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)

HBcAg

HBeAg  (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

Incidence of acute hepatitis B, by year
United States, 2006-2016

https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#overview
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

- Birth
- 1-6 mos
- 7-12 mos
- 1-4 yrs
- 5+ yrs

Carrier risk (%) vs. Age of infection
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

https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm#B2_down
Hepatitis B (HepB) Vaccine

- Composition: Recombinant HBsAg
- Efficacy: 95% (Range, 80%-100%)
- Duration of Immunity: 20 years or more
- Schedule: 2 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
- **Schedule**: 3 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)**
  - 20 mcg/0.5 ml
## Recommended Dosage of HepB Vaccine

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Recombivax HB Dose (mcg)</th>
<th>Engerix-B Dose (mcg)</th>
<th>Heplisav-B (mcg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children/Adolescents birth through 17 years</td>
<td>0.5 mL (5)</td>
<td>0.5 mL (10)</td>
<td>Not approved</td>
</tr>
<tr>
<td>Adolescents 18-19 years</td>
<td>0.5 mL (5)</td>
<td>0.5 ml (10)</td>
<td>0.5 mL (20)</td>
</tr>
<tr>
<td>Adults 20 years of age and older</td>
<td>1.0 mL (10)</td>
<td>1.0 mL (20)</td>
<td>0.5 mL (20)</td>
</tr>
</tbody>
</table>
# Heplisav-B

<table>
<thead>
<tr>
<th><strong>Storage</strong></th>
<th>Store in the refrigerator between 2°C and 8°C (36°F and 46°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ages</strong></td>
<td>18 years of age and older</td>
</tr>
<tr>
<td><strong>Schedule</strong></td>
<td>Administer 2 doses separated by 4 weeks</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>Intramuscular (IM) injection in the deltoid</td>
</tr>
<tr>
<td></td>
<td>Can be administered at the same clinical visit as other vaccines. Administer in separate injection sites, 1 inch apart (if possible)</td>
</tr>
<tr>
<td><strong>Contraindication</strong></td>
<td>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</td>
</tr>
</tbody>
</table>
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.

https://www.cdc.gov/mmwr/volumes/67/wr/mm6715a5.htm

New!
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

CDC Current Vaccine Shortages and Delays [https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html](https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html)
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

2017 ACIP Immunization Schedule for Children 18 Years of Age and Younger [www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html](http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html)
### HepB Vaccine Routine Infant Schedule

<table>
<thead>
<tr>
<th>Dose&lt;sup&gt;+&lt;/sup&gt;</th>
<th>Usual Age</th>
<th>Minimum Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>Birth&lt;sup&gt;§&lt;/sup&gt;</td>
<td>---</td>
</tr>
<tr>
<td>Primary 2</td>
<td>1-2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3&lt;sup&gt;+&lt;/sup&gt;</td>
<td>6-18 months*</td>
<td>8 weeks**</td>
</tr>
</tbody>
</table>

<sup>§</sup> 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

<sup>+</sup> 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

<table>
<thead>
<tr>
<th>Dose(^+)</th>
<th>Minimum Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>---</td>
</tr>
<tr>
<td>Primary 2</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3(^+)</td>
<td>8 weeks and at least 16 weeks after the 1(^{st}) dose</td>
</tr>
</tbody>
</table>

\(^+\) 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)

<table>
<thead>
<tr>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 3</th>
<th>Dose 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>2 mo</td>
<td>4 mo</td>
<td>6 mo</td>
</tr>
<tr>
<td>EngerixB → Pediarix → Pediarix → Pediarix</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or RecombivaxHB</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Minimum age for dose 3
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

<table>
<thead>
<tr>
<th>Dose</th>
<th>Usual Interval</th>
<th>Minimum Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Primary 2</td>
<td>1 month</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3</td>
<td>5 months</td>
<td>8 weeks*</td>
</tr>
</tbody>
</table>

* 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
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

NLP 3.4. Prevalence of hepatitis B virus infection

## HepB Schedule: Adult

<table>
<thead>
<tr>
<th>Dose</th>
<th>Routine Interval</th>
<th>Minimum Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Primary 2</td>
<td>1 month</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3</td>
<td>5 months</td>
<td>8 weeks and at least 16 weeks from Dose 1*</td>
</tr>
</tbody>
</table>

* 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 2 add’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
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

<table>
<thead>
<tr>
<th>Health-care personnel status</th>
<th>Postexposure testing</th>
<th>Postexposure prophylaxis</th>
<th>Postvaccination serologic testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Source patient (HBsAg)</td>
<td>HCP testing (anti-HBs)</td>
<td>HBIG*</td>
</tr>
<tr>
<td>Documented responder(^9) after complete series (≥3 doses)</td>
<td>No action needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documented nonresponder (^9) after 6 doses</td>
<td>Positive/unknown</td>
<td>—(^{**})</td>
<td>HBIG x2 separated by 1 month</td>
</tr>
<tr>
<td>Response unknown after 3 doses</td>
<td>Negative</td>
<td></td>
<td>No action needed</td>
</tr>
<tr>
<td>Unvaccinated/incompletely vaccinated or vaccine refusers</td>
<td>Positive/unknown</td>
<td>&lt;10mIU/mL(^{**})</td>
<td>HBIG x1</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>&lt;10mIU/mL</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Any result</td>
<td>≥10mIU/mL</td>
<td>No action needed</td>
</tr>
</tbody>
</table>

**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.
- 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 mIU/mL).
- A responder is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.
- A nonresponder is defined as a person with anti-HBs <10 mIU/mL after ≥6 doses of HepB vaccine.
- HCP who have anti-HBs <10mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.
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 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**

1. Assess Children and Teens in Need of Vaccination against HBV infection based on the following criteria:
   - Lack of documentation of at least 2 doses of hepatitis B vaccine (HepB) with the third dose given at least 14 weeks after the first dose, at least 6 weeks after the second dose, and when no younger than 24 weeks.
2. Screen for contraindications and precautions.
   - Do not give HepB to a child or teen who has experienced a serious reaction (e.g., anaphylaxis) to a dose of the vaccine or any of its components. For information on vaccine components, refer to the manufacturer’s package insert (http://www.immunize.org/catg.d/p3076a.pdf) or go to www.cdc.gov/vaccines/pubs/pinkbook/down loads/supplements/E8/02hepb.pdf.
   - Do not give any HepB to a child or teen who has experienced hypersensitivity to yeast.
3. Provide Vaccine Information Statements.
   - Provide all patients (or, in the case of infants, 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 none is available and desired, these can be found at www.immunize.org (for information about how to document that the VIS was given, see section 4.6.2 “Document Vaccination”).
4. Prepare to Administer Vaccine.
   - Choose the needle gauge, needle length, and injection site according to the following chart.

**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 healthcare 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 in Need of Vaccination against HBV infection according to the following criteria:
   - Any person who wants to be protected from HBV infection.
   - Person with diabetes mellitus (Note: for those age 60 yrs or older, diabetes mellitus or the diagnosis of the treating clinician).
   - Person with end-stage renal disease, including patients receiving hemodialysis, HBV 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).
   - Getting evaluation or receiving treatment for a sexually transmitted infection (STI).
   - A male who has sex with males.
   - A current or recent injection drug user.
   - Any occupational risk of infection through exposure to blood or blood-contaminated body fluids (e.g., health care worker, public safety worker, trainer in a health professional or allied health school).
   - A resident or staff of an institution for persons with developmental disabilities.
   - A person who was not previously infected with HBV (HBsAg negative). This includes an adoptive or biological child.
   - Planned travel to a country with high or intermediate prevalence of hepatitis B infection (for hepatitis B travel information from CDC, go to www.cdc.gov/travel/diseases/hepatitisB).
   - People living in correctional facilities.
   - All teenagers ages 16 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.
   - Do not give HepB to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or any of its components. For a list of vaccine components, refer to the manufacturer’s package insert (http://www.immunize.org/catg.d/p3076a.pdf) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendixes/pinkbook supplements/E8hepb.pdf.
   - Precautions: Moderate or severe acute illness with or without fever.

Immunization Action Coalition


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

<table>
<thead>
<tr>
<th></th>
<th>Adults</th>
<th>Infants and Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at injection site</td>
<td>13%-29%</td>
<td>3%-9%</td>
</tr>
<tr>
<td>Mild systemic complaints</td>
<td>11%-17%</td>
<td>0%-20%</td>
</tr>
<tr>
<td>(fatigue, headache)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature greater 37.7°C</td>
<td>1%</td>
<td>0.4%-6%</td>
</tr>
<tr>
<td>Severe systemic reactions</td>
<td>rare</td>
<td>rare</td>
</tr>
</tbody>
</table>
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 sound-alike vaccines; e.g., HepA, Hib, HPV

Vaccine storage label example
Available at [www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
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