Hepatitis B: Key Tools and Techniques for an Effective Public Health Response

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Disclosure: Speaker receives no financial gains, and is not a commercial supporter of any product or device. Speaker does not discuss non-FDA approved or investigational use of products/devices.
Hepatitis B Disease

- Caused by hepatitis B virus (HBV)
  - Virus can live in the environment for ~7 days
- 9th leading cause of death worldwide
- Primary cause of liver cancer and second leading cause for liver transplant
- Incubation period: 90 days (60-150 days)
- Common symptoms: anorexia, nausea, malaise, fever, vomiting, abdominal pain, dark urine, jaundice
- Likelihood of developing symptoms is age related
  - 1% of infants
  - 5-15% of children 1-5 years
  - 30-50% of > 5 year olds
  - 50-70% of adults
- No specific treatment is available for acute hepatitis B
  - Antiretroviral drugs are approved to treat chronic hepatitis B
Prevalence of Chronic HBV Infection

<table>
<thead>
<tr>
<th>Level of endemicity</th>
<th>% of general population with chronic HBV infection</th>
<th>% of world population</th>
</tr>
</thead>
<tbody>
<tr>
<td>high endemicity</td>
<td>greater than 7%</td>
<td>about 45%</td>
</tr>
<tr>
<td>intermediate endemicity</td>
<td>2% to 7%</td>
<td>about 43%</td>
</tr>
<tr>
<td>low endemicity</td>
<td>less than 2%</td>
<td>about 12%</td>
</tr>
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</table>
HBV Modes of Transmission

- HBV is most commonly spread by coming in contact with blood or body fluids of an infected person
  - Sexual contact
  - Perinatal transmission—mother to child at birth
  - Injection drug users, shared needles, syringes, or drug preparation equipment
  - Contact with blood or open sores of infected person
  - Bites from an infected person
  - Sharing contaminated personal hygiene items, razors, toothbrushes
  - Sharing contaminated objects that pierce the skin, tattoo and body-piercing and acupuncture equipment
  - Needlesticks or other sharp instrument exposures
HBV Persons at Risk

- **Risk behaviors**
  - Men who have sex with men (MSM)
  - Person with multiple sexual partners
  - History of STDs
  - Co-infection with HIV/HCV
  - Injection/illicit drug users
  - Healthcare & public safety workers
  - Hemodialysis patients
- Residents & staff of facility for developmentally disabled
- **Household contact of infected person**
- Received blood transfusions in the past before blood testing was available (1975)
- Persons with record of incarceration
- Internationally adopted
- Travelers to HBV endemic regions
- **Children of first-generation immigrants from countries where HBV is endemic**
- **Children born to HBsAg+ mothers**
- Foreign born persons
HBV Prevention: National strategy to eliminate HBV infection

- **Universal Vaccination** of all infants at birth

- Vaccination of previously unvaccinated children & adolescents

- Vaccination of high-risk adults
  - MSM
  - HCWs
  - STD clients
  - HCV/HIV
  - Incarcerated persons
  - IVDU
  - Hemodialysis
Protection* by Age Group and Dose

<table>
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<tr>
<th>Dose</th>
<th>Infants**</th>
<th>Teen and Adults***</th>
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<tbody>
<tr>
<td>1</td>
<td>16% - 40%</td>
<td>20%-30%</td>
</tr>
<tr>
<td>2</td>
<td>80%-95%</td>
<td>75%-80%</td>
</tr>
<tr>
<td>3</td>
<td>98%-100%</td>
<td>90%-95%</td>
</tr>
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</table>

*Anti-HBs antibody titer of 10 mIU/mL or higher
**Preterm infants less than 2kg have been shown to respond to vaccination less often
***Factors that may lower vaccine response rates are age older than 40 years, male gender, smoking, obesity, and immune deficiency
Acute, Chronic, and Perinatal Hepatitis B Infections
Acute HBV Infection

• Clinical symptoms of all acute hepatitis infections are similar and can include:
  • Fever/Fatigue
  • Loss of appetite
  • Nausea/Vomiting
  • Abdominal pain/joint pain/rash
  • Clay-colored stools/dark urine
  • Jaundice

• Clinical signs & symptoms inversely related to age
  • Acute infection: greater severity among older persons

• Asymptomatic or symptomatic infection
Acute HBV Infection

- Incubation period- 6 weeks to 6 months
  - Average – Symptoms begin 90 days after exposure
  - Symptoms can last for weeks to 6 months

- Person is considered infectious
  - 2 months before to 2 months after diagnosis or until certain serologic markers become negative

- No treatment for acute infection
  - Infection can be self-limited or develop into chronic infection
Chronic HBV Infection

• HBV - classified as chronic when the person has persistent virus present in the blood

• Viral markers are present in his or her serum for more than 6 months

• Chronically infected are referred to as “carriers”

• Source of transmission of HBV to others
Chronic HBV in Pregnancy

HBsAg and anti-HBs tests

HBsAg (-)
If anti-HBs (-) and at high risk consider vaccination of the pregnant woman during pregnancy or postpartum

HBsAg (+)
Order additional tests:
- ALT
- HBeAg, anti-HBe
- HBV DNA level

HBeAg (+)
- or-
HBV DNA >20,000 IU/mL
- or-
ALT elevated*
Refer to specialist immediately during pregnancy

HBeAg (-)
HBV DNA <2,000 IU/mL
ALT normal
Refer to specialist or primary care provider postpartum

Recommended screening of all household and sexual contacts

HBsAg (-) Anti-HBs (-)
Vaccinate

HBsAg (-) Anti-HBs (+)
Immune (No follow-up required)

HBsAg (+)
Primary care provider to evaluate and monitor

*New norms establish elevated ALT as ≥19 IU/L for women, ≥30 IU/L for men

Abbreviations: ALT, alanine aminotransferase; HBsAg, hepatitis B surface antigen; anti-HBs, antibody to HBsAg; HBeAg, hepatitis B e-antigen; anti-HBe, antibody to HBeAg.
Risk of Chronic HBV Carriage by Age of Infection
Perinatal HBV Infection

- Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis.

- HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother
Follow-up for ≥ 3 HBV vaccine doses & HBIG

Follow-up for post-vaccine serology

Protected Infants
HBsAg (-) & anti-HBs ≥10mIU/mL

Unprotected Infants
HBsAg (-) & anti-HBs <10mIU/mL

Report number HBV exposed & infected infants

Physicians, hospitals, & out-of-state notifications

Laboratory Reporting
anti-HBs serology for ≤36 months age

Electronic Birth Certificate Data

NJ Immunization Information System

HBsAg (+) pregnant women, who deliver

Follow-up for ≥ 3 HBV vaccine doses & HBIG

Confirmed infection
HBsAg (+)

Not infected
Hepatitis B Tests
Surface Antigen & Surface Antibody

- **Hepatitis B surface antigen (HBsAg):**
  - A protein on the surface of hepatitis B virus
  - Can be detected in high levels in serum during acute or chronic hepatitis B virus infection
  - The presence of HBsAg indicates that the person is infectious
  - The body normally produces antibodies to HBsAg as part of the normal immune response to infection.

- **Hepatitis B surface antibody (HBsAb or anti-HBs):**
  - Generally interpreted as indicating recovery and immunity from hepatitis B virus infection
  - Anti-HBs also develop in a person who has been successfully vaccinated against hepatitis B
e-Antigen & e-Antibody

- **Hepatitis B e-Antigen (HBeAg):**
  - This is a viral protein that is secreted by hepatitis B infected cells
  - Marker of active viral disease and a patient's degree of infectiousness
  - Positive result indicates the person has high levels of virus and greater infectiousness
  - Negative result indicates low to zero levels of virus in the blood and a person is considered less infectious

- **Hepatitis B e-Antibody (HBeAb or anti-HBe):**
  - Antibody is made in response to the e-antigen
  - Detected in patients who have recovered from hepatitis B infections as well as those who are chronically infected (with lower infectivity)
  - Chronically infected individuals who stop producing e-antigen sometimes produce e-antibodies
Hepatitis B Core Antibody/IgM

- **Total hepatitis B core antibody (anti-HBc):**
  - Total includes IgM anti-HBc and IgG anti-HBc
  - Earliest antibody to develop in response to acute hepatitis B virus (HBV) infection
  - Appears at the onset of symptoms in acute hepatitis B and persists for life
  - Indicates previous or ongoing infection with hepatitis B virus in an undefined timeframe
  - Predominantly IgM anti-HBc at about 6 to 8 weeks after infection
  - After about 6 months the total anti-HBc mainly consists of IgG anti-HBc.

- **IgM antibody to hepatitis B core antigen (IgM anti-HBc):**
  - Positivity indicates recent infection with hepatitis B virus (<6 mos)
  - However, with chronic HBV infection, the IgM anti-HBc can remain detectable at very low levels, even years after infection
Other Hepatitis B Laboratory Tests

• **HBV DNA:**
  • Measure of circulating DNA
  • Marker of active HBV replication
  • HBV DNA levels are detectable by 30 days following infection; generally reach a peak at the time of acute hepatitis
  • Used to assess and monitor treatment of persons chronically infected

• **Liver Function Tests:**
  • Alanine Aminotransferase (ALT/SGPT)
  • Aspartate Aminotransferase (AST/SGOT)
  • Bilirubin, Total and Direct, Serum
Case Definitions

Acute

Hepatitis B, acute

2012 Case Definition

CSTE Position Statement(s)
11-ID-03

Clinical Description
An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

“A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

Laboratory Criteria for Diagnosis

- HBsAg positive, AND
- Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

Case Classification

Confirmed
A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B.

Chronic

Hepatitis B, chronic

2012 Case Definition

CSTE Position Statement(s)
11-ID-04

Clinical Description
No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

Laboratory Criteria for Diagnosis

- Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B "e" antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR
- HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) OR HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Case Classification

Probable
A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Confirmed
A person who meets either of the above laboratory criteria for diagnosis.

Comment(s)
Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a “hepatitis panel.” Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative AND HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

Related Case Definition(s)

- 2011, January Case Definition
- 2007, January Case Definition
- 2003, January Case Definition
Test Result Examples
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### Example #1

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**Example #2**

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<td><strong>ASPARTATE AMINOTRANSFERASE (AST) (SGOT)</strong></td>
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<tr>
<td><strong>HEPATITIS B VIRUS CORE AB.IGM</strong></td>
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<tr>
<td><strong>HEPATITIS B VIRUS SURFACE AG</strong></td>
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<tr>
<td><strong>HEPATITIS B VIRUS SURFACE ANTIGEN</strong></td>
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<tr>
<td><strong>HEPATITIS B VIRUS DNA</strong></td>
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**Example #3**

**Communicable Disease Reporting and Surveillance System**

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<td>HEPATITIS B VIRUS SURFACE AG</td>
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<tr>
<td>ALANINE AMINOTRANSFERASE (ALT) (SGPT)</td>
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<td>ALKALINE PHOSPHATASE</td>
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<td>BILIRUBIN, TOTAL</td>
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## Example #4

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<td>04/28/2013</td>
<td>POSITIVE/REACTIVE</td>
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Hepatitis B Investigation Steps

• Request lab report
  • LabCorp: 1-800-524-0249
  • ARUP: 1-800-522-2787
  • Quest Nationwide: 1-866-697-8378
  • Quest Teterboro: 1-201-393-5300

• Speak with provider re: diagnosis, signs/symptoms, previous diagnosis, risk factors, pregnancy status for women 15-44 years, etc.

• Speak with case re: signs/symptoms, risk factors, contacts
Dear Health Care Provider,

Hepatitis B, a communicable disease, is a concern of the New Jersey Department of Health. It is the responsibility of New Jersey Administrative Code (NJAC) 8:57. Persons with Hepatitis B who wish to obtain absence from work due to illness must provide doctor's orders for the purpose of preserving their confidentiality.

Given the complexity of the Hepatitis B epidemic, additional information is needed by public health authorities. Your cooperation is a necessity to determine the case status.

Public Health Department:

Contact (For Question):

Name of Patient (First):

Address:

Regional Lab:

1. Was the patient diagnosed as having (check all that apply):
   a. Acute Hepatitis B (HBeAg positive or HBeAg negative)
   b. Chronic Hepatitis B (HBeAg positive or HBeAg negative)
   c. Immune to Hepatitis B
   d. Immune due to past infection
      (1) Anti-HBs present
      (2) Hepatitis B Surface (HBs) antibody
      (3) Other positive lab results
   e. Immune from Hepatitis B vaccination
   f. Patient returning for follow-up test

2. For females 15-44 years of age, indicate pregnancy:
   a. If yes, please indicate estimated date of delivery
      (1) EDD (expected date of delivery)
      (2) History of delivery
   b. Patient has been informed and consented: (Yes No) Date
   c. Patient has been informed of the protocol for medical management of their pregnancy to prevent perinatal Hepatitis B transmission: (Yes No)
   d. Patient has been informed of the transmission risk to household and sexual contacts: (Yes No)

3. Acute Hepatitis B infection is defined as:
   a. Discrete onset of symptoms and/or level of transaminase elevation above normal.
   b. Laboratory tests for diagnosis:
      (1) IgM antibody to Hepatitis B core antigen (HBcAg) positive (if done) or
      (2) Hepatitis B surface antigen (HbsAg) positive
      (3) Anti-HAV negative (if done)
      (4) If the patient was HbsAg positive at any time:
         a. Was jaundice present? (Yes No)
         b. Did the patient die?
         c. Did the patient have jaundice? (Yes No)

4. Chronic Hepatitis B:
   a. Chronic Hepatitis B is defined as having a positive or antibody to HBeAg positive lab result on one of the following:
      i. HbsAg positive
      ii. Anti-HBs positive or HBsAg positive
      iii. Anti-HBe positive and HBsAg positive
      iv. Anti-HBc positive

Your assistance is needed to determine the case status.

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Public Health Responsibility

• Ensure case is aware of diagnosis and provide information regarding transmission, risk factors, etc.

• Obtain contact information of close contacts

• Recommend testing of household contacts

• Follow up testing for perinatal cases
Questions?