Epidemiology

Hepatitis B virus (HBV) belongs to the family of Hepadnaviridae that includes other animal hepatitis viruses. These are small DNA viruses with envelope proteins.

Humans are the only natural hosts of the virus. Primates (chimpanzees, gorilla and gibbon) may be infected experimentally. People with chronic HBV infection are the primary reservoirs for infection.

Hepatitis B in Louisiana

It is estimated that there were approximately 1,300 new HBV infections in Louisiana in 2000, down from 5,000 infections in 1980. The introduction of the HBV vaccine in 1982 and the generalization of immunizations resulted in a steady decline in the number of reported cases of hepatitis B over the past ten years. The number of cases (newly acquired symptomatic infections) reported to the state ranges between 100 and 200 cases/year. This is an incidence of about 0.25 new cases of HBV per population of 100,000.

Approximately 0.5% of the population of Louisiana (21,000 people) are estimated to be chronic carriers of HBV, meaning that they are chronically infected with the virus. These people are easily diagnosed by the presence of the Hepatitis surface antigen in the blood (HBsAg+). Among those chronically infected with HBV, some 5 to 10% (1,000-2,000 people) develop chronic liver disease during their lifetimes.

Of the 200 to 500 infants born to mothers who are carriers of HBV HBsAg+, approximately fifteen become infected with the virus due to prevention failure. The great majority of infants infected at birth will become chronic carriers.

There are several modes of transmission for HBV:

HBV is found in virtually in all body secretions; however, only blood (and serum-derived fluids), saliva, semen and vaginal fluids have been shown to be infectious. The frequency with which these fluids (other than blood) contribute to infections is unknown and appears minimal. Transmission occurs principally through blood, sexual and perinatal exposure.

Direct Parenteral exposure

Hepatitis B was known historically as serum hepatitis because the cases seem to result from blood transfusions, blood products, clotting factor concentrates which were not treated (by heat or solvent extraction) and accidental contamination with needles.

Before development of vaccine HBV infection was common among health care workers exposed to blood and blood products: Infectiousness depends on the viral titer in the blood. Individuals with HBeAg are the most infectious (40% transmission of infection after needle stick). Those who are simply HBsAg carrier (but no HBeAg) are much less infectious (2% transmission after needle stick). Those who are below the laboratory detection for HBsAg are very rarely infectious.

- Transmission after a needle stick is the main mode of transmission to HCWs. Sharing or using non-sterilized needles or syringes is a main source of infection among drug abusers.
• Mucosal exposure or exposure of non intact skin (eczema, other dermatitis) may also result in infection.
• HBV infection is NOT transmitted by aerosolized blood. The HBV pathogen may be present in body fluids such as saliva, semen, vaginal secretions and any body fluids visibly contaminated with blood.

HBV during human bites has been reported and bite wounds inflicted by HBV infected patients warrant HBV prophylaxis even though the risk of infection is very low. Mucosal contact with saliva poses little if any risk.

**Perinatal Transmission**
The risk of perinatal HBV infection among infants born to HBV-infected mothers is about 70% (ranges from 10% to 85%, depending on several factors, the most important being the mother's concentration of viral DNA in the serum and her hepatitis B e antigen status). The risk of infection in utero is small (5-10%), most of the risk is concentrated at the time of delivery by penetration of the newborn mucous membranes by HBV. Infected newborns usually become HBV carriers and are at high risk for developing chronic liver disease.

**Sexual transmission** accounts for an estimated one-third to two-thirds of new HBV infections.

**Inapparent Exposure**
Some transmission seems to occur in households although at a very low rate. In households where a chronically infected person lives, the environment is heavily contaminated with HBV; transmission may occur through sharing of toothbrushes, washcloths and close personal contact with blood contaminated fomites. Hepatitis B virus is not transmitted by the fecal-oral route.

**Environmental transmission**
Personnel from clinical laboratory, hemodialysis unit, and other areas with frequent environmental contamination by blood are at much higher risk of acquiring HBV infection. Most acquired infections in these health care workers are not acquired by needle stick or any other definite exposure. Inapparent exposure of skin or mucosal exposure to blood contaminated environment seems to be responsible. HBV transmission by inanimate objects has been demonstrated.

**Population at higher risk:**
• Household contacts of people with acute or chronic HBV infection
• Sexual contacts of people with an acute or chronic infection
• Residents of institutions for the developmentally disabled
• Hemodialysis patients
• Patients with clotting disorders and others repeatedly receiving blood products
• Users of injection drugs
• People with multiple heterosexual partners
• Young men who have sex with men
• People with occupational exposure to blood or body fluids
• Staff of institutions and nonresidential child care programs for the developmentally disabled

Approximately one third of infected people do not have a readily identifiable risk factor. In child care facilities in the United States, the risk of transmission has become negligible as a result of infant hepatitis B vaccine coverage.

The **incubation period** for acute infection is 45 to 160 days, with an average of 90 days.

**Infectivity period:** Chronic carriers can shed virus for years.

**Clinical Description**

**Asymptomatic infection:** Infections acquired during childhood are usually asymptomatic.
Acute Hepatitis B
Acute hepatitis B cannot be differentiated clinically from other types of hepatitis. The prodromal phase includes malaise, weakness, anorexia, myalgia and arthralgia, macular rash (30%). After a few days, 30% of patients develop jaundice that may persist for weeks. Liver enzyme abnormalities are the result of liver toxicity. Extrahepatic manifestations, such as arthralgias, arthritis, macular rashes, thrombocytopenia, or papular acrodermatitis (Gianotti-Crosti syndrome), can occur early in the course of the illness and may precede jaundice.

Fulminant hepatitis B develops in about 1% of adults with jaundice.

Chronic infection: The risk of chronic HBV infection is correlated with age: 90% in newborns, 30% in children ≤5 years of age and 5 to 10% in older age groups. Patients who develop acute HBV infection while immunosuppressed or with an underlying chronic illness have an increased risk of developing chronic infection.

Many patients with chronic hepatitis B are asymptomatic (unless they progress to decompensated cirrhosis or have extrahepatic manifestations), while others have nonspecific symptoms such as fatigue. Some patients experience exacerbations of the infection which may be asymptomatic, mimic acute hepatitis, or manifest as hepatic failure.

The two major extrahepatic complications of chronic HBV are polyarteritis nodosa and glomerular disease.

Primary Hepatocellular carcinoma (PHC): Several epidemiologic studies have shown an association between PHC and chronic HBV infection.

Mortality is caused by fulminant viral hepatitis, primary hepatocellular carcinoma and cirrhosis of the liver.

Surveillance

Acute Hepatitis B and Chronic Carriage of HBV are reportable conditions. Past infection, asymptomatic infection without evidence of persistent viral antigens in the blood, are not reportable.

Case Definition

1-Acute Hepatitis B

Clinical case definition: An acute illness with discrete onset of symptoms and jaundice or elevated serum aminotransferase levels: AST ≥ 80 and ALT ≥ 80 (approx. 2 times upper limit of normal range).

Laboratory confirmation
1- IgM antiHAV negative,
and 2- IgM antiHBc positive or HBsAg positive (if IgM antiHBc is unknown/not tested),

2-Hepatitis B chronic infection (carrier)

Clinical case definition: Most cases are asymptomatic with no evidence of jaundice.

Laboratory confirmation:
HbsAg positive and anti-HBc positive and anti-HBc IgM negative or
HbsAg positive two times at 6 months interval  
Note: A single HBsAg is insufficient to classify someone as a carrier. While over 95% of infants who are HBsAg positive become carrier, only 5% of children or adults who are HBsAg positive become carriers.

Confirmed: A case that meets the lab case definition  
Suspect: A case that is HBsAg positive but has no other confirmatory lab results.

Simple rules to classify cases: Cases having a positive hepatitis B result will be entered as acute HBV disease or chronic carriers. Cases with past HBV infection who are not carriers are not entered in the surveillance database.

<table>
<thead>
<tr>
<th>Anti-HBc IgM Pos + symptoms</th>
<th>Acute</th>
<th>Carriers</th>
<th>Not a case</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ high ALT</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ no other info F2 then</td>
<td>✓</td>
<td>✓ 1*</td>
<td></td>
</tr>
<tr>
<td>Anti-HBc total positive, nothing else</td>
<td>✓ 2*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBs positive, nothing else</td>
<td>✓ 3*</td>
<td></td>
<td></td>
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<tr>
<td>HBe positive or anti-Hbe positive: FCons</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg Positive, F2 then Age ≤2</td>
<td>✓ 4*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F2 then Age &gt;2</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- case reports will not be rejected because anti-HAV test results are missing.
- F2: Fax /mail the test results to the DSS. Give 2 weeks to complete the investigation. If the investigation did not yield additional information classify according to the table. Some Surveillance Epi may choose to keep a copy of the original to follow up at 2 weeks.
- FCons: Request from DSS additional information and consult with senior epidemiologist regarding final disposition. Rationale: These cases are extremely infectious and need to be evaluated carefully.
- 1* Rationale: These cases are late IgM positive therefore they are no longer acute and are not proven to be carriers
- 2* Rationale: If no other tests were done, these are probably old infection, not carriers. HBsAg should have been done if carriage was suspected.
- 3* Rationale: These are probably vaccine status checks
- 4* These must be followed up as Perinatal HBV cases. Perinatal case definition: HbsAg positivity in any infant between one and 24 months, born in the US or US territories to an HbsAG+ mother - Notify Immunization Program.
- Pregnancy: Inform the HBV/Immunization Nurse. Actual prevention will result from this notification
- HBIG and vaccine series recommended for sexual contacts of persons with acute HBV infection. Household and sexual contacts of HBV carriers should be immunized.
- In the event that a minor greater than or equal to 13 years of age is reported with hepatitis B, information relating to the diagnosis should not be disclosed to the patient’s parent or guardian. If the patient must be contacted by phone, the surveillance epidemiologist/ specialist should ask for the patient by name but should not identify themselves as a member of the health department.

Laboratory Tests

Hepatitis B is confirmed by demonstration of viral antigens as well as antibodies.
Hepatitis B surface antigen (HBsAg) is the most commonly performed test for HBV. This antigen is detectable prior to the onset (as early as one month after exposure) and usually persists 3-4 months after onset. HBsAg positive - indicates acute hepatitis B infection, or, without a history of acute disease exposure, a chronic carrier of antigen.

Short HBsAg positivity after vaccination: for 1 to 7 days (rarely up to 21 days) after administering hepatitis B vaccine, HBsAg tests may be positive. Blood transfusion centers usually defer donors from to 7 days after HBV vaccine.

The e antigen of the HBV (HBeAg) does correlate more closely with infectivity than HBsAg. Testing for HBeAg is important when transmission of HBV is of public health concern. HBeAg positive - indicates infectivity.

The antibody to the surface antigen (Anti-HBs) results from a past HBV infection or immunization. It indicates immunity to subsequent infection. Anti-HBs positive - indicates past infection or immunization - presently immune to HBV.

Antibody to the core component of HBV (Anti-HBc) (includes both IgG and IgM) can indicate past or present infection, depending on the surface antigen and antibody test results.

Anti-HBc IgM positive - indicates acute or recent infection.

Nucleic acid tests: In addition, hybridization assays and gene amplification techniques (eg, polymerase chain reaction, branched DNA methods) are available to detect and quantitate HBV DNA.

Progression of lab tests: Hepatitis B surface antigen is detectable during acute infection. If the infection is self-limited, HBsAg disappears in most patients before serum anti-HBs can be detected (termed the window phase of infection). The IgM anti-HBc is highly specific for establishing the diagnosis of acute infection, because it is present early in the infection and during the window phase in older children and adults. However, IgM anti-HBc usually is not present in infants infected perinatally. People with chronic HBV infection have circulating HBsAg and anti-HBc; on rare occasions, anti-HBs also is present. Both anti-HBs and anti-HBc are detected in people with resolved infection, whereas anti-HBs alone is present in people immunized with hepatitis B vaccine. The presence of HBeAg in serum correlates with higher titers of HBV and greater infectivity. Tests for HBeAg and HBV DNA are useful in the selection of candidates to receive antiviral therapy and to monitor the response to therapy.

The state laboratory has the capability of performing HBsAg, Anti-HBs, Anti-HBc (total) and Anti-HBc (IgM) testing. Collect one red-topped tube of blood. The blood is to either be spun down and the sera sent or the whole blood sent refrigerated.

Hepatitis B surface antigen (HBsAg) testing will also be offered to health unit personnel who have been stuck by a needle while in the process of conducting work-related activities. Occasionally, such testing is done, i.e., when screening residents and/or employees of state operated institutions for the developmentally disabled. Any such request must be approved by the Infectious Disease Epidemiology Section.

Interpretation of Lab Test:
The interpretation of results is as follows:

**Case Investigation**

- Upon receipt of a report of hepatitis B, complete the Viral Hepatitis Case Record (CDC 53.1). This may be done by phone if the case is reported by a physician, hospital, or other source.

- Confirm the diagnosis with lab test: Contact the health care provider to obtain lab test results. The lab tests results are indispensable for case confirmation. It is important to have the results of blood tests in
order to distinguish carrier status from acute illness, past infection from present infection in conjunction with clinical symptoms. The state laboratory will not routinely test specimens for hepatitis B. If there are special circumstances, contact the Infectious Disease Epidemiology Section for further information.

- Ask about additional cases (outbreaks?)
- Inquire about special risks:
  -- Accidental exposure to potentially contaminated blood or body fluids, such as through occupational exposures, should follow the protocol established by CDC with regards to screening and vaccination.
  -- Cases among health care workers and patients of health care facilities should be thoroughly investigated, particularly among lab technicians, and hemo-dialysis workers, clients and staff of institutions for the developmentally disabled.

- Counseling:
  -- Advise patients of risk of chronic hepatitis and recommend they consult a physician. Approximately 5-10% of persons who experience HBV infection become chronic carriers of HBsAg and are considered infectious throughout the life span of the individual. Once the diagnosis of acute hepatitis B is made, patients should be retested periodically until the HBsAg clears. Persistence of HBsAg after six months from the acute onset of illness is considered prognostic for the development of chronic carriage.
  -- Provide health education to the patient and family regarding hepatitis B. Discuss mode of transmission, the need for precautions for sexual contacts and household contacts of a carrier, how to handle exposure to blood, inform the patient that he should not donate blood, and discuss the possible need for HBIG and/or hepatitis vaccine for the household members.
  -- Counsel the patient (acute or chronic) in avoiding alcohol ingestion and eating raw shellfish (i.e., raw oysters).

- Prophylaxis of contacts:
  -- Household Contacts of Persons With Acute HBV Infection.
    --- Infants (i.e., younger than 12 months of age) who have close contact with primary care-givers with acute infection and who have begun the immunization series should complete the series on schedule. If immunization has not been initiated, the infant should receive HBIG (0.5 mL), and hepatitis vaccine should be given in accordance with the routinely recommended 3-dose schedule.
    --- Prophylaxis with HBIG for other unimmunized household contacts of persons with acute HBV infection is not indicated unless they have identifiable blood exposure to the index patient, such as by sharing of toothbrushes or razors. Such exposures should be treated as in sexual exposures to a person with acute HBV infection. All such persons, however, should be immunized as soon as possible against hepatitis B because of the possibility of future household exposures.

  --Sexual Partners of Persons With Acute HBV Infection. Susceptible sex partners should receive a single dose of HBIG (0.06 mL/kg) and should begin the hepatitis B vaccine series. Sexual partners of persons with acute HBV infection are at increased risk for infection, and HBIG is 75% effective for preventing these infections. The period after sexual exposure during which HBIG is effective is unknown, but is unlikely to exceed 14 days. Even though prophylaxis of the following contacts is not currently available from the Office of Public Health, these recommendations should be made and the contacts of the acute hepatitis B case referred to their private provider.

IG (or immune globulin) that is available for post-exposure prophylaxis of household contacts of hepatitis A cases, should not be administered to contacts of hepatitis B cases and is not an appropriate substitute for HBIG.

- Questions from the general public:
  -- Answer questions from the public on the mode of transmission of hepatitis B and who may be at risk of exposure.
--Answer questions regarding safety of HBV infected persons in some professions: Health care workers, food-handlers, teachers do not need to be excluded from work based on the diagnosis of Hepatitis B (whether acute or chronic) unless the person is physically incapacitated to perform work duties or as directed by his/her physician’s evaluation.

--Because of the increased risk of environmental exposure to needles or syringes through either medical or public waste, provide post exposure recommendations to exposed persons. Enforce proper handling and disposal of needles and medical waste in the community. The state lab does not test environmental needles which may be the source of an exposure because the results would not be reliable.

Tattoos and piercing: Commercial establishments performing tattoos and piercing should be inspected routinely. Proper disposal of needles and equipment and decontamination of reusable equipment should be enforced.

Isolation of the Hospitalized Patient: Standard precautions are indicated for patients with acute or chronic HBV infection. For infants born to HBsAg-positive mothers, no special care other than removal of maternal blood by a gloved attendant and standard precautions is necessary.

**Outbreak investigation**

Outbreaks are rare and difficult to identify due to the lengthy incubation period. Suspected outbreaks must be thoroughly investigated. Consult the Infectious Disease Epidemiology Section for assistance.

**Hepatitis B Immunoprophylaxis.**

Hepatitis B Immune Globulin is prepared from hyperimmunized donors whose plasma is known to contain a high concentration of anti-HBs and to be negative for antibodies to HIV and hepatitis C virus (HCV). The process used to prepare HBIG inactivates or eliminates HIV and HCV. Standard Immune Globulin is not effective for postexposure prophylaxis against HBV infection, because concentrations of anti-HBs are too low. Two types of products are available for immunoprophylaxis. Hepatitis B Immune Globulin provides short-term protection (3-6 months) and is indicated only in specific postexposure circumstances.

**Indications for Hepatitis B immuno-prephylaxis**

-- **Pregnancy:** see section Hepatitis B perinatal program

-- **Household Contacts of People With Acute HBV Infection.** Infants (≤ 12 months of age) who have close contact with primary caregivers with acute infection require immunoprophylaxis. If at the time of exposure, the infant has been immunized fully or has received at least 2 doses of vaccine, the infant should be presumed protected, and HBG is not required. If only one dose of vaccine has been administered, the second dose should be administered if the interval is appropriate, or HBIG should be administered if immunization is not due. If immunization has not been initiated, the infant should receive HBIG (0.5 mL), and hepatitis B vaccine should be given in accordance with the routinely recommended 3-dose schedule.

-- **Prophylaxis with HBig for other unimmunized household contacts** of people with acute HBV infection is not indicated unless they have identifiable blood exposure to the index patient, such as by sharing of toothbrushes or razors. Such exposures should be treated in the same way as sexual exposures to a person with acute HBV infection. All such people should be immunized as soon as possible against hepatitis B because of the possibility of future household exposures.

-- **Sexual Partners of People With Acute HBV Infection.** Susceptible sexual partners should receive a single dose of HBIG (0.06 mL/kg) and should begin the hepatitis B vaccine series. Sexual partners of people
with acute HBV infection are at increased risk of infection, and HBIG is 75% effective for preventing these infections. The period after sexual exposure during which HBIG is effective is unknown, but is unlikely to exceed 14 days.

-- Victims of Sexual Assault or Abuse. If previously immunized, sexual assault victims should be assumed to be protected from acute and chronic HBV infection. For unimmunized victims, active postexposure prophylaxis (ie, vaccine alone) should be initiated, with the first dose of vaccine given as part of the initial clinical evaluation. Unless the offender is known to have acute hepatitis B, HBIG is not required to achieve a high level of postexposure protection. In the case of children, sexual abuse commonly occurs over a prolonged period, often making it difficult to define the last exposure. However, when sexual abuse is identified, hepatitis B immunization should be initiated in previously unimmunized children.

-- Exposure to Blood That Contains (or Might Contain) HBsAg. For inadvertent percutaneous (e.g., needlestick, laceration, or bite) or permucosal (eg, ocular or mucous membrane) exposure to blood, the decision to give HBIG prophylaxis and to immunize the exposed person includes consideration of whether the HBsAg status of the person who was the source of the exposure is known and the hepatitis B immunization and response status of the exposed person. Immunization is recommended for any person who was exposed but not previously immunized. If possible, a blood specimen from the person who was the source of the exposure should be tested for HBsAg and appropriate prophylaxis should be administered according to the hepatitis B immunization status and anti-HBs response status (if known) of the exposed person.

-- Detailed guidelines for the management of health care professionals and other people exposed to blood that is or might be HBsAg-positive is provided in the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

-- Child Care. All children, including children in child care, should receive hepatitis B vaccine as part of their routine immunization schedule. Immunization not only will decrease the potential for transmission after bites but also will allay anxiety about transmission from attendees who may be HBsAg positive.

Children who are HBsAg-positive and who have no behavioral or medical risk factors, such as unusually aggressive behavior (eg, biting), generalized dermatitis, or a bleeding problem, should be admitted to child care without restrictions. Under these circumstances, the risk of HBV transmission in child care settings is negligible, and routine screening for HBsAg is not warranted. Admission of HBsAg-positive children with behavioral or medical risk factors should be assessed on an individual basis by the child's physician, the program director, and the responsible public health authorities.

Immunization

The immunization program includes the following 4 components:
1-Immunization of infants, children, adolescents, and adults at increased risk of infection (1982);
2-Prevention of perinatal HBV infection through routine screening of all pregnant women and appropriate treatment of children born to HBsAg-positive women (1988);
3-Routine immunization of infants (1992);
4-Routine immunization of adolescents who previously have not been immunized (1995).

Groups at increased risk of infection are:
• Ethnic populations at high risk of HBV infection
• Sexually Active Heterosexual Adolescents and Adults. People diagnosed with a sexually transmitted disease or people who have had more than 1 sexual partner during the previous 6 months should be immunized.
• Household Contacts and Sexual Partners of People With Chronic HBV Infection.
• Health Care Professionals and Others With Occupational Exposure to Blood.
• Residents and Staff of Institutions for People With Developmental Disabilities.
Attendees in nonresidential programs: Immunization should be considered for all attended by HBsAg-positive people and is encouraged strongly if an attendee who is HBsAg-positive behaves aggressively or has special medical problems (eg, exudative dermatitis or open skin lesions).

- Patients Undergoing Hemodialysis.
- Adoptees and their household contacts from countries where HBV infection is endemic.
- Inmates in Juvenile Detention and Other Corrections Facilities. If the length of stay is not sufficient to complete the immunization series, the series should be initiated and follow-up mechanisms with a health care facility should be established to ensure completion of the series.
- Patients With Bleeding Disorders Who Receive Clotting Factor Concentrates.
- International Travelers. People traveling for 6 months or longer to areas where HBV infection is of high or intermediate endemicity who will have close contact with the local population should be immunized. People who are traveling for a shorter duration but likely will have contact with blood (eg, in a medical setting or through drug use) or sexual contact with residents also should be immunized.

**Hepatitis B vaccine:** The recombinant vaccines contain 5 to 40 µg of HBsAg protein per mL adsorbed to aluminum hydroxide. All pediatric formulations contain no thimerosal or only trace amounts. Although the concentration of recombinant HBsAg protein differs among vaccine products, rates of seroconversion are equivalent when given to immunocompetent infants, children, adolescents, or young adults in the doses recommended.

Hepatitis B vaccine can be given concurrently with other vaccines. The hepatitis B vaccines are interchangeable within an immunization series.

Vaccine is administered intramuscularly in the anterolateral thigh or deltoid area, depending on the age and size of the recipient. Administration in the buttocks or intradermally has been associated with decreased immunogenicity and is not recommended.

**Efficacy, Duration of Protection and Booster.** Hepatitis B vaccines licensed in the United States have a 90% to 95% efficacy for preventing HBV infection and clinical hepatitis B among susceptible children and adults. Long-term studies of adults and children indicate that immune memory remains intact for 15 years or more and protects against clinical acute infections and chronic HBV infection, even though anti-HBs concentrations may become low or undetectable over time. For children and adults with normal immune status, routine booster doses of vaccine are not recommended. For hemodialysis patients and other immunocompromised people at continued risk of infection, the need for booster doses should be assessed by annual anti-HBs testing, and a booster dose should be given when the anti-HBs concentration is less than 10 mIU/mL.

**Adverse Reactions:** The most commonly reported adverse effects in adults and children are pain at the injection site and fever ≥ 37.7°C (99.8°F). Anaphylaxis is uncommon, occurring in approximately one in 600,000 recipients. Large, controlled epidemiologic studies show no association between hepatitis B vaccine and sudden infant death syndrome, diabetes mellitus, or demyelinating disease, including multiple sclerosis.

No adverse effect on the developing fetus has been observed when pregnant women have been immunized. Because HBV infection may result in severe disease in the mother and chronic infection in the newborn, pregnancy is not a contraindication to immunization. Lactation is not a contraindication.

Routine postimmunization testing for anti-HBs is not necessary, but is recommended 1 to 2 months after the third vaccine dose for the following specific groups:
1-- Hemodialysis patients;
2-- HIV infected individuals
3-- People at occupational risk of exposure from sharps injuries
4-- Immunocompromised patients at risk of exposure to HBV
5-- Regular sexual contacts of HBsAg-positive people
6-- Infants born to HBsAg-positive mothers should be tested for HBsAg and anti-HBs at 9 to 15 months of age.

**Management of Non-responders.** Vaccine recipients who do not develop a serum anti-HBs response (≤ 10 mIU/mL) after a primary vaccine series should be reimmunized (unless they are determined to be HBsAg positive) with an additional 3-dose series. People who remain anti-HBs negative after a re-immunization series are unlikely to respond to additional doses of vaccine.

**Case Management - Treatment**

No therapeutic measure has proved to have beneficial effect on the disease process in the liver during acute viral hepatitis.

Goals of therapy of chronic hepatitis B include the suppression or complete resolution of active hepatitis (or associated nonhepatic disease such as glomerulonephritis or polyarteritis), halting progression of liver disease, and rendering patients noninfectious. Recombinant interferon-alpha (INF-alpha) and the nucleoside lamivudine (3TC) in the United States are used for therapy of chronic hepatitis B. It is preferable that patients be managed by physicians experienced with the treatment of chronic hepatitis B.

**Environment: HBV on contaminated surfaces**

Hepatitis B surface antigen (HBsAg) can be detected on surfaces contaminated with blood which were improperly cleaned and disinfected. HBV in dried blood at room temperature remains viable for up to 1 week. In hemodialysis centers, HBV has been detected on clamps, scissors, dialysis machine control knobs, door knobs and other surfaces.

Hepatitis B virus can survive in the environment for 1 week or longer but is inactivated by commonly used disinfectants, including household bleach diluted 1:10 with water.

**Hepatitis B prenatal program**

Transmission of perinatal HBV infection can be prevented in approximately 95% of infants born to HBsAg-positive mothers by early active and passive immunoprophylaxis of the infant (i.e., immunization and HBIG administration).

The purpose of identifying HBsAg Positive pregnant females is to afford early protection to the newborn from developing acute hepatitis B illness, reduce the likelihood of becoming a chronic carrier and decreasing the risk of mortality associated with cirrhosis and liver cancer. Newborns born to HBsAg Positive females require high priority in assuring administration of HBIG immediately after delivery in conjunction with the first dose of hepatitis B vaccine with continual follow-up until the hepatitis B vaccine series is completed.

**Case Management:**

-- Upon receipt of a report of hepatitis B, contact the physician and/or hospital to confirm the diagnosis. For females of childbearing age that are reported as HBsAg positive, follow-up with the physician to determine pregnancy status.

-- Reports of HBsAg positive mothers and their infants should be sent to the Immunization Section registry.
-- All pregnant women should be tested during an early prenatal visit with every pregnancy. Testing should be repeated during late pregnancy for HBsAg-negative women who are at high risk of HBV infection (e.g., injection drug users and those with intercurrent sexually transmitted diseases) or who have had clinical hepatitis.

-- Women found to be HBsAg positive should be counseled regarding their own health and the risks to their sexual and household contacts. Household contacts and sexual partners of HBsAg-positive women should be immunized.

-- Infants born to HBsAg positive mothers should receive
  - HBIG (0.5ml) intramuscularly (IM) once they are physiologically stable, preferably within 12 hours after birth.
  - Hepatitis B vaccine should be given concurrently with HBIG but at a different site. If vaccine is not immediately available, the first dose can be given within seven days after birth. The second dose should be given at two months of age (at least one month after the first dose) and the third dose should be given at six months of age. HBIG and HBV do not interfere with routine childhood immunizations and can be given simultaneously with all other vaccines. The initial dose of hepatitis B vaccine and the HBIG should be administered at the hospital, the local health unit is responsible for tracking the infant and administering the other two vaccine doses.

-- Household or sexual contacts of HBV carriers (not acute cases) identified as part of the perinatal Hepatitis B program should be screened and/or vaccinated

-- If a pregnant woman has not been screened for HBsAg prenatally, or if test results are not available at the time of admission for delivery, HBsAg testing should be done on admission. While awaiting results, the infant should receive the first hepatitis B vaccine dose within 12 hours of birth in the dose recommended for infants born to HBsAg-positive mothers.

Because hepatitis B vaccine when given at birth is highly effective for preventing perinatal infection in term infants, the possible added value and the cost of HBIG do not warrant its immediate use in term infants when the mother's HBsAg status is not known. If the woman is found to be HBsAg-positive, term infants should receive HBIG (0.5 mL) as soon as possible, but within 7 days of birth, and should complete the hepatitis B immunization series as recommended.

-- Follow up testing of infants: Infants born to HBsAg-positive women should be tested for anti-HBs and HBsAg after completion of the immunization series, at 9 to 15 months of age. Testing should not be performed before 9 months of age to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infections. Testing for HBsAg will identify infants who become chronically infected despite immunization (because of intrauterine infection or vaccine failure) and will aid in their long-term medical management.

-- Non responders: Infants with anti-HBs concentrations of less than 10 mIU/mL and who are HBsAg-negative should receive 3 additional doses of vaccine in a 0-, 1-, and 6-month schedule followed by testing for anti-HBs 1 month after the third dose. Alternatively, additional doses (1-3) of vaccine can be administered, followed by testing for anti-HBs 1 month after each dose to determine whether subsequent doses are needed.

-- Breastfeeding. Breastfeeding of the infant by an HBsAg-positive mother poses no additional risk of acquisition of HBV infection by the infant.