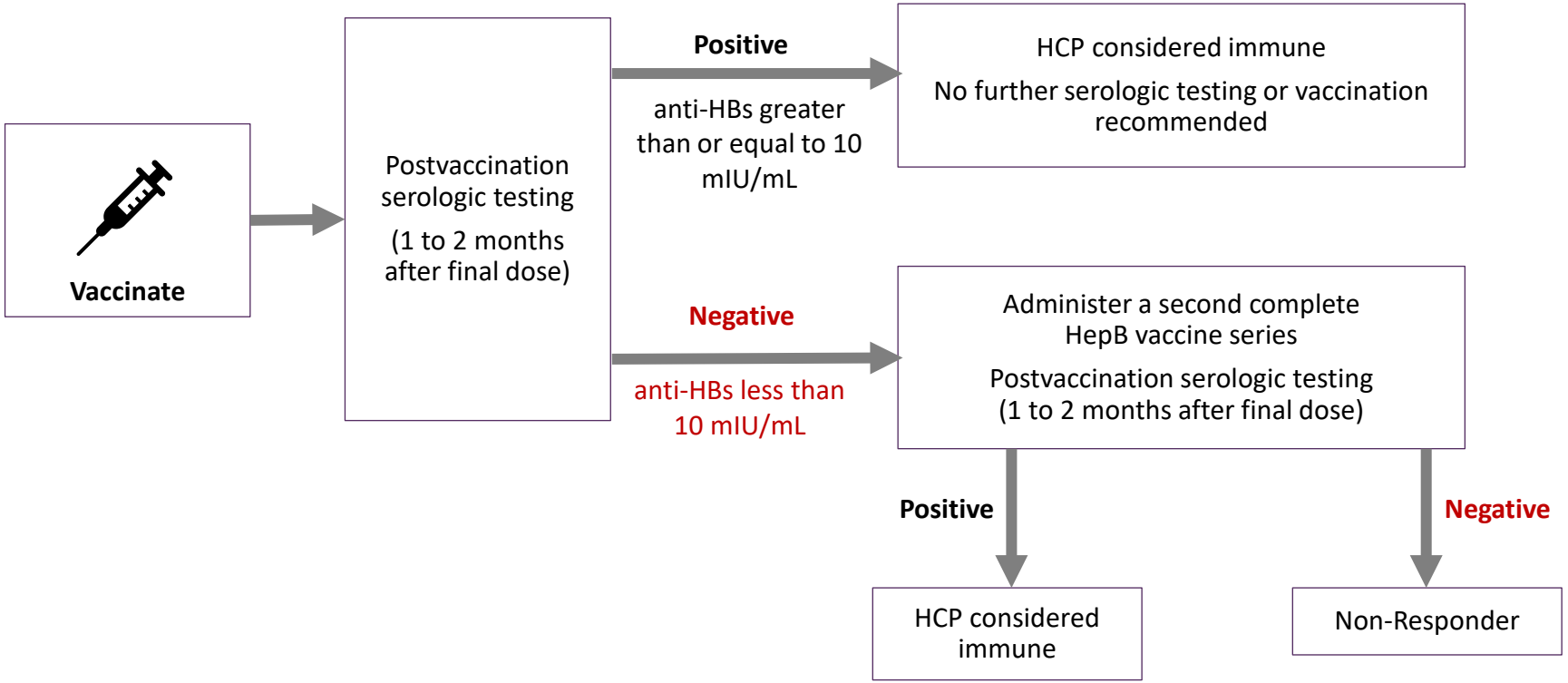
HCP with Documentation of Complete Vaccine Series But No Anti-HBs Results



HCP with Documentation of Complete Vaccine Series But No Anti-HBs Results

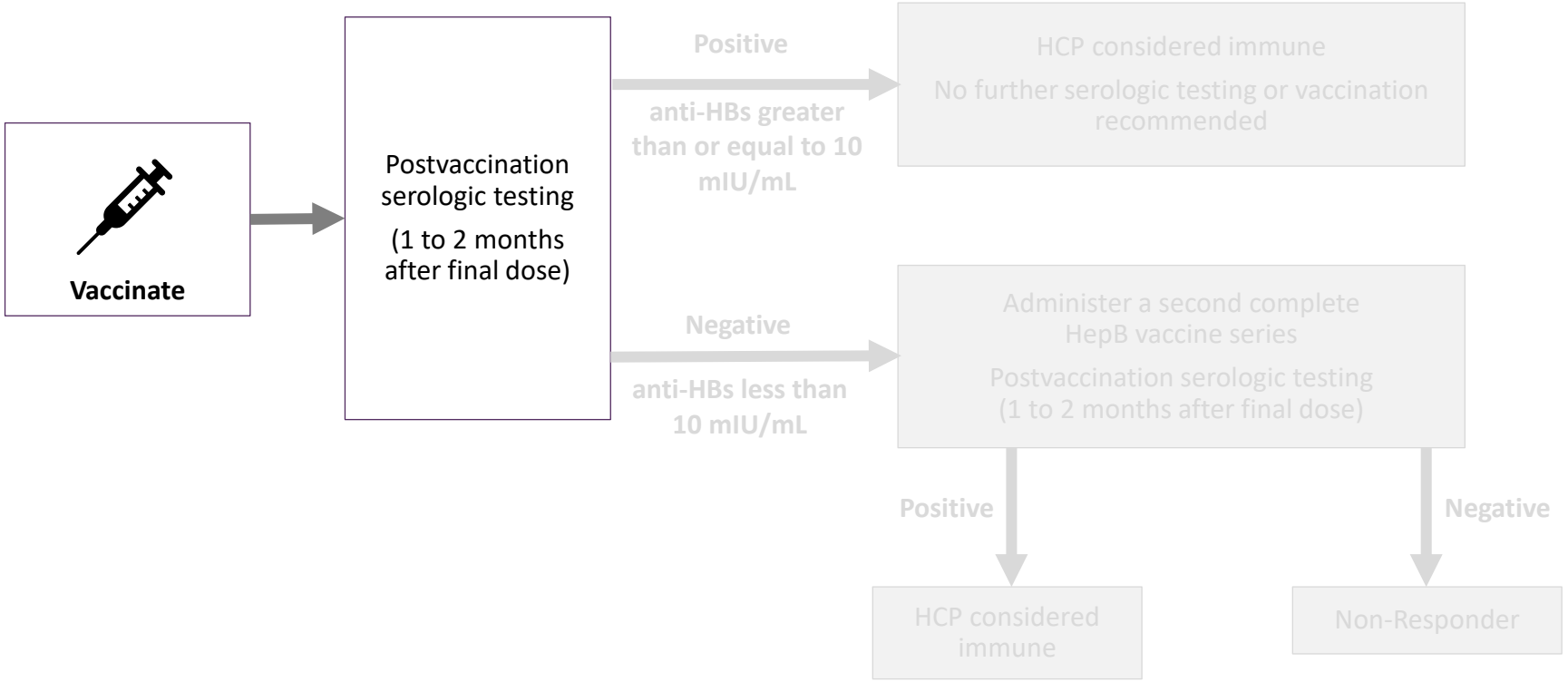


Unvaccinated or Incompletely Vaccinated HCP

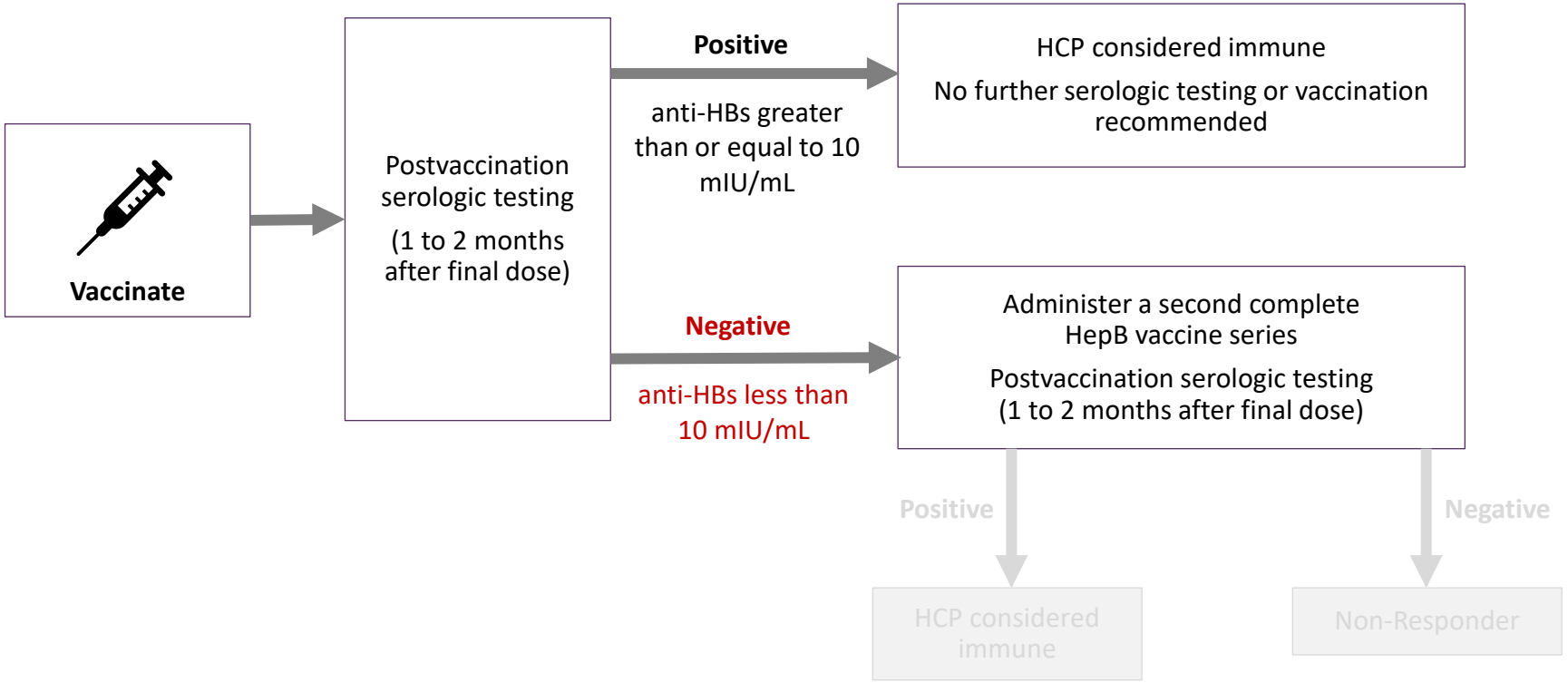


Unvaccinated or Incompletely Vaccinated HCP

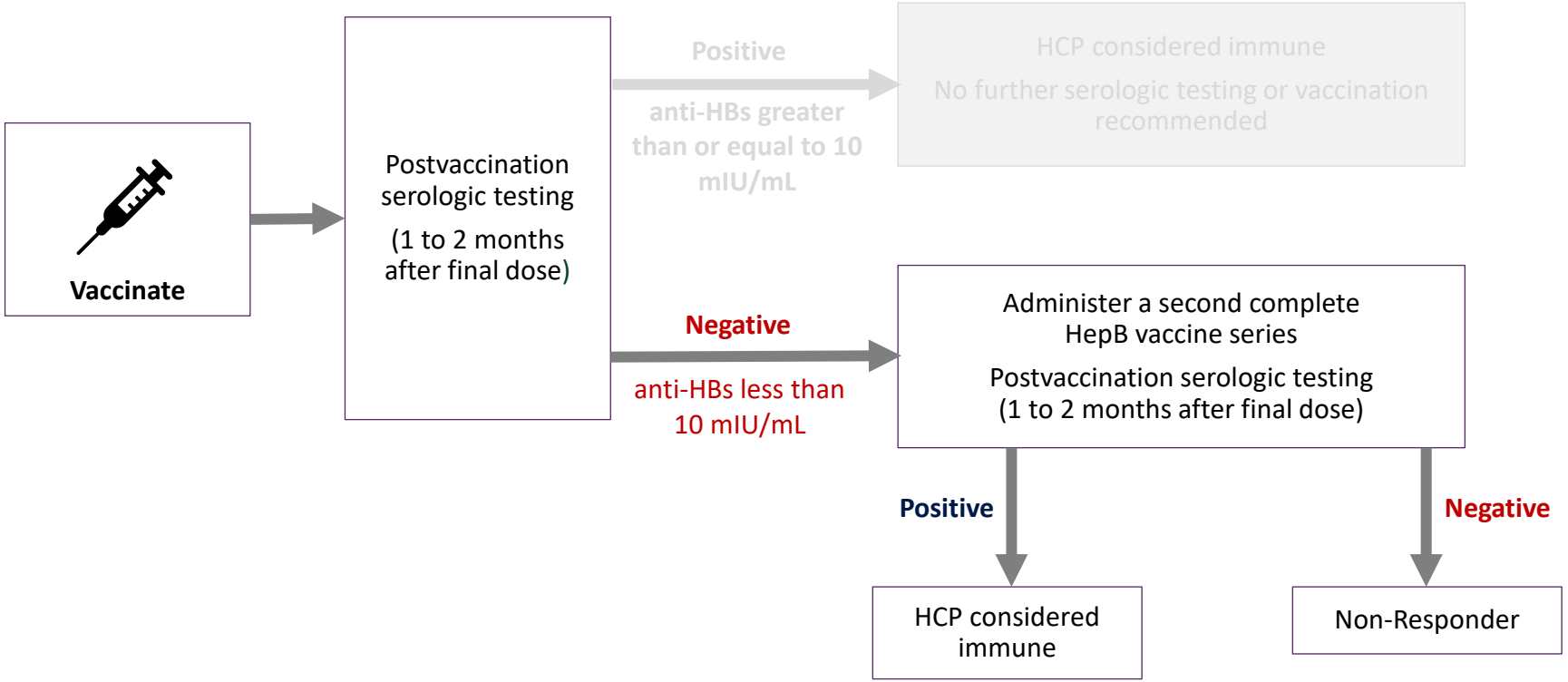
Unvaccinated or Incompletely Vaccinated HCP



Unvaccinated or Incompletely Vaccinated HCP



Unvaccinated or Incompletely Vaccinated HCP



Persistent Nonresponse to HepB Vaccine

- **Fewer than 5% of vaccinated persons do not develop anti-HBs after six (6) valid doses.**
  - May be nonresponder or “hyporesponder”
- **Test for chronic HBV infection (HBsAg and anti-HBc)**
- **If exposed, treat as nonresponder with postexposure prophylaxis (HBIG)**

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Postexposure Prophylaxis of Vaccinated HCP

- **HCP with written documentation of a complete HepB vaccine series and *with* subsequent documented anti-HBs ≥10 mIU/mL**
  - Testing the source patient for HBsAg is unnecessary.
  - No postexposure prophylaxis for HBV is necessary, regardless of the source patient's HBsAg status.
- **HCP with written documentation of a complete HepB vaccine series and *without* previous antiHBs testing**
  - HCP should be tested for anti-HBs *and*
  - Source patient (if known) should be tested for HBsAg as soon as possible after the exposure.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Postexposure Prophylaxis of Unvaccinated or Incompletely Vaccinated HCP (1)

- **Source patient should be tested for HBsAg as soon as possible.**
  - Testing unvaccinated or incompletely vaccinated HCP for anti-HBs is ***not*** necessary and is potentially misleading.
- **If source patient is HBsAg-positive or has an unknown HBsAg status, HCP should:**
  - Receive 1 dose of HBIG and 1 dose of HepB vaccine
  - Complete the HepB vaccine series.
    - To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed approximately 1–2 months after the final vaccine dose.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Postexposure Prophylaxis of Unvaccinated or Incompletely Vaccinated HCP (2)

- **If source patient is HBsAg-negative**
  - HCP should complete the HepB vaccine series.
  - To document the vaccine response status, anti-HBs testing should be performed approximately 1–2 months after the final vaccine dose.
    - HCP with anti-HBs ≥10 mIU/mL after receipt of the primary vaccine series are considered immune.
    - HCP with anti-HBs <10 mIU/mL after receipt of the primary series should be *revaccinated*.
      - 2nd complete series should be followed by anti-HBs testing 1–2 months after the final dose.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Health Care Personnel and Postexposure Management

TABLE 5. Postexposure management of health care personnel after occupational percutaneous or mucosal exposure to blood or body fluids, by health care personnel HepB vaccination and response status

	Postexposure testing		Postexposure prophylaxis		
HCP status	**Source patient (HBsAg)**	**HCP testing (anti-HBs)**	**HBIG**	**Vaccination**	**Postvaccination serologic testing**
Documented responder after complete series			No action needed		
Documented nonresponder after two complete series	Positive/unknown	—*	HBIG x2 separated by 1 month	—	N/A
	Negative		No action needed		
Response unknown after complete series	Positive/unknown	<10 mIU/mL	HBIG x1	Initiate revaccination	Yes
	Negative	<10 mIU/mL	None	Initiate revaccination	Yes
	Any result	≥10 mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	—	HBIG x1	Complete vaccination	Yes
	Negative	—	None	Complete vaccination	Yes

Abbreviations: anti HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen; HCP = health care personnel; N/A = not applicable.
* Not indicated.

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices | MMWR

Knowledge Check

A medical-school student has written, documentation of a completed, age-appropriate series during infancy but no documentation of a titer which he needs for clinicals. What is the first step towards documenting immunity?

A. Another dose of Hepatitis B vaccine

B. Another complete, 3-dose Hepatitis B vaccine series

C. An anti-HBs test

D. An HBsAg test

Knowledge Check

A medical-school student has written, documentation of a completed, age-appropriate series during infancy but no documentation of a titer which he needs for clinicals. What is the first step towards documenting immunity?

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B. Another complete, 3-dose Hepatitis B vaccine series

C. An anti-HBs test

D. An HBsAg test

5

Safety

Contraindications

- **Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component**
- **Hypersensitivity to yeast**

Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)
Twinrix (fda.gov)

Precautions

- **Moderate or severe acute illness with or without fever**

Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)
Twinrix (fda.gov)

Common Side Effects

Soreness, redness, or swelling in the arm where the shot was given

Fever

Headache

Hepatitis B Vaccine Safety | Vaccine Safety | CDC

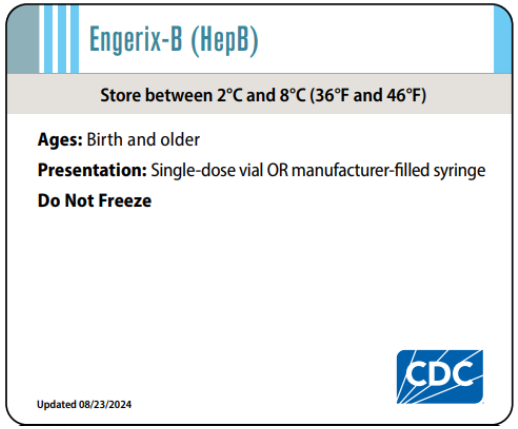
6 Storage and Handling

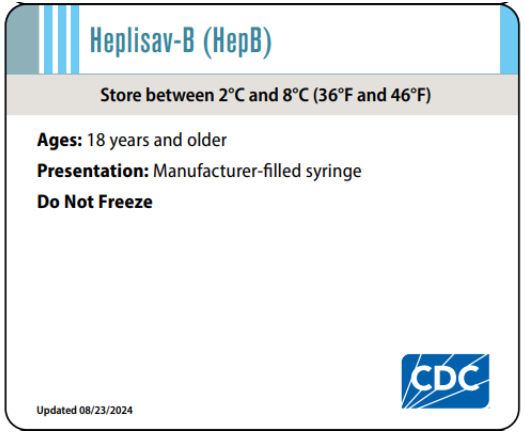
HepB Vaccine Storage and Handling

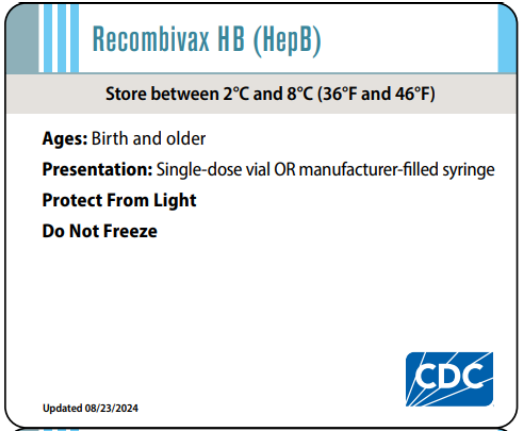
- **Store HepB-containing vaccines in a refrigerator between 2°C and 8°C (36°F and 46°F).**
- **Do not freeze.**
- **Store in the original packaging with the lids closed in a clearly labeled bin and/or area of the storage unit.**
- **Store pediatric and adult formulations separately, away from each other and other look- or sound-alike vaccines (e.g., HepA, Hib, HPV).**

Package Insert - PEDIARIX (fda.gov)
Package Insert - VAXELIS (fda.gov)
Twinrix (fda.gov)

Storage Labels for HepB Single Component Vaccines

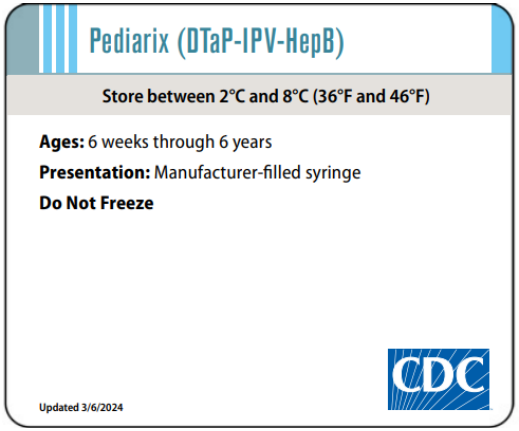


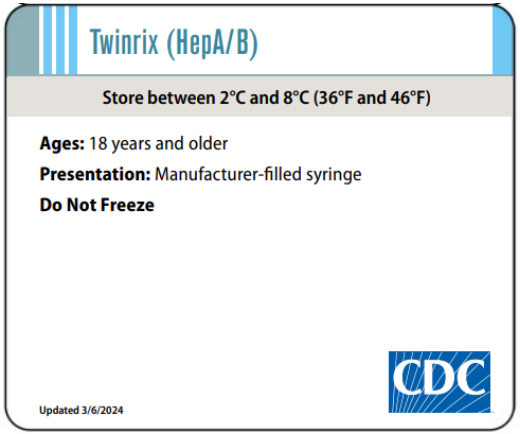


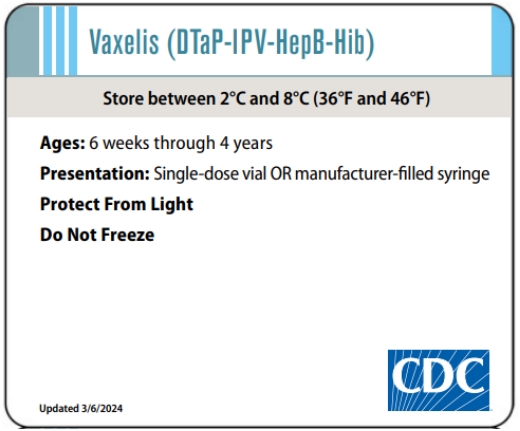


Vaccine Labels: Storage and Beyond-Use Date Tracking (cdc.gov)

HepB Combination Vaccine Storage Labels







[Vaccine Labels: Storage and Beyond-Use Date Tracking (cdc.gov)]

7

Hepatitis B Resources

CDC Clinical Resources

- www.cdc.gov/vaccines/
  - Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations and Guidelines
  - Recommended Immunization Schedules
  - You Call The Shots (YCTS)
  - Vaccine Storage and Handling Toolkit
  - Vaccine Information Statements

Pink Book Training Materials

Continuing Education Information

- To claim continuing education (CE) for this course, please follow the steps below by July 1, 2026.
- Search and register for course **WD4810-091924** in **CDC TRAIN**.
- Pass the post-assessment at 80%.
- Complete the evaluation.
- Visit “Your Learning” to access your certificates and transcript.
- If you have any questions, contact **CDC TRAIN** at train@cdc.gov or CE Coordinator, Melissa Barnett, at MBarnett2@cdc.gov

https://www.train.org/cdctrain/welcome

Email Us Your Immunization Questions:

nipinfo@cdc.gov

Thank You From Atlanta!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.