Centers for Disease Control and Prevention





Hepatitis B and Hepatitis B Vaccine

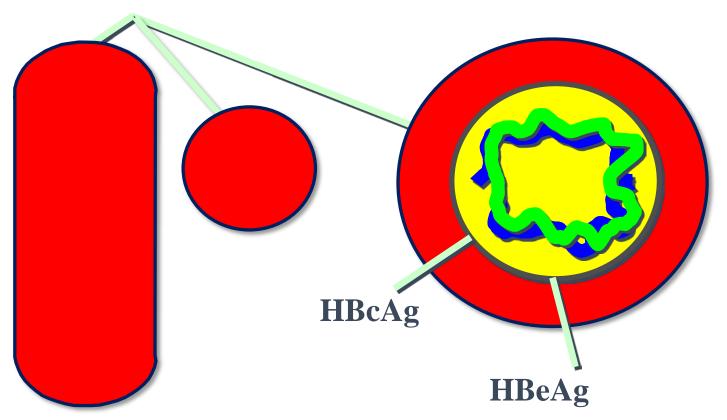
Raymond A. Strikas, MD, MPH
Medical Officer
Communications and Education Branch

Hepatitis B Virus

- Hepadnaviridae family (DNA)
- Numerous antigenic components
- Humans are only known host
- May retain infectivity for more than 7 days at room temperature

Hepatitis B Virus

HBsAg (Australia antigen)

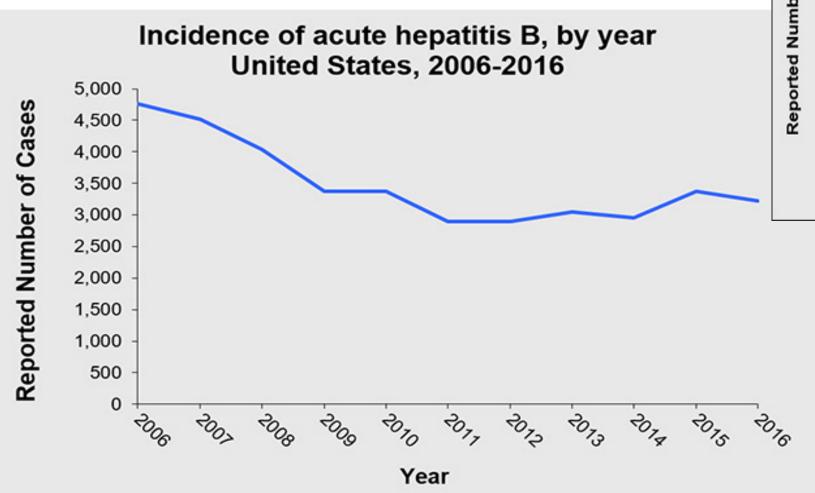


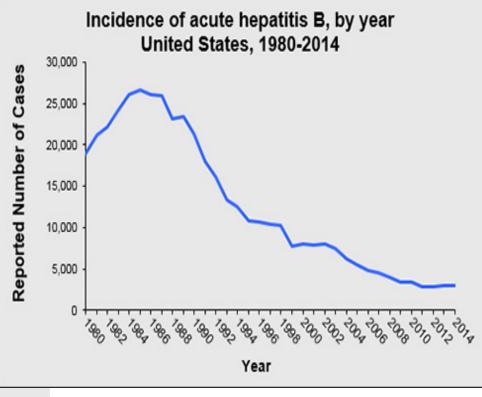
(presence indicates high infectivity)

Hepatitis B Virus Infection

- 850,000–2.2 million chronic infections in US
- 257 million chronically infected worldwide
- Established cause of chronic hepatitis and cirrhosis
- Human carcinogen—cause of up to 50% of hepatocellular carcinomas
- Causes about 887,000 deaths worldwide

Hepatitis B Incidence, United States 1980-2016



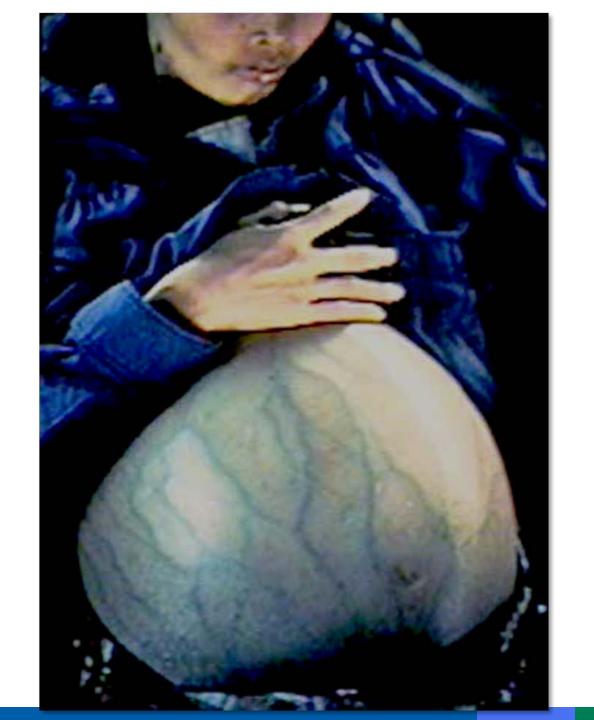


Hepatitis B Clinical Features

- Incubation period 60-150 days (average 90 days)
- Illness not specific for hepatitis B
- Nonspecific prodrome of malaise, fever, headache, myalgia
- 30% to 50% of infections are symptomatic

Hepatitis B Complications

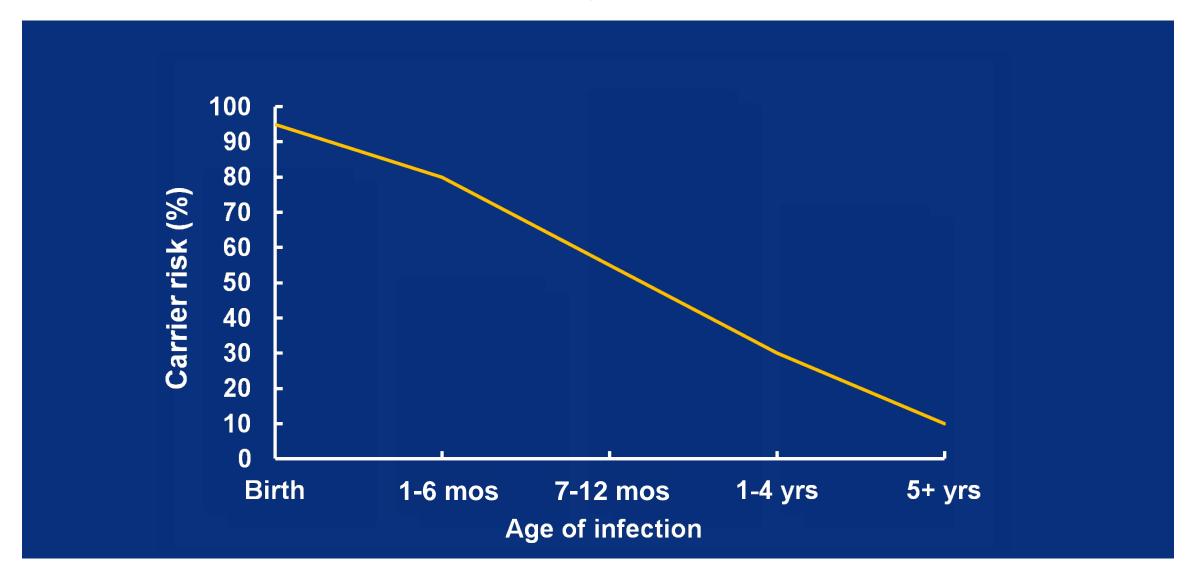
- Fulminant hepatitis (<1%)
- Hospitalization
- Cirrhosis
- Hepatocellular carcinoma
- Death



Chronic Hepatitis B Virus Infection – 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

Risk of Chronic HBV Carriage



Hepatitis B Perinatal Transmission*

- If mother positive for HBsAg and HBeAg
 - 70%-90% of infants infected
 - 90% of infected infants become chronically infected
- If positive for HBsAg
 - only 10% of infants infected
 - 90% of infected infants become chronically infected

^{*}in the absence of postexposure prophylaxis

Hepatitis B Epidemiology

Reservoir

Human

Transmission

Bloodborne
Subclinical cases transmit

Communicability

1-2 months before and after onset of symptoms

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

Infectious on environmental surfaces for at least 7 days

Risk Factors for Hepatitis B

- Injection drug use
- 2 or more sexual partners
- Men who have sex with men
- Household contacts
- Developmentally disabled persons in long-term-care facilities
- Correctional facilities
- Persons at risk for occupational exposure to HBV

- Hemodialysis patients
- Persons with HCV infection
- Persons with chronic liver disease
- Travelers to countries where HBV is endemic
- HIV infection
- Persons with Diabetes

Strategy to Eliminate Hepatitis B Virus Transmission— United States

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



Universal vaccination of all infants at birth

- Routine vaccination of previously unvaccinated children aged <19 years
- Vaccination of adults in high-risk groups

Hepatitis B (HepB) Vaccine

Composition
 Recombinant HBsAg

• **Efficacy** 95% (Range, 80%-100%)

Duration of Immunity
 20 years or more

Schedule2 or 3 Doses

Booster doses not routinely recommended

HepB Vaccine Indications

All children through 18 years of age beginning at birth

 Persons 19 years and older at increased risk of exposure because of behavior (multiple sexual partners, injection drug use) or occupation (exposure to blood or sharps injury)

Hepatitis B-Containing Vaccines

- 3 single component products
 - EngerixB
 - Recombivax HB
 - Heplisav-B
- EngerixB and RecombivaxHB have pediatric and adult formulations
 - Pediatric formulation
 - Adult formulation
- 2 combination vaccine products
 - Pediarix–DTaP, IPV and HepB vaccines
 - Twinrix—HepA and HepB vaccines

Engerix and Recombivax

Composition
Recombinant HBsAg

• **Efficacy** 95% (Range, 80%-100%)

Duration of Immunity
 20 years or more

Schedule3 doses

Booster doses not routinely recommended

HepB Vaccine Formulations

- Recombivax HB (Merck)
 - 5 mcg/0.5 ml (pediatric)
 - 10 mcg/1 ml (adult)
 - 40 mcg/1 ml (dialysis)
- Engerix-B (GSK)
 - 10 mcg/0.5 ml (pediatric)
 - 20 mcg/1 ml (adult)
- Heplisav-B (Dynavax Technologies)
 - 20mcg/0.5ml

Recommended Dosage of HepB Vaccine

	Recombivax HB Dose (mcg)	Engerix-B Dose (mcg)	Heplisav-B (mcg)
Children/Adolescents birth through 17 years	0.5 mL (5)	0.5 mL (10)	Not approved
Adolescents 18-19 years	0.5 mL (5)	0.5 ml (10)	0.5 mL (20)
Adults 20 years of age and older	1.0 mL (10)	1.0 mL (20)	0.5 mL (20)

Heplisav-B



Storage Store in the refrigerator between

2°C and 8°C (36°F and 46°F)

Ages 18 years of age and older

Schedule Administer 2 doses separated by 4 weeks

Administration Intramuscular (IM) injection in the deltoid

Can be administered at the same clinical visit as other

vaccines. Administer in separate injection sites, 1 inch

apart (if possible)

Contraindication History of severe allergic reaction (e.g. anaphylaxis) after a

previous dose of any hepatitis B vaccine or to any

component of Heplisav-B, including yeast

Heplisav-B Vaccine ACIP Recommendations



- HEPLISAV-B may be used to vaccinate persons age 18 years and older against infection caused by all known subtypes of HBV
- ACIP does not state a preference for one vaccine product versus another if the patient is eligible for more than 1 product
- The 2-dose HepB 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

Vaccine Supply: Pediatric RecombivaxHB

- Merck is not currently distributing hepatitis B vaccine, pediatric and adult formulations, through 2018
- GSK is addressing the gap for pediatric hepatitis B vaccine using a combination of single-component hepatitis B vaccine and DTaP-HepB-IPV (Pediarix)
- CDC anticipates there will be approximately 10% less single component pediatric hepatitis B vaccine than normal during the rest of 2018
- GSK has sufficient supplies of adult hepatitis B vaccine to address these anticipated gaps
 - Preferences for a specific presentation (i.e., vial versus syringe) may not consistently be met

Vaccine Supply: Adult Recombivax

- Merck is not currently distributing its adult hepatitis B vaccine and does not expect to be distributing adult Hepatitis B vaccine throughout the remainder of 2018
- GSK has sufficient supplies of adult hepatitis B vaccines to address the anticipated gap in Merck's supply of adult hepatitis B vaccine during this period

Combination Vaccines

Pediarix DTaP/IPV/HepB

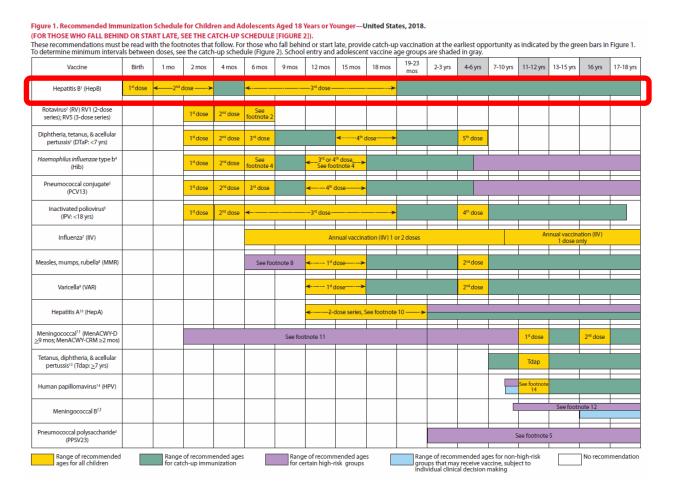
- Ages: 6 weeks through 6 years
- Routine schedule: 2, 4, 6 months of age
- Approved for dose 1, 2, 3 of Hep B (Do NOT use for the birth dose)

Twinrix HepA/HepB

- Ages: 18 years of age and older
- Routine schedule:3 doses at 0, 1, 6 months, or
- 0, 7, 21-30 days and a booster dose at 12 months
- Each dose of Twinrix contains an adult dose of hepatitis B vaccine

ACIP HepB Vaccine Recommendations: Pediatric

 Routinely recommended for all children through 18 years of age beginning at birth



Birth Dose Hepatitis B

- Single component hepatitis B vaccine should be administered within 24 hours of birth for medically stable infants weighing ≥2,000 g born to hepatitis B surface antigen (HBsAg)-negative mothers
 - Infants weighing less than 2,000 g born to HBsAg-negative mothers should receive the first dose of vaccine 1 month after birth or at hospital discharge
- All infants born to HBsAg-positive women should receive HepB vaccine and HBIG within 12 hours of birth
 - For infants weighing < 2,000 g, the birth dose should not be counted as part of the vaccine series
- Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists should be managed as if born to an HBsAg-positive mother

HepB Vaccine Routine Infant Schedule

Dose ⁺	Usual Age	Minimum Interval
Primary 1	Birth§	
Primary 2	1- 2 months	4 weeks
Primary 3 ⁺	6-18 months*	8 weeks**

[§] The birth dose of Monovalent Hepatitis B vaccine should be administered within 24h of birth for medically stable infants weighing ≥2,000 grams born to hepatitis B surface antigen (HBsAg)-negative mothers.

^{*} Infants whose mothers are HBsAg+ or whose HBsAg status is unknown should receive the third dose at 6 months of age

^{**} At least 16 weeks after the first dose

⁺ An additional dose at 4 months is acceptable if the clinician prefers to use a combination vaccine that contains hepatitis B vaccine

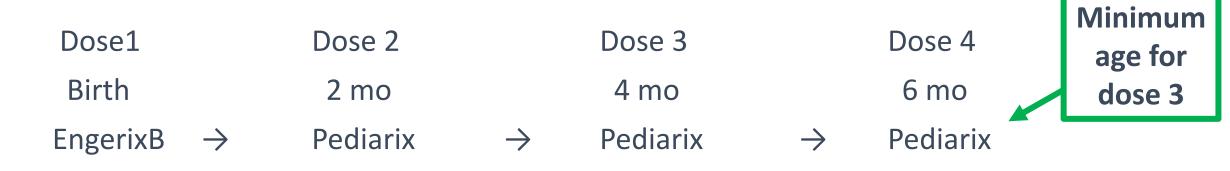
HepB Schedule: Minimum Intervals

Dose ⁺	Minimum Interval
Primary 1	
Primary 2	4 weeks
Primary 3 ⁺	8 weeks and at least 16 weeks after the 1 st dose

⁺ An additional dose at 4 months is acceptable if the clinician prefers to use a combination vaccine that contains hepatitis B vaccine

Pediarix

 Can be given at 2, 4, and 6 months in infants who received a dose of HepB vaccine at birth (total of 4 doses)



RecombivaxHB

or

Pediarix

- Minimum age 6 weeks
 - Cannot be used for HepB birth dose
- Can be given at 2, 4, and 6 months in infants who received a birth dose of HepB vaccine (total of 4 doses)
- May be used in infants whose mothers are HBsAg positive or status unknown*

HepB Vaccine Adolescent Vaccination

- Vaccinate previously unvaccinated adolescents and those missing doses
- Routinely recommended through age 18 years
- Integrate assessment and vaccination (if needed) into routine adolescent clinical visits

HepB Vaccine Adolescent and Adult Schedule

Primary 2

1 month

4 weeks

5 months

8 weeks*

^{*} Third dose must be separated from first dose by at least 16 weeks

Alternative Adolescent Vaccination Schedule

 Two 1.0 mL (10 mcg) doses of Recombivax HB separated by 4 to 6 months

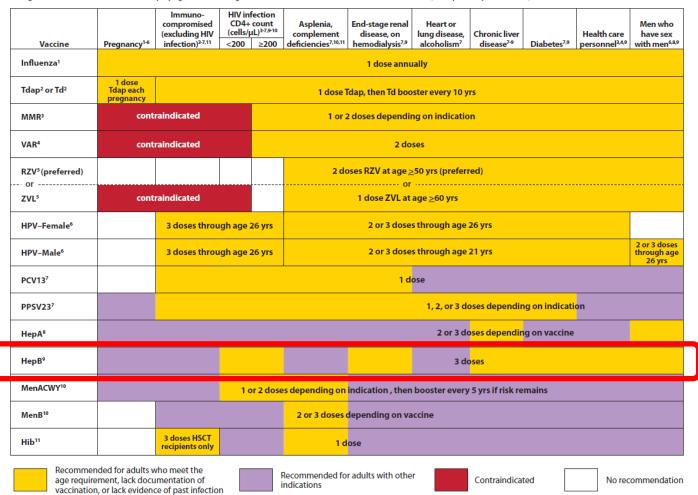
- Approved only for adolescents 11–15 years of age
- Only applies to Merck HepB vaccine

ACIP HepB Vaccine Recommendations: Adult

 Vaccinate previously unvaccinated adults at increased risk

Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise



Adults at Risk for HBV Infection

Sexual exposure

- Sex partners of HBsAg-positive persons
- Sexually active persons not in a long-term, mutually monogamous relationship*
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Men who have sex with men

^{*} Persons with more than one sex partner during the previous 6 months

Adults at Risk for HBV Infection

- Percutaneous or mucosal exposure to blood
 - Current or recent IDU
 - Household contacts of HBsAg-positive persons
 - Residents and staff of facilities for developmentally disabled persons
 - Healthcare and public safety workers with risk for exposure to blood or blood-contaminated body fluids
 - Persons with end-stage renal disease
 - Persons with diabetes mellitus
 - Persons with hepatitis C infection
 - Persons with chronic liver disease
 - Incarcerated persons

Hepatitis B and Diabetes Mellitus

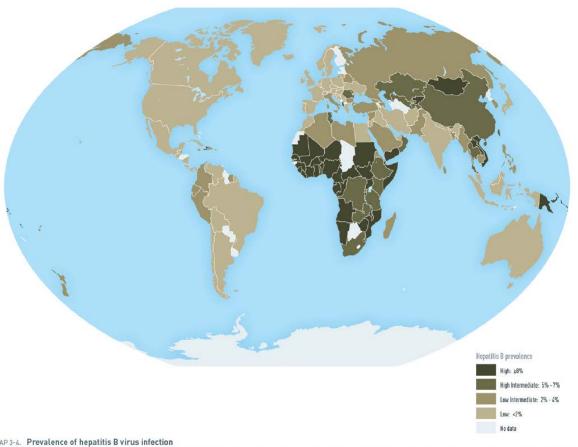
- Compared with adults without diabetes, adults with diabetes have a 60% higher prevalence of past or present HBV infection and twice the odds of acquiring acute HBV
- Repeated outbreaks of HBV infection associated with assisted blood glucose monitoring underscore the continued risk for this population
- Data also suggest the possibility of a higher case-fatality proportion among persons with diabetes acutely infected with HBV compared with those without diabetes

ACIP Recommendation for Persons with Diabetes Mellitus

- HepB vaccine (3-dose series) should be administered to unvaccinated adults (19 through 59 years of age) with diabetes (insulin and non-insulin dependent)
- HepB vaccine (3-dose series) may be administered to unvaccinated adults (60 years of age and older) with diabetes (insulin and non-insulin dependent)

Adults at Risk for HBV Infection

- Other groups
 - International travelers to regions with high or intermediate levels (HBsAg prevalence of 2% or higher) of endemic HBV infection
 - Persons with HIV infection



¹ Disease data source: Schweitzer A, Horn J, Mikolajczyk R, Krause G, Ott J. Estimations of worldwide prevalence of chronic hepatitis B virus infection: a systematic review of data published between 1965 and 2013, www.thelancet.com, 2015.Vol 386

HepB Schedule: Adult

Dose

Routine Interval

Minimum Interval

Primary 1

Primary 2

1 month

4 weeks

Primary 3

5 months

8 weeks and at least 16 weeks from Dose 1*

^{*} Third dose must be separated from first dose by at least 16 weeks

Twinrix

Combination HepA vaccine (pediatric dose) and HepB (adult dose)

- Schedules
 - 0, 1, 6 months, or
 - 0, 7, 21- 30 days and a booster dose at 12 months

Approved for persons 18 years of age and older

Prevaccination Serologic Testing

Recommended for:

- Household, sexual, or needle contacts of HBsAg-positive persons
- HIV-positive persons
- Persons with elevated alanine aminotransferase/aspartate aminotransferase of unknown etiology
- Hemodialysis patients
- Men who have sex with men
- Past or current persons who inject drugs
- Persons born in countries of high and intermediate HBV endemicity
- U.S.-born persons not vaccinated as infants whose parents were born in countries with high HBV endemicity
- Persons needing immunosuppressive therapy
- Donors of blood, plasma, organs, tissues, or semen

Postvaccination Serologic Testing

- Serologic testing is NOT routinely recommended following vaccination of most infant, children, or adults
- Recommended for:
 - Infants born to HBsAg—positive mothers or mothers whose HBsAg status remains unknown
 - Health care personnel and public safety workers
 - Hemodialysis patients and others who might require outpatient hemodialysis
 - HIV-infected persons
 - Other immunocompromised persons
 - Sex partners of HBsAg-positive persons

Postvaccination Serologic Testing

- Testing should be performed 1 to 2 months after administration of the final dose of the vaccine series
- Testing HCP with documentation of complete HepB vaccination, followed by one or more additional doses of HepB vaccine for HCP with anti-HBs <10 mIU/mL, helps to ensure that HCP will be protected if they have an exposure to HBV-containing blood or body fluids.

Management of Nonresponse to HepB Vaccine

- Complete a second series of 3 doses
- Should be given on the usual schedule of 0, 1, and 6 months
 - May be given on a 0,1, and 4 month or 0, 2 and 4 month schedule
- Retest 1-2 months after completing the second series

Persistent Nonresponse to HepB Vaccine

Less than 5% of vaccinees do not develop anti-HBs after 6 valid doses

May be nonresponder or "hyporesponder"

Check HBsAg status

• If exposed, treat as nonresponder with postexposure prophylaxis

HepB Vaccine

 Once a person has tested positive for anti-HBs, no additional testing or "booster" doses are recommended

 Provide the person with a copy of the laboratory result sand advise that it be kept forever

HCP and Documentation

Test for anti-HBs

If ≥10 mIU/mL, stop (the person is immune) If <10 mIU/mL, administer 1 dose

Test for anti-HBs 1 to 2 months later

- If ≥10 mIU/mL, stop (the person is immune)
- If <10 mIU/mL,administer 2add'l doses

Revaccination

- Revaccination is generally not recommended for persons with a normal immune status
- Recommended for the following:
 - Completely vaccinated HCP with anti-HBs < 10 mIU/mL
 - Hemodialysis patients should be assessed by annual anti-HBs testing and booster dose administered when anti-HBS < 10 mIU/mL
 - Immunocompromised persons should be considered for annual anti-HBs testing if have ongoing risk for exposure



Morbidity and Mortality Weekly Report

December 20, 2013

CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management

TABLE 2. Postexposure management of health-care personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by health-care personnel HepB vaccination and response status

Health-care personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	serologic testing†
Documented responders after complete series (>3 doses)	No action needed				
Documented nonresponder [¶] after 6 doses	Positive/unknown	_**	HBIG x2 separated by 1 month	-	No
	Negative	No action needed			
Response unknown after 3 doses	Positive/unknown	<10mlU/mL**	HBIG x1	Initiate	Yes
	Negative	<10mlU/mL	None	revaccination	
	Any result	≥10mlU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown		HBIG x1	Complete vaccination	Yes
	Negative	-	None	Complete vaccination	Yes

Abbreviations: HCP = health-care personnel; HBsAg = hepatitis B surface antigen; anti-HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin.

* 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.

A nonresponder is defined as a person with anti-HBs < 10 mlU/mL after > 6 doses of HepB vaccine.

[↑] Should be performed 1–2 months after the last dose of the HepB vaccine series (and 4–6 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 mlU/mL).

[§] A responder is defined as a person with anti-HBs ≥ 10 mlU/mL after ≥3 doses of HepB vaccine.

^{**} HCP who have anti-HBs <10mlU/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.

Vaccine Administration

- Route: IM Injection
 - Needle gauge: 22–25 gauge
 - Needle length*: 5/8 − 1.5 inch depending on the patient's age and/or weight
- Site*:
 - -Birth-11 months: Vastus lateralis muscle is preferred
 - 1–3 years: Vastus lateralis muscle is preferred; deltoid muscle may be used if the muscle mass is adequate
 - 4 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 including local reaction, number of vaccine to be administered age and muscle mass

Vaccine Administration Errors

- Adult formulation administered to a child
 - -MORE antigen than the recommended dose was administered
 - If the dose meets minimum age and interval, it may be counted
- Pediatric formulation administered to an adult
 - LESS antigen than the recommended dose was administered
 - The dose does not count and should be repeated ASAP
 - There is no time/spacing interval that must be met

HepA instead of HepB vaccine

Hepatitis B Standing Order Templates Children and Adults

Standing orders for other vaccines are available at www.immunize.org/standing-orders.
NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a counters, please acknowledge IAC as its source.

STANDING ORDERS FOR

Administering Hepatitis B Vaccine to Children and Teens

Purpose

To reduce morbidity and mortality from hepatitis B virus (HBV) by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for and vaccinate children and teens who meet any of the criteria below.

Procedure

- Assess Children and Teens in Need of Vaccination against HBV infection based on the following criteria:
- Lack of documentation of at least 3 doses of hepatitis B vaccine (HepB) with the third dose given at least 16
 weeks after the first dose, at least 8 weeks after the second dose, and when no younger than age 24 weeks
- 2 Screen for contraindications and precautions

Contraindications

- Do not give HepB to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a prior dose of
 the vaccine or to any of its components. For information on vaccine components, refer to the manufacturers'
 package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- . Do not give any HepB to a child or teen who has experienced hypersensitivity to yeast.

Precaution

. Moderate or severe acute illness with or without fever

3 Provide Vaccine Information Statements

Provide all patients (or, in the case of minors, their parent, or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart

AGE OF INFANT/CHILD/TEEN	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5/6"	Anterolateral thigh muscle
Infants (1-12 months)	1*	Anterolateral thigh muscle
	1-11/4"	Anterolateral thigh muscle**
Toddlers (1-2 years)	%*-1*	Deltoid muscle of arm
citi and	%*-1*	Deltoid muscle of arm**
Children (3-10 years)	1-11/4"	Anterolateral thigh muscle
Adolescents and Teens	%±-1"	Deltoid muscle of arm**
(11-18 years)	1-11/2"	Anterolateral thigh muscle

^{*} A 3%* needle may be used for children for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

CONTINUED ON THE NEXT PAGE

Technical content reviewed by the Centers for Disease Control and Prevention

| MMUNIZATION ACTION COALITION | Saint Paul, Minnesota - 651-647-9009 - www.immunize.org - www.vaccineinformation.org | www.immunize.org/catg.djp3076a.pdf - ltem #P3076a (10/17)

Standing orders for other vaccines are available at www.immunize.org/standing.orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courteey, please acknowledge IAC as its source.

STANDING ORDERS FOR Administering Hepatitis B Vaccine to Adults

Purpose

To reduce morbidity and mortality from hepatitis B virus (HBV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

- 1 Assess Adults for Need of Vaccination against HBV infection according to the following criteria:
- · Any person who wants to be protected from HBV infection
- Patient with diabetes mellitus (Note: for those age 60 years or older with diabetes mellitus, at the discretion of the treating clinician)
- Patient with end-stage renal disease, including patients receiving hemodialysis; HIV infection; or chronic liver disease
- Sexually active and not in a long-term, mutually monogamous relationship (e.g., more than 1 sex partner during the previous 6 months)
- · Seeking evaluation or receiving treatment for a sexually transmitted infection (STI)
- · A male who has sex with males
- A current or recent injection-drug user
- At occupational risk of infection through exposure to blood or blood-contaminated body fluids (e.g., health care
 worker, public safety worker, trainee in a health professional or allied health school)
- Residents or staff of an institution for persons with developmental disabilities
- Sex partner or household member of a person who is chronically infected with HBV (HBsAg-positive). (This includes an HBsAg-positive adopted child.)
- Planned travel to a country with high or intermediate prevalence of endemic HBV infection (for hepatitis B travel information from CDC, go to wwwnc.cdc.gov/travel/diseases/hepatitis-b)
- · People living in correctional facilities
- All teenagers ages 18 and younger who are not fully vaccinated (see standing orders for children and teens at www.immunize.org/catg.d/p3076a.pdf)

2 Screen for Contraindications and Precautions

Contraindications

Do not give hepatitis B vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

Precautions

Moderate or severe acute illness with or without fever

CONTINUED ON THE NEXT PAGE

| Immunization Action Coalition | Saint Paul, Minnesota - 651-647-9009 - www.immunize.org - www.vaccineinformation.org | www.

^{*} Preferred site.

HepB Vaccine Contraindications and Precautions

- Contraindication
 - Severe allergic reaction to a vaccine component or following a prior dose

- Precaution
 - Moderate or severe acute illness

HepB Vaccine Adverse Reactions

	Adults	Infants and Children
Pain at injection site	13%-29%	3%-9%
Mild systemic complaints (fatigue, headache)	11%-17%	0%-20%
Temperature greater 37.7 C	1%	0.4%-6%
Severe systemic reactions	rare	rare

Hepatitis B Vaccine Storage and Handling

- Store HepB-containing vaccines in a refrigerator between 2°C - 8°C (36°F - 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 soundalike 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 ti 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





Morbidity and Mortality Weekly Report

Recommendations and Reports

December 23, 2005 / Vol. 54 / No. RR-1

A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States

> Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents







INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION



Recommendations and Reports

December 8, 2006 / Vol. 55 / No. RR-16

A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States

Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html www.cdc.gov/mmwr/pdf/rr/rr6210.pdf



Morbidity and Mortality Weekly Report

CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management

Morbidity and Mortality Weekly Report

Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

homes and assisted-living facilities, were reported to CDC; of these, 25 involved adults with diabetes receiving assisted blood glucose

monitoring (1; CDC, unpublished data, 2011). These outbreaks prompted the Hepatitis Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP) to evaluate the risk for HBV infection among all adults with diagnosed diabetes. The Work Group reviewed HBV infection-related morbidity and mortality and the effectiveness of implementing infection prevention and control measures. The strength of scientific evidence regarding protection was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology," and safety, values, and cost-effectiveness were incorporated into a recommendation using the GRADE system. Based on the Work Group findings, on October 25, 2011, ACIP recommended that all previously unvaccinated adults aged 19 through 59 years with diabetes mellitus (type 1 and type 2) be

vaccinated against hepatitis B as soon as possible after a diagnosis of

Hepatitis B virus (HBV) causes acute and chronic infection of the

liver leading to substantial morbidity and mortality. In the United

States, since 1996, a total of 29 outbreaks of HBV infection in

one or multiple long-term-care (LTC) facilities, including nursing

risk for HBV infection among adults with diagnosed diabetes was estimated from 865 confirmed cases of acute HBV infection reported during 2009-2010 from eight Emerging Infections Program (EIP) sites constituting approximately 17% of the U.S. population. The analysis was restricted to persons aged ≥23 years because of high rates of vaccination among younger persons. In multivariate analyses that considered persons without hepatitis B-related risk behaviors (i.e., injection-drug use, male sex with a male, and sex with multiple partners), persons aged 23 through 59 years with diabetes had 2.1 (95% confidence interval [CI] = 1.6-2.8) times the odds of developing acute hepatitis B as those without diabetes; the odds were 1.5 (CI = 0.9-2.5) times as likely for persons aged ≥60 years. The annual incidence of reported cases of acute HBV infection among adults with diabetes was 1.8 per 100,000 (CI = 1.5-2.2) (2). Acute HBV infection incidence is underestimated; an additional 10.5 new cases of infection likely occurred for each reported, confirmed case (3).

Data for the period 1999-2010 from the National Health and Nutrition Examination Survey (NHANES), a nationally representative sample of the noninstitutionalized U.S. population, indicated a 60% (nc0.001) higher seroprevalence of antibody



Hepatitis B Resources

- ACIP's Hepatitis B Recommendations web page www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html
- CDC's Hepatitis B Infection web page www.cdc.gov/hepatitis/HBV/index.htm
- CDC's Hepatitis B Vaccination web page www.cdc.gov/vaccines/vpd-vac/hepb/default.htm
- Immunization Action Coalition Hepatitis B web page www.immunize.org/hepatitis-b/
- Children's Hospital of Philadelphia Vaccine Education Center Hepatitis B web page

www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/hepatitis-b-vaccine.html