



Hepatitis B Vaccines

Pink Book Web-on-Demand Series **September 27, 2022**

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Learning Objectives

- Describe the Advisory Committee on Immunization Practices General Best Practice Guidelines on Immunization.
- 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.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: **WD4564-092722**
- CE credit expires: **July 1, 2024**
- CE instructions are available on the **Pink Book Web-on-Demand Series** web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

The screenshot shows the TCEO website interface. At the top, there is a blue header with the text "Training and Continuing Education Online (TCEO)". Below the header is the TCEO logo, which consists of the letters "TCEO" in a bold, blue font, with a green circular arrow icon to the right. Underneath the logo, the text "TRAINING AND CONTINUING EDUCATION ONLINE" is displayed in a smaller, blue font. To the left of the main content area is a vertical navigation menu with five blue buttons: "TCEO Home", "Search Courses", "Create Account", "9 Simple Steps to Earn CE", "Frequently Asked Questions", and "Contact TCEO". The main content area has a white background and contains three sections of text. The first section is titled "New to TCEO?" and includes the text "Visit Create Account. Once your account has been created, you will be able to search for courses and complete requirements to receive CE." The second section is titled "Already have a TCEO account from the previous system?" and includes the text "To move your account to the new system please sign in above using your existing TCEO username and password. Once signed in, follow the prompts to verify and update your account. After your account is verified, you will use this email address and password to sign in." The third section is titled "Not sure how to get started?" and includes the text "Follow these 9 Simple Steps to earn continuing education for the courses you have taken or conferences you have attended!". Below the text sections is a row of four small images: a woman in scrubs talking to a child, a man in a suit looking at a screen, a doctor in a white coat holding a dog, and a woman sitting at a desk working on a laptop. At the bottom of the page, there is a "Welcome to TCEO" heading and a short paragraph of introductory text.

Disclosure Statements

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Disclosure Statements

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.

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**Hepatitis B
Disease**

Serologic Markers for Hepatitis B Virus (HBV) Infection

- **HBsAg (hepatitis B surface antigen)**
 - Indicative of current HBV infection
- **Anti-HBs (antibody to hepatitis B surface antigen)**
 - Generally indicative of immunity to HBV infection; can be from vaccination or prior infection
- **Anti-HBc (antibody to hepatitis B core antigen)**
 - IgM anti-HBc: indicative of acute or recent infection
 - IgG anti-HBc: indicative of past infection
- **HBeAg* (hepatitis B e antigen)**
 - Associated with increased infectivity
- **Anti-HBe (antibody to hepatitis B e antigen)**
 - Associated with decreased infectivity

*Largely replaced by HBV DNA testing

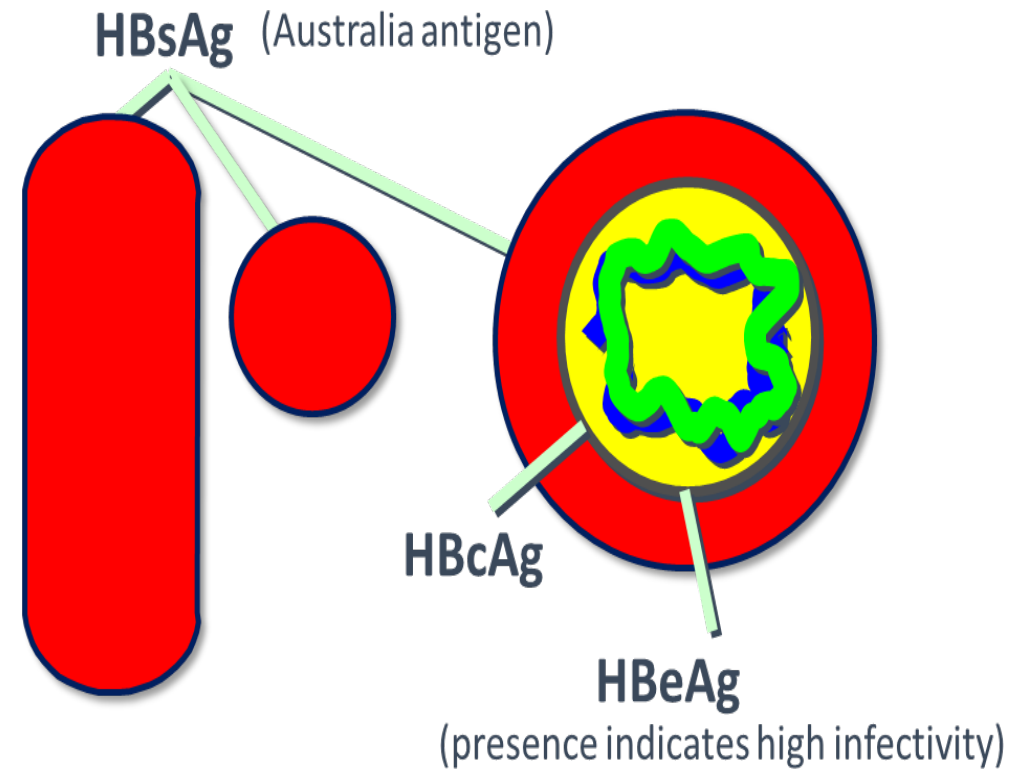
Hepatitis B Virus (HBV)

■ Hepadnaviridae family

- Partially double-stranded DNA genome
- Humans only known host

■ Highly transmissible

- May retain infectivity for more than 7 days on environmental surfaces



Hepatitis B Virus (HBV) Infection

296 million
chronic infections
worldwide

Causes
50%
of hepatocellular
carcinomas

**880,000–
2.4 million**
U.S. chronic
infections

820,000
deaths
worldwide

Hepatitis B Epidemiology

Reservoir

Human

Transmission

Percutaneous (i.e., puncture through the skin) or mucosal contact with infectious blood or body fluids (e.g., semen)

Communicability

Persons with either acute or chronic HBV infection with HBsAg present in blood

1–2 months before and after onset of symptoms

Risk Factors for Hepatitis B Virus (HBV) Infection

- Sex partners of HBV-infected persons
- Sexually-active persons not in a long-term, mutually monogamous relationship
- Persons seeking evaluation for treatment of STI
- Men who have sex with men
- Persons who use injection drugs
- Household contacts of persons with HBV
- Persons with diabetes
- Persons at risk for occupational exposure to HBV
- Residents and staff of facilities for developmentally disabled persons
- Dialysis patients
- Persons with HCV infection
- Persons with chronic liver disease
- Travelers to countries where HBV is endemic
- Persons with HIV
- Persons who are incarcerated

Hepatitis B Clinical Features

- **Incubation period 60-150 days (average 90 days) until onset of jaundice**
- **Nonspecific prodrome of malaise, fever, headache, myalgia**
- **Icteric phase with jaundice, light stools, hepatic tenderness**
- **Children younger than 5 years and newly infected immunosuppressed adults generally asymptomatic**
 - 30%-50% of persons 5 years and older have signs and symptoms

Hepatitis B Complications

- Fulminant hepatitis (<1%)
- Cirrhosis
- Hepatocellular carcinoma
- Death

Acute infection



Chronic infection

Chronic Hepatitis B – 4 Phases

■ Immune tolerant

- Minimal or no hepatic inflammation or fibrosis

■ Immune active

- Hepatic inflammation with or without fibrosis

■ Immune inactive

- Improvement of hepatic inflammation and fibrosis

■ Reactivation

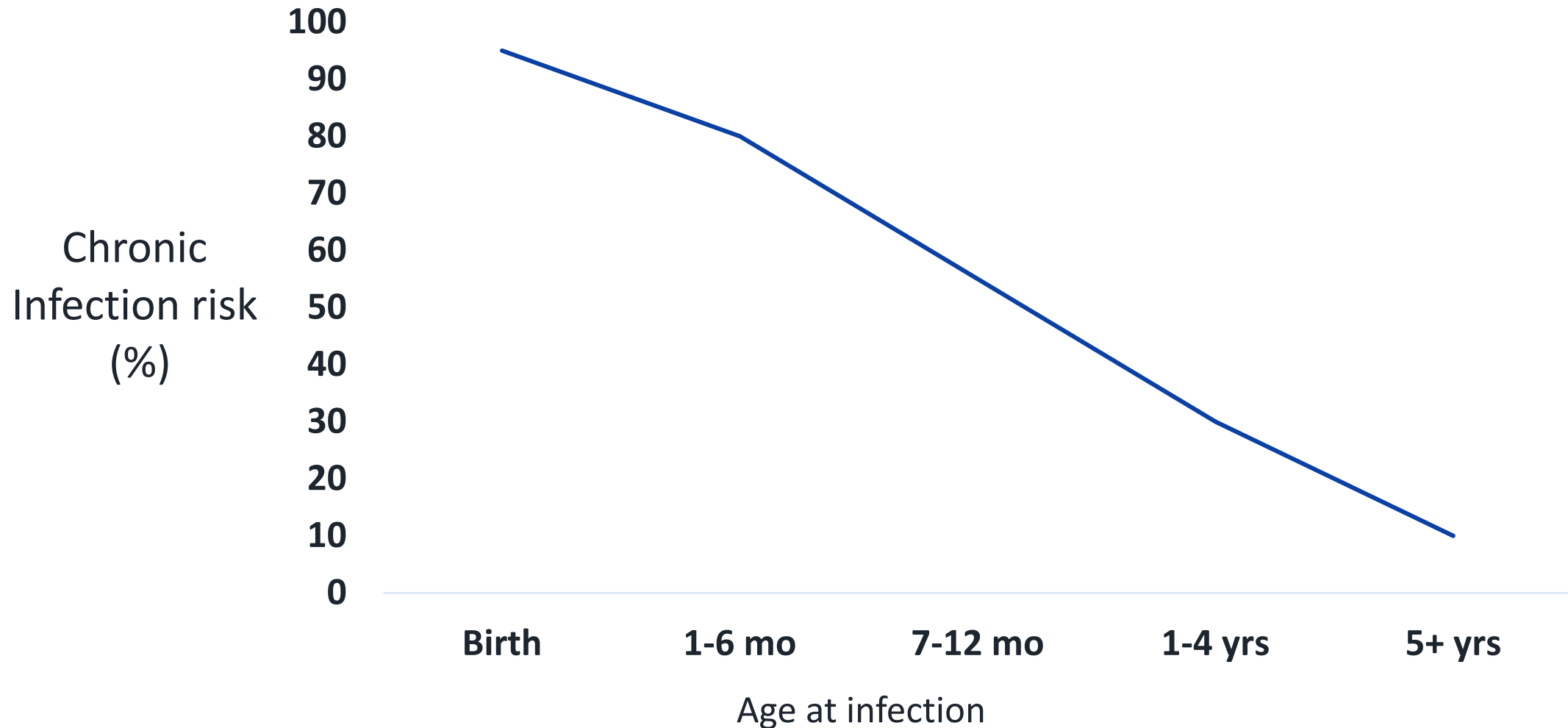
- Active hepatic inflammation with or without fibrosis

Chronic Hepatitis B

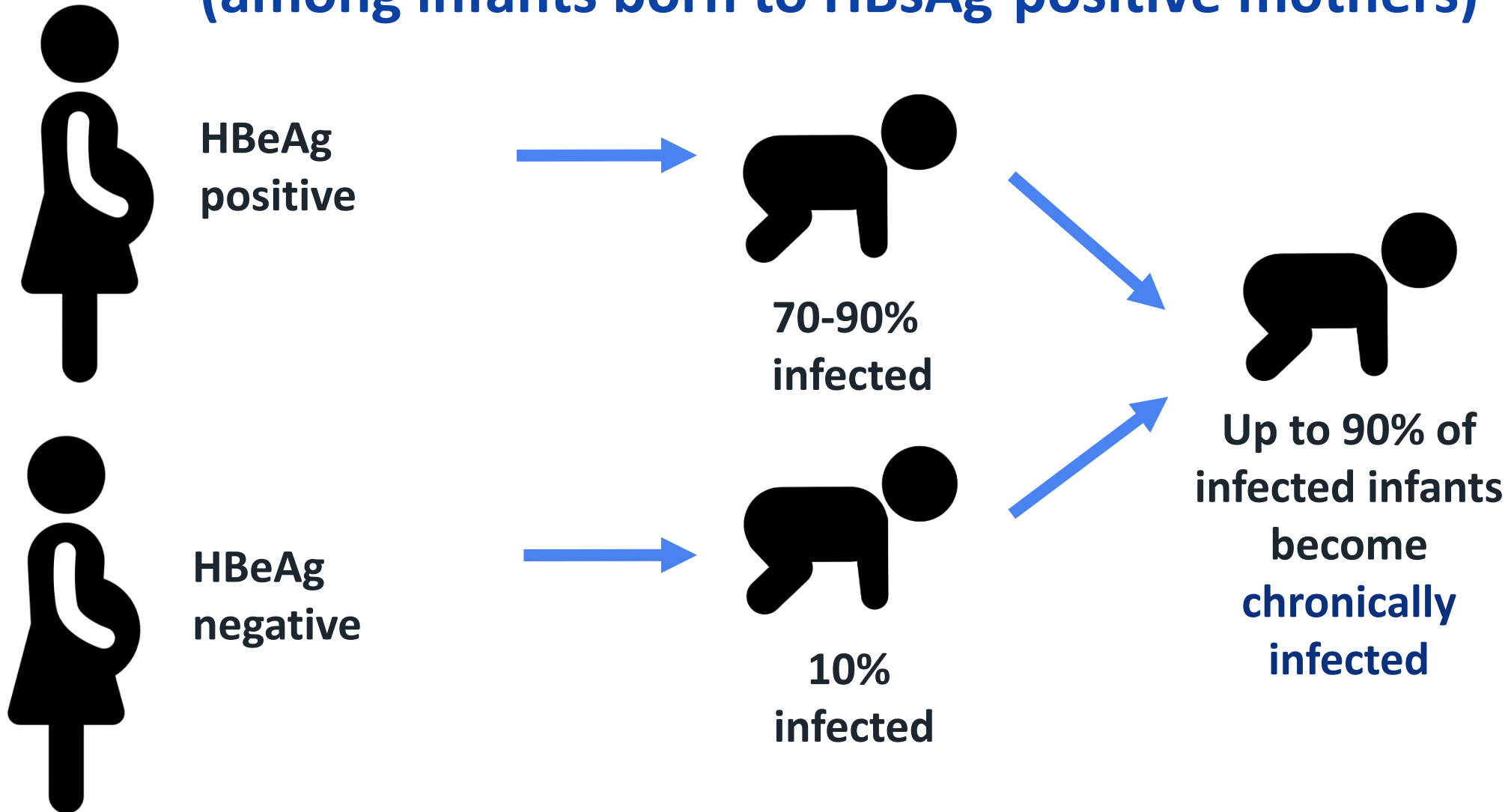
- **Chronic hepatitis B develops in:**
 - 80%-90% of persons infected during infancy
 - 30% of persons infected before age 6 years
 - 1%-12% of persons infected as an older child or adult

- **Approximately 25% of persons chronically infected during childhood and 15% chronically infected after childhood will die prematurely from cirrhosis or liver cancer**

Risk of Chronic Hepatitis B by Age at Infection



Perinatal Hepatitis B Virus (HBV) Transmission (among infants born to HBsAg-positive mothers)*



*In the absence of postexposure prophylaxis

Perinatal Hepatitis B Virus (HBV) Infection

- **Post-exposure prophylaxis prevents 85%-95% of perinatal hepatitis B virus infections**
 - Infants with perinatal hepatitis B have ~90% risk for chronic infection
 - ~25% risk of premature death from cirrhosis/liver cancer
- **All pregnant people should be tested routinely for HBsAg during an early prenatal visit**
 - Testing should occur during each pregnancy, even if pregnant person has been previously vaccinated or tested

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

- **Prevent perinatal HBV transmission**
 - Routine testing of all pregnant people for HBsAg
 - Prophylaxis (HepB vaccine and HBIG) for infants born to HBsAg-positive pregnant people
 - HBV DNA testing for HBsAg-positive pregnant people and antiviral therapy if HBV DNA is greater than 200,000 IU/mL
- **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**

Weng MK, Doshani M, Khan MA, et al. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:477–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7113a1>

Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2018;67(No. RR-1):1–31. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1external icon>.

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**Hepatitis B
Vaccines**

Hepatitis B Child and Adult Vaccination Schedule

Vaccine	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)	1 st dose	← 2 nd dose →			← 3 rd dose →												

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			

- Non-live vaccines
- Administered by IM (Intramuscular) injection

Hepatitis B-Containing Vaccine Products*

Vaccine product	Age indications
Single-component vaccines	
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	
PreHevbrio	
18 years and older	
Combination vaccines	
Pediarix–DTaP, HepB, and IPV vaccines	6 weeks–6 years
Vaxelis–DTaP, IPV, Hib, and HepB vaccines	6 weeks–4 years
Twinrix–HepA and HepB vaccines	18 years and older

*ACIP does not state a preference

Hepatitis B (HepB) Vaccines

	Engerix-B*	Recombivax HB†	Hepelisav-B	PreHevbrio
Composition	Recombinant HBsAg	Recombinant HBsAg	Novel Adjuvanted Recombinant HBsAg	3 Antigen Recombinant HBsAg
Schedule	3 doses	3 doses	2 doses	3 doses
Route	IM	IM	IM	IM

*Pediatrix contains the pediatric formulation of Engerix-B and Twinrix contains the adult formulation of Engerix-B

†Vaxelis contains the pediatric formulation of Recombivax HB but in an increased amount

Recommended Dosage of HepB Vaccines

	Engerix-B* Dose (mcg)	Recombivax HB† Dose (mcg)	Heplisav-B Dose (mcg)	PreHevbrio Dose (mcg)
Children: Birth through 19 years	0.5 mL (10)	0.5 mL (5)	N/A	N/A
Adults: 20 years and older	1 mL (20)	1 mL (10)	0.5 mL (20) ≥18 years	1 mL (10) ≥18 years

*Pediatrix contains the pediatric formulation of Engerix-B and Twinrix contains the adult formulation of Engerix-B

†Vaxelis contains the pediatric formulation of Recombivax HB but in an increased amount

Combination Vaccines

■ Pediarix (DTaP-HepB-IPV)

- Ages: 6 weeks–6 years
- Routine schedule: 2, 4, 6 months of age
- Approved for dose 2, 3, 4 of HepB series (do NOT use for the birth dose)
 - Administering 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

Combination Vaccines, cont.

■ Vaxelis (DTaP-IPV-Hib-HepB)

- Ages: 6 weeks–4 years
- Routine schedule: 2, 4, 6 months of age
- Approved for dose 2, 3, 4 of HepB series (do NOT use for the birth dose)
 - Administering 4 doses of HepB is acceptable when a combination vaccine containing HepB is used after the birth dose
- Vaxelis contains the pediatric formulation of Recombivax HB but in an increased amount

Combination Vaccines, cont.

■ 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

Anti-HBs and Vaccine-Induced Protection

- **Anti-HBs ≥ 10 mIU/mL is a correlate of vaccine-induced protection when following a complete, ≥ 3 -dose vaccine series**
 - “Responders”
- **Anti-HBs after HepB vaccine series wanes over time**
 - Even when anti-HBs decreases to < 10 mIU/mL, breakthrough HBV infection is uncommon in immunocompetent vaccine responders
- **Anti-HBs < 10 mIU/mL at a time distant from vaccine completion does not distinguish responders from non-responders**

Factors Associated with Decreased HepB Vaccine Immunogenicity

- Prematurity
- Immunosuppression
- HIV
- Hemodialysis
- Older Age
- Diabetes
- Tobacco smoking

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**Clinical
Considerations**

ACIP HepB Vaccine Recommendations: Children

- Routinely recommended for all children birth through 18 years of age
- Vaccinate previously unvaccinated children and those missing doses
 - “Catch-up”

Vaccine	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)	1 st dose	2 nd dose			← 3 rd dose →												

HepB Schedule: Routine Infant

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

†The birth dose of single-component hepatitis B vaccine should be administered within 24 hours of birth for medically stable infants weighing $\geq 2,000$ 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

Birth Dose Considerations: Birth Weight 2000 grams or more

HBsAg-*NEGATIVE*
mother



Administer HepB
vaccine within
24 hours of birth

HBsAg-*POSITIVE*
mother



Administer HepB
vaccine and HBIG*
within 12 hours of birth

HBsAg *UNKNOWN*
mother



Administer HepB
vaccine within 12 hours
of birth and test to
determine mother's
status ASAP

*Administer HepB vaccine and HBIG in separate limbs

Birth Dose Considerations: Birth Weight Less Than 2000 grams

HBsAg-*NEGATIVE*
mother



Administer HepB vaccine at hospital discharge or at 1 month of age

HBsAg-*POSITIVE*
mother



Administer HepB vaccine and HBIG* within 12 hours of birth

HBsAg-*UNKNOWN*
mother



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

*Administer HepB 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.**
 - HepB vaccine and HBIG can be administered at the same time, in different limbs
 - HepB and HBIG are both 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 mo, 2-3 mo, 6 mo
- **Perform Post-Vaccination Serologic Testing (PVST) at 9-12 months of age, i.e., the next well-child check following completion of the HepB vaccine series**
 - Check HBsAg and anti-HBs

Medical Considerations: Infants Whose Mothers are Hepatitis B Surface Antigen UNKNOWN

- **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 mother is determined to be hepatitis B surface antigen-positive, give HBIG as soon as possible, but no later than age 7 days
 - Infants weighing less than 2000 grams: If the mother tests positive or HBsAg status cannot be determined, administer HBIG within 12 hours of birth
- **Perform Post-Vaccination Serologic Testing (PVST) at 9-12 months of age, i.e., the next well-child check following completion of the HepB vaccine series**
 - Check HBsAg and anti-HBs

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



Answer

- 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**



Post-Vaccination Serologic Testing (PVST)

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

PVST Considerations

- **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**
 - Passively acquired maternal anti-HBc might be detected in infants born to HBV-infected mothers up to age 24 months
- **Delayed PVST may result in false negative anti-HBs and unnecessary revaccination**

PVST Interpretation

- **HBsAg negative infants with anti-HBs ≥ 10 mIU/mL: 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; if anti-HBs remains < 10 mIU/mL administer 2 more doses to complete the 2nd series and again perform PVST
 - A second 3-dose series and PVST 1-2 months after the final dose of vaccine
- **HBsAg positive infants: Should receive appropriate follow-up**

Importance of Ordering Both Tests

- **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

Knowledge Check

- Which of the following regarding postvaccination serologic testing of infants is true?
 - A. Testing should occur between 9-12 months of age
 - B. Testing should be performed for infants born to HBsAg-positive and HBsAg-negative mothers
 - C. Testing consists of anti-HBs testing only
 - D. Infants with anti-HBs less than 10 mIU/mL are deemed protected

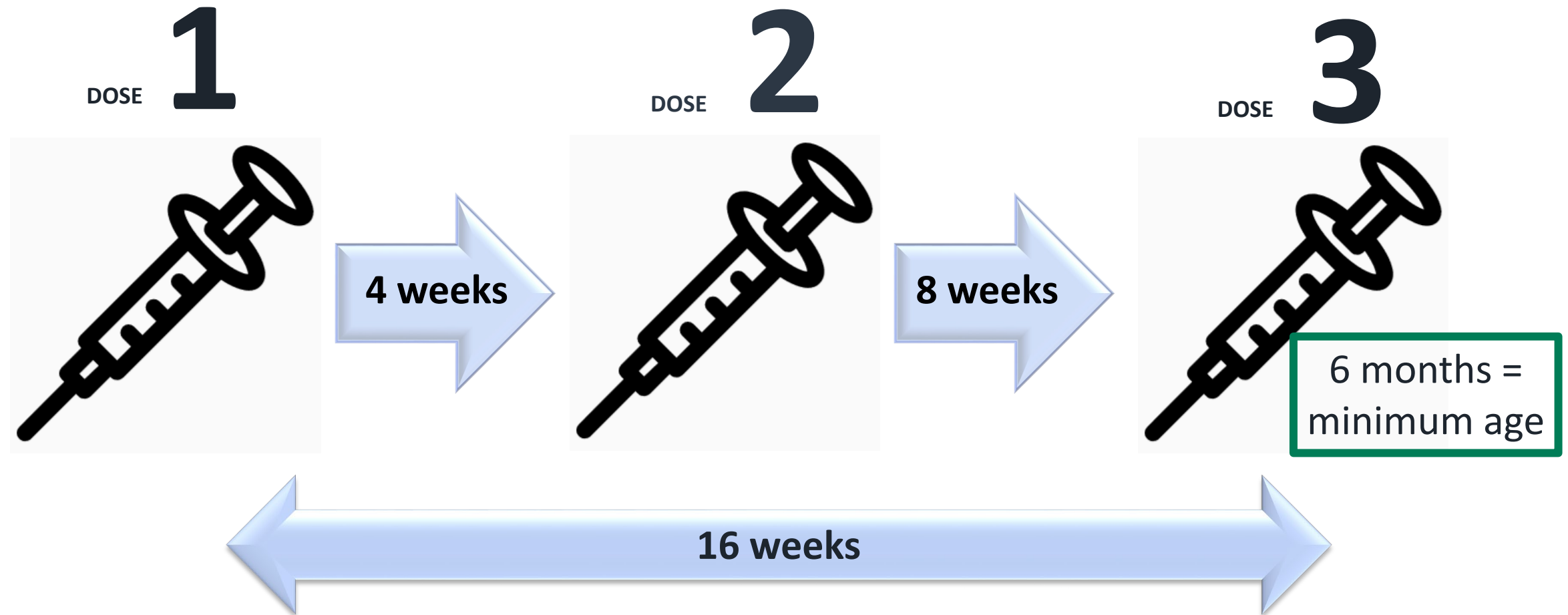


Answer

- Which of the following regarding postvaccination serologic testing of infants is true?
 - A. Testing should occur between 9-12 months of age
 - ~~B. Testing should be performed for infants born to HBsAg-positive and HBsAg-negative mothers~~
 - ~~C. Testing consists of anti-HBs testing only~~
 - ~~D. Infants with anti-HBs less than 10 mIU/mL are deemed protected~~



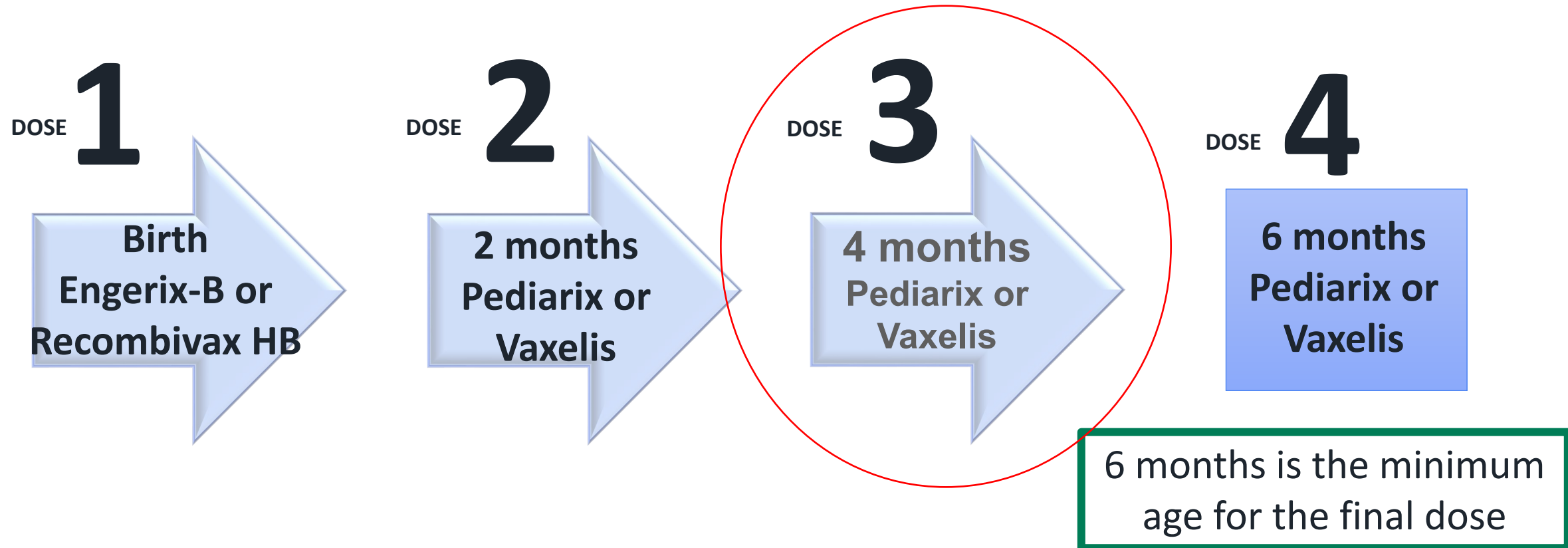
HepB Vaccine Schedule: Minimum Age and Intervals



4-day grace period can be applied to minimum age and intervals

Pediarix or Vaxelis Schedule Considerations

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



ACIP HepB Vaccine Recommendations: Adults

- Vaccination recommended for unvaccinated adults 19–59 years of age, and adults 60 years and older at risk for HBV infection
 - Acknowledgement of a specific risk factor not required

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			

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease, on hemodialysis	Heart or lung disease, alcoholism ¹	Chronic liver disease	Diabetes	Health care personnel ²	Men who have sex with men
			<200	≥200							
HepB											2 or 3 doses depending on vaccine

Pregnancy

- **Until safety data are available for Heplisav-B and PreHevbrio, providers should vaccinate pregnant people needing HepB vaccine with either:**
 - Engerix-B
 - Recombivax HB
 - Twinrix

HepB Vaccine Schedule: Adult Recombivax HB, Engerix-B, or PreHevbrio

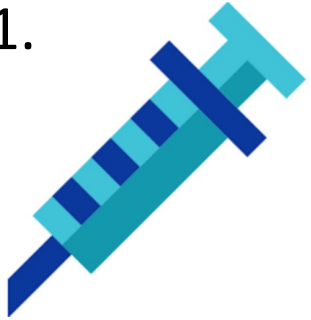
Dose	Routine Interval	Minimum Interval
Dose 1	0 month	---
Dose 2	1 month	4 weeks after Dose 1
Dose 3	6 months	8 weeks after Dose 2 and 16 weeks after Dose 1

HepB Vaccine Schedule: Heplisav (HepB-CpG)

- **2 doses separated by 4 weeks**
- **2-dose HepB series only applies 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

Scenarios

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

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

HepB Vaccine Recommendations: Health Care Personnel (HCP)



- All health care personnel (HCP) whose work-, training-, and volunteer-related activities involve reasonably anticipated risk for exposure to blood or body fluids should be vaccinated with a complete HepB vaccine series.

Evidence of Vaccine-Induced Seroprotection

- **Written documentation of a complete, ≥ 3 -dose HepB vaccine series**

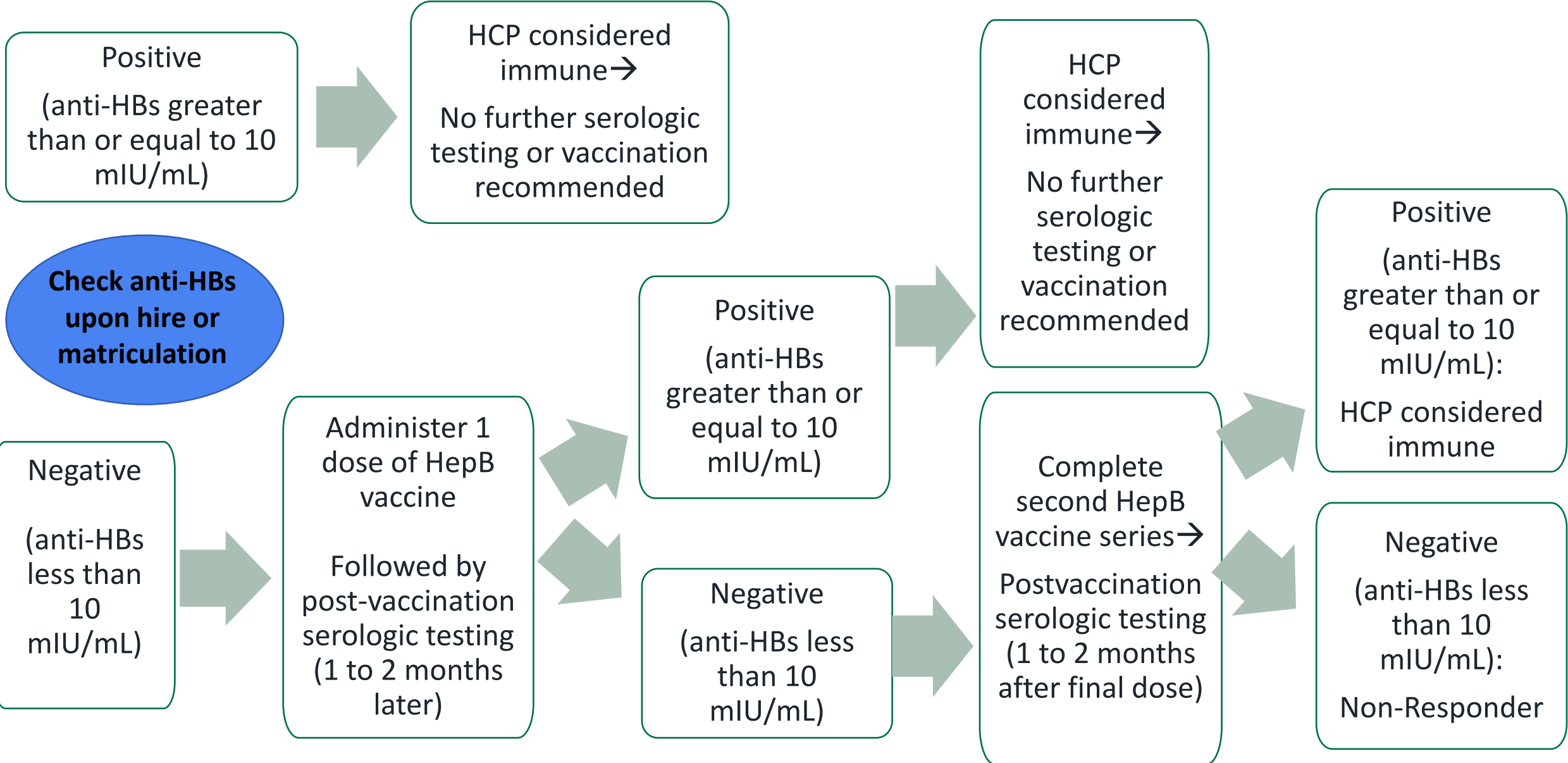
AND

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

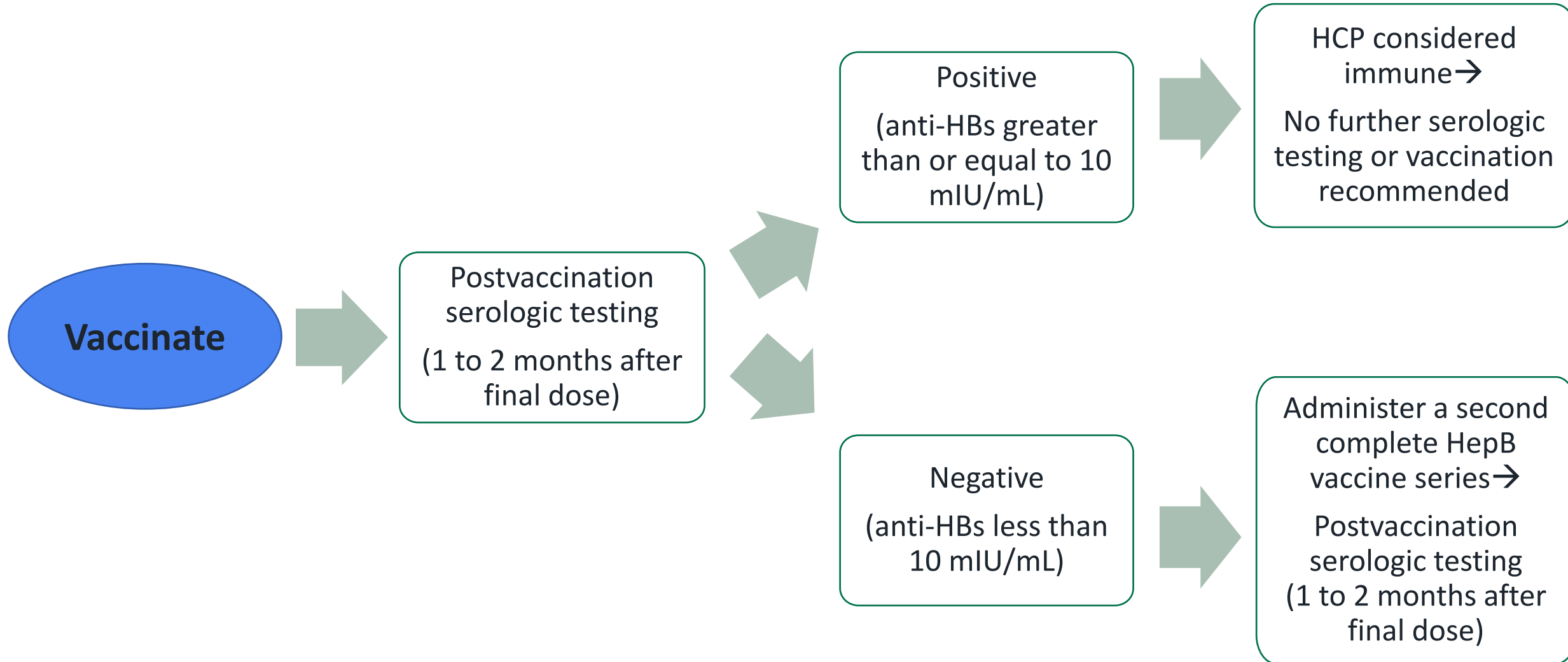
Documentation of Complete Vaccine Series AND Anti-HBs ≥ 10 mIU/mL

- HCP considered immune
- No additional serologic testing or vaccine booster doses
 - As long as they are immunocompetent
- Advise to keep a copy of the vaccination record and positive titer

Documentation of Complete Vaccine Series but No Anti-HBs Results



Unvaccinated or Incompletely Vaccinated



Persistent Nonresponse to HepB Vaccine

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

Healthcare 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

HCP 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 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.

Knowledge Check

- **A student going to medical school has documentation of an age-appropriate HepB vaccine series from infancy but no documentation of a titer. At matriculation, what is the first action to document 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



Answer

- A student going to medical school has documentation of an age-appropriate HepB vaccine series from infancy but no documentation of a titer. At matriculation, what is the first action to document 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~~



Prevaccination Serologic Testing*

■ Recommended for:

- Household, sex, and needle-sharing contacts of HBsAg-positive persons†
- HIV-positive persons†
- Persons with elevated liver enzymes of unknown etiology†
- Hemodialysis patients†
- Men who have sex with men†
- Injection drug users†
- Persons born in countries of high and intermediate hepatitis B virus (HBV) endemicity (HBsAg prevalence $\geq 2\%$)
- U.S.-born persons not vaccinated as infants whose parents were born in countries with high HBV endemicity ($\geq 8\%$)
- Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders
- Donors of blood, plasma, organs, tissues, or semen

*Serologic testing comprises testing for HBsAg, anti-HBs, anti-HBc

†Denotes persons also recommended for hepatitis B vaccination. Serologic testing should occur prior to vaccination

Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1external icon>.

Postvaccination Serologic Testing*

- **Serologic testing is NOT routinely recommended following vaccination of most persons**
- **Recommended for:**
 - Infants born to HBsAg-positive mothers (or to mothers whose HBsAg status remains 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+ persons

*Postvaccination serologic testing for persons other than infants born to HBsAg-positive (or HBsAg-unknown) mothers consists of anti-HBs. Postvaccination serologic testing for infants born to HBsAg-positive (or HBsAg-unknown) mothers consists of anti-HBs and HBsAg.

Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31. DOI: http://dx.doi.org/10.15585/mmwr.rr6701a1external_icon.

Vaccine Administration

■ Route: IM Injection

- Needle gauge: 22 through 25 gauge
- Needle length*: 5/8 through 1.5 inch depending on the patient's age and/or weight

■ Site*

- Birth through 11 months: Vastus lateralis muscle is preferred
- 1 through 2 years: Vastus lateralis muscle is preferred; deltoid muscle may be used if the muscle mass is adequate
- 3 years and older: Deltoid muscle is preferred; vastus lateralis muscle may be used

*Professional judgement should be used to determine the proper needle length and site. Factors influencing site include local reaction, number of vaccines to be administered, age, and muscle mass.

4

Safety

Contraindications

Hepatitis B

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

Hypersensitivity to yeast

Precautions

Hepatitis B

Moderate or severe acute illness with or without fever

Adverse Reactions

Hepatitis B

Anaphylaxis

1.1 cases per million vaccine doses

4

**Storage &
Handling**

Hepatitis B 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)

HepB (Engerix-B)-Pediatric Formulation

Ages: Birth through 19 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepB (Recombivax HB)-Pediatric Formulation

Ages: Birth through 19 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Vial stopper and syringe plunger stopper and tip cap contain latex

HepB (Engerix-B)-Adult Formulation

Ages: 20 years and older
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

HepB (Recombivax HB)-Adult Formulation

Ages: 20 years and older
Use for: Any dose in the series
Alternate Adolescent Schedule for 11 through 15 year olds:
Two 1 mL doses 4 to 6 months apart
Route: Intramuscular (IM) injection

Vial stopper and syringe plunger stopper and tip cap contain latex

5

Resources

Resources

- **Ask the Experts–Hepatitis B FAQs**
 - https://www.immunize.org/askexperts/experts_hepb.asp
- **CDC Viral Hepatitis–Hepatitis B Information:**
 - <https://www.cdc.gov/hepatitis/hbv/index.htm>
- **CDC Hepatitis B Vaccination:**
 - <https://www.cdc.gov/vaccines/vpd/hepb/index.html>
- **Hepatitis B Facts–Testing and Vaccination:**
 - <https://www.immunize.org/catg.d/p2110.pdf>
- **Interpretation of Hepatitis B Serologic Test Results:**
 - <https://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf>

Resources

- **Hepatitis B and Health Care Personnel–FAQs:**
 - <https://www.immunize.org/catg.d/p2109.pdf>
- **Infection Prevention during Blood Glucose Monitoring and Insulin Administration:**
 - <https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
- **Preexposure Evaluation for Health Care Personnel Previously Vaccinated with Complete ≥ 3 -Dose HepB Vaccine Series Who Have Not Had Postvaccination Serologic Testing (Figure 3):**
 - <https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf>

Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: **WD4564-092722**
- CE credit expires: **July 1, 2024**
- CE instructions are available on the **Pink Book Web-on-Demand Series** web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov

The screenshot shows the TCEO website interface. At the top, there is a blue header with the text "Training and Continuing Education Online (TCEO)". Below the header is the TCEO logo, which consists of the letters "TCEO" in a bold, blue font with a green leaf-like shape above the "O". Underneath the logo, the text "TRAINING AND CONTINUING EDUCATION ONLINE" is displayed in a smaller, blue font. To the left of the main content area is a vertical navigation menu with several blue buttons: "TCEO Home", "Search Courses", "Create Account", "9 Simple Steps to Earn CE", "Frequently Asked Questions", and "Contact TCEO". The main content area has a white background and contains three sections of text. The first section is titled "New to TCEO?" and includes the text "Visit Create Account. Once your account has been created, you will be able to search for courses and complete requirements to receive CE." The second section is titled "Already have a TCEO account from the previous system?" and includes the text "To move your account to the new system please sign in above using your existing TCEO username and password. Once signed in, follow the prompts to verify and update your account. After your account is verified, you will use this email address and password to sign in." The third section is titled "Not sure how to get started?" and includes the text "Follow these 9 Simple Steps to earn continuing education for the courses you have taken or conferences you have attended!". Below the text sections is a row of four small images: a woman smiling at a child, a man in a suit looking thoughtful, a doctor in a white coat holding a dog, and a woman sitting at a desk working on a laptop. At the bottom of the page, there is a "Welcome to TCEO" heading and a short paragraph of introductory text.

E-mail Your Immunization Questions to Us

- NIPINFO@cdc.gov



Thank You From Atlanta!

